Enforcement Actions: Significant Actions Resolved

Quarterly Progress Report
April-June 1993

Manuscript Completed: August 1993
Date Published: September 1993

Office of Enforcement
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

MASTER

ob
DISTRIBUTION OF THIS DOCUMENT IS UNLIMITED

ABSTRACT

This compilation summarizes significant enforcement actions that have been resolved during one quarterly period (April - June 1993) and includes copies of letters, Notices, and Orders sent by the Nuclear Regulatory Commission to licensees with respect to these enforcement actions. It is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by the NRC, so that actions can be taken to improve safety by avoiding future violations similar to those described in this publication.

CONTENTS

	<u>Page</u>
ABSTRACT.....	iii
INTRODUCTION.....	1
SUMMARIES.....	3
 I. REACTOR LICENSEES	
A. Civil Penalties and Orders	
Commonwealth Edison Company, Downers Grove, Illinois (Braidwood Generating Station) EA 93-063.....	I.A-1
Duke Power Company, Seneca, South Carolina (Oconee Nuclear Station) EA 92-211.....	I.A-8
Duke Power Company, York, South Carolina (Catawba Nuclear Station) EA 93-054.....	I.A-31
GPU Nuclear Corporation, Forked River, New Jersey (Oyster Creek Nuclear Generating Station) EA 93-055.....	I.A-38
Gulf States Utilities, St. Francisville, Louisiana (River Bend Station) EA 93-060.....	I.A-47
Houston Lighting & Power Company, Houston, Texas (South Texas Project Electric Generating Station) EA 92-175.....	I.A-53
Houston Lighting & Power Company, Houston, Texas (South Texas Project Electric Generating Station) EA 93-023.....	I.A-61
Houston Lighting & Power Company, Houston, Texas (South Texas Project Electric Generating Station) EA 93-047.....	I.A-70
Houston Lighting & Power Company, Houston, Texas (South Texas Project Electric Generating Station) EA 93-057.....	I.A-78
Northeast Nuclear Energy Company, Hartford, Connecticut EA 92-212.....	I.A-89

CONTENTS (Continued)

Tennessee Valley Authority, Chattanooga, Tennessee
(Sequoyah Nuclear Plant)
EAs 92-257 and 93-034.....I.A-103

University of Michigan, Ann Arbor, Michigan
EA 93-069.....I.A-115

B. Severity Level III Violation, No Civil Penalty

Arizona Public Service Company, Phoenix, Arizona
(Palo Verde Nuclear Generating Station)
EA 93-039.....I.B-1

Northern States Power Company, Minneapolis, Minnesota
(Prairie Island Nuclear Generating Plant)
EA 92-096.....I.B-10

Portland General Electric Company, Portland, Oregon
(Trojan Nuclear Plant)
EA 92-223.....I.B-15

Virginia Electric and Power Company
Glen Allen, Virginia
(North Anna Power Station)
EA 93-094.....I.B-20

II. MATERIALS LICENSEES

A. Civil Penalties and Orders

Aircraft Components, Inc., Branford, Connecticut
EA 92-171.....II.A-1

American Testing and Inspection, Inc.
Joliet, Illinois
EA 92-102.....II.A-13

Chestnut Hill Hospital, Philadelphia, Pennsylvania
EA 93-086.....II.A-29

Cleveland Clinic Foundation, Cleveland, Ohio
EA 92-110.....II.A-42

Rhoda H. Cobin, M.D., Midland Park, New Jersey
EA 92-230.....II.A-49

Jersey Technology Laboratories, Incorporated
Newark, New Jersey
EA 93-049.....II.A-73

CONTENTS (Continued)

Memorial Hospital of Laramie County Cheyenne, Wyoming EA 93-011.....	II.A-81
Mercy Catholic Medical Center, Darby, Pennsylvania EA 93-052.....	II.A-89
Metropolitan Hospital, Inc., Richmond, Virginia EA 93-076.....	II.A-102
Michigan State University, East Lansing, Michigan EA 93-062.....	II.A-110
Northern Virginia Endocrinologists Annandale, Virginia EA 93-061.....	II.A-120
Randall C. Orem, D. O., Dayton, Ohio EA 91-154.....	II.A-126
Overhoff Technology Corporation, Milford, Ohio EA 92-219.....	II.A-148
Professional Service Industries, Inc. Lombard, Illinois EA 93-021.....	II.A-163
Radiation Oncology Center at Marlton Marlton, New Jersey EA 93-041.....	II.A-170
Sequoyah Fuels Corporation, Gore, Oklahoma EA 93-010.....	II.A-178
Southwest X-Ray Corporation, Rock Springs, Wyoming EA 93-001.....	II.A-187
Standard Nuclear Consultants, Ltd. Elburn, Illinois EA 93-048.....	II.A-192
Wahiawa General Hospital, Wahiawa, Hawaii EA 92-259.....	II.A-198
Wayne General Hospital, Wayne, New Jersey EA 93-093.....	II.A-216
Western Technologies, Inc., Phoenix, Arizona EA 92-216.....	II.A-227

CONTENTS (Continued)

Westinghouse Electric Corporation
Columbia, South Carolina
EA 93-044.....II.A-245

Winchester Medical Center, Winchester, Virginia
EA 93-090.....II.A-257

B. Severity Level III Violation, No Civil Penalty

C&R Laboratories, Pearl City, Hawaii
EA 93-084.....II.B-1

Albert Einstein Medical Center
Philadelphia, Pennsylvania
EA 93-083.....II.B-5

Froehling and Robertson, Inc., Richmond, Virginia
EA 93-080.....II.B-11

Ivinson Memorial Hospital, Laramie, Wyoming
EA 93-163.....II.B-16

Riverside Methodist Hospital, Columbus, Ohio
EA 93-113.....II.B-22

III. INDIVIDUAL ACTIONS

Richard J. Gardecki
IA 93-001.....III-1

ENFORCEMENT ACTIONS: SIGNIFICANT ACTIONS RESOLVED

April - June 1993

INTRODUCTION

This issue of NUREG-0940 is being published to inform NRC licensees about significant enforcement actions and their resolution for the second quarter of 1993. Enforcement actions are issued by the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support (DEDS), the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operation and Research (DEDR), and the Regional Administrators. The Director, Office of Enforcement, may act for the DEDS or DEDR in the absence of the DEDS or DEDR or as directed. The actions involved in this NUREG involve NRC's civil penalties as well as significant Notices of Violation.

An objective of the NRC Enforcement Program is to encourage licensees to improve their performance and, by example, the performance of the licensed industry. Therefore, it is anticipated that the information in this publication will be widely disseminated to managers and employees engaged in activities licensed by NRC, so all can learn from the errors of others, thus improving performance in the nuclear industry and promoting the public health and safety as well as the common defense and security.

A brief summary of each significant enforcement action that has been resolved in the second quarter of 1993 can be found in the section of this report entitled "Summaries." Each summary provides the enforcement action (EA) number to identify the case for reference purposes. The supplement number refers to the activity area in which the violations are classified according to guidance furnished in the U.S. Nuclear Regulatory Commission's "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, 57 Fed. Reg. 5791 (February 18, 1992). Violations are categorized in terms of five levels of severity to show their relative importance within each of the following activity areas:

Supplement I	- Reactor Operations
Supplement II	- Facility Construction
Supplement III	- Safeguards
Supplement IV	- Health Physics
Supplement V	- Transportation
Supplement VI	- Fuel Cycle and Materials Operations
Supplement VII	- Miscellaneous Matters
Supplement VIII	- Emergency Preparedness

Part I.A of this report consists of copies of completed civil penalty or Order actions involving reactor licensees, arranged alphabetically. Part I.B includes copies of Notices of Violation that were issued to reactor licensees for a Severity Level III violation, but for which no civil penalties were assessed. Part II.A contains civil penalty or Order actions involving materials licensees. Part II.B includes copies of Notices of Violation that have been issued to material licensees, but for which no civil penalty was assessed.

Part III contains enforcement actions taken against an individual. In promulgating the regulations concerning deliberate misconduct by unlicensed persons (55 FR 40664, August 15, 1991), the Commission directed that a list of all persons who are currently the subject of an order restricting their employment in licensed activities be made available with copies of the Orders. Part III of this volume contains that information. These enforcement actions will be included for each person as long as the actions remain effective. The Commission believes this information may be useful to licensees in making employment decisions.

SUMMARIES

I. REACTOR LICENSEES

A. Civil Penalties and Orders

Commonwealth Edison Company, Downers Grove, Illinois
(Braidwood Generating Station), Supplement I, EA 93-063

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued May 21, 1993, to emphasize the importance of maintaining proper control of the valve alignment of important plant systems, especially for valves that could render multiple flow paths inoperable. The action was based on the discovery by licensee personnel that, contrary to the unit technical specifications, during the previous operating cycle the unit operated without an operable reactor vessel head vent system. Both trains of the system were inoperable due to a closed common manual isolation valve which was not properly aligned to the open position following the previous refueling. The licensee responded and paid the civil penalty on June 17, 1993.

Duke Power Company, Seneca, South Carolina
(Oconee Nuclear Station) Supplement I, EA 92-211

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$100,000 was issued December 28, 1992, to emphasize the importance of ensuring that corrective actions for conditions adverse to quality are promptly developed and implemented. The action was based on a violation for the failure to take corrective action for a condition adverse to quality. Specifically, during the performance of a periodic test on the Low Pressure Service Water system the potential for degraded cooling flow through the 3B Low Pressure Injection Cooler was identified, but not followed up. Based upon questions from the NRC resident inspector during the subsequent unit outage, the licensee performed additional testing on the system and identified a partially closed valve that was restricting flow. The licensee responded February 25, 1993, and after considering the response an Order Imposing Civil Penalty was issued May 14, 1993. The licensee paid the civil penalty June 10, 1993.

Duke Power Company, York, South Carolina
(Catawba Nuclear Station) Supplement I, EA 93-054

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$75,000 was issued April 30, 1993, to emphasize the importance of ensuring that an

important safety system is maintained in an operable state for all expected design bases conditions. The action was based on a violation for both loops of the Nuclear Service Water system being inoperable from August 1992 through February 25, 1993, due to incorrect torque switch settings on three of the four pump discharge valves. The licensee responded and paid the civil penalty May 27, 1993.

GPU Nuclear Corporation, Forked River, New Jersey
(Oyster Creek Nuclear Generating Station) Supplement I,
EA 93-055

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued May 17, 1993, to emphasize the importance of (1) maintaining proper control of activities affecting quality so as to ensure the plant is operated and maintained in accordance with TS limits, and (2) ensuring that changes to approved plant procedures receive a level of review commensurate with their significance. The action was based on an inadequate temporary procedure change that resulted in a plant heatup above 212 degrees F without certain Technical Specification requirements being met. The licensee responded and paid the civil penalty on June 16, 1993.

Gulf States Utilities, St. Francisville, Louisiana
(River Bend Station) Supplement I, EA 93-060

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$50,000 was issued May 21, 1993, to emphasize the importance of understanding the plant design bases and ensuring that modifications do not result in a reduction of the intended level of safety. The action was based on violations that occurred while the licensee was performing activities associated with the containment and drywell airlock interlock mechanisms. The licensee responded and paid the civil penalty on June 16, 1993.

Houston Lighting & Power Company, Houston, Texas
(South Texas Project Electric Generating Station)
Supplement I, EA 92-175

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$75,000 was issued April 19, 1993, to emphasize the need for managers, when necessary, to promptly and properly interface with the NRC-licensed personnel in the control room and the importance of plant management personnel following or properly modifying established procedures. The action was based on a number of violations of established

procedures which resulted in the failure to inform NRC licensed operators in the control room of potentially significant conditions that could have affected the operation of the plant. The licensee responded and paid the civil penalty on May 19, 1993.

Houston Lighting & Power Company, Houston, Texas
(South Texas Project Electric Generating Station)
Supplement I, EA 93-023

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$25,000 was issued April 19, 1993, to emphasize the importance of attention to detail, i.e., doing the job right the first time, and the need for the licensee to be aggressive in implementing corrective actions of a lasting nature. The action was based on numerous examples of personnel errors involving individuals working on equipment on the wrong train or wrong unit. While none of these errors resulted in adverse safety consequences, collectively they represented a significant regulatory concern. The licensee responded and paid the civil penalty on May 19, 1993.

Houston Lighting & Power Company, Houston, Texas
(South Texas Project Electric Generating Station)
Supplement I, EA 93-047

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$75,000 was issued April 19, 1993, to emphasize the importance of ensuring that identified problems that have the potential to affect the operability of safety systems are resolved in a timely manner, and are resolved commensurate with their relevance to ensuring compliance with plant Technical Specifications. The action was based on the licensee's failure to take corrective actions for a failed motor on a motor operated valve in the Unit 2 Low Head Safety Injection System. A safety-related valve went unrepaired for 18 months despite multiple opportunities to recognize the significance of the problem and the operations personnel did not recognize the technical specification implications of operating the reactor with the valve inoperable. The licensee responded and paid the civil penalty on May 19, 1993.

Houston Lighting & Power Company, Houston, Texas
(South Texas Project Electric Generating Station)
Supplement I, EA 93-057

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$325,000 was issued May 28, 1993, to emphasize the importance of ensuring the

operability of safety equipment through proper maintenance, adequate testing and the correction of recurring problems. The actions were based on the inoperability of the Unit 1 turbine-driven auxiliary feedwater pump for approximately 33 days, and the most significant violation involved the inoperability of one of the Unit 1 emergency diesel generators for a period of approximately 24 days. The licensee responded and paid the civil penalties on June 25, 1993.

Northeast Nuclear Energy Company, Hartford, Connecticut
Supplement VII, EA 92-212

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$100,000 was issued May 4, 1993, to emphasize the importance of licensees providing a work environment that is free of harassment, intimidation and discrimination against those who raise safety issues. The action was based on a violation related to the harassment, intimidation and discrimination against an instrumentation and control supervisor for raising safety issues. The licensee responded and paid the civil penalty on June 3, 1993.

Tennessee Valley Authority, Chattanooga, Tennessee
(Sequoyah Nuclear Plant) Supplement I
EAs 92-257 and 93-034

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$225,000 was issued March 23, 1993, to emphasize the importance of (1) ensuring procedural adherence during operations important to safety, (2) the adequacy of control room staffing and procedures, and (3) maintaining configuration control. The action was based on (1) several mispositioned safety system throttle valves, (2) the failure to maintain the RWST temperature above technical specification limits, and (3) a loss of Reactor Coolant Pump seal injection during recovery from a dual unit trip on December 31, 1992. The licensee responded and paid the civil penalties on April 21, 1993.

University of Michigan, Ann Arbor, Michigan
Supplement I, EA 93-069

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3,750 was issued May 21, 1993, to emphasize the need for the licensee's strict compliance with the license. The action was based on exceeding the licensed power level by 15 percent for approximately 10 minutes. The licensee responded and paid the civil penalty on June 18, 1993.

B. Severity Level III Violation. No Civil Penalty

**Arizona Public Service Company, Phoenix, Arizona
(Palo Verde Nuclear Generating Station)
Supplement IV, EA 93-039**

A Notice of Violation was issued April 27, 1993 based on violations involving an instance of worker radiation exposure. The violations included (1) whole-body radiation exposure of 2.445 rems to a contract worker during the fourth quarter of 1992, (2) failure to conduct a radiation survey, (3) failure to supply appropriate personnel monitoring equipment as specified, and (4) ten instances of failure to follow procedures for personnel radiation protection. A civil penalty was not proposed because the licensee identified the excessive exposure which resulted from the thoroughness of the licensee's investigation of a dosimeter discrepancy, the broad scope and promptness of the licensee's corrective actions and the licensee's overall good performance in Health Physics.

**Northern States Power Company, Minneapolis, Minnesota
(Prairie Island Nuclear Generating Plant)
Supplements III and VII, EA 92-096**

A Notice of Violation was issued June 25, 1993, involving (a) failure to make a management and medical determination of the fitness for duty of the individual who had been subject to a treatment program for alcohol abuse prior to granting the individual unescorted access to the plant; and (b) permitting the same individual to act as an armed guard at the plant, even though the individual could not demonstrate that he had successfully completed a rehabilitation program. A civil penalty was not proposed because the licensee identified the violation and voluntarily reported the matter, and the length of time that has passed since the licensee notified the NRC of the access issue.

**Portland General Electric Company, Portland, Oregon
(Trojan Nuclear Plant) Supplement VII, EA 92-223**

A Notice of Violation was issued April 16, 1993, based on a violation of NRC requirements prohibiting employment discrimination. Specifically, licensee security management actions had the effect of discouraging the plant security officers from raising concerns to management and the NRC. A civil penalty was not issued because of steadily improving performance both during and after the violation; reorganization of the security force, including replacement of the manager responsible for creating the atmosphere discussed above,

and evidence that the new managers had made progress in that area; and a decline in the number of allegations.

Virginia Electric and Power Company, Glen Allen, Virginia
(North Anna Power Station) Supplement I, EA 93-094

A Notice of Violation was issued June 21, 1993, based on a violation involving actions taken by operators following the Unit 2 reactor trip on April 16, 1993, in which the automatic start function of the auxiliary feedwater pumps was defeated for at least 18 minutes while a valid start signal was present. A civil penalty was not proposed because the licensee identified the violation, took corrective action, and the licensee had good prior performance.

II. MATERIALS LICENSEES

A. Civil Penalties and Orders

Aircraft Components, Inc., Branford, Connecticut
EA 92-171

A Order Modifying License (Effective Immediately) and Demand for Information was issued on September 21, 1992, based on an inspection which determined that the licensee deliberately exceeded the NRC license possession limit for thorium. The Order required the Licensee to survey the facility and develop a decommissioning plan with appropriate financial assurance. The Demand for Information required a statement of why, in light of the willful violation, the licensee should not be required to promptly decommission the facility and the license be revoked. On December 6, 1992, the Licensee requested that the license be terminated. The license was terminated on June 3, 1993.

American Testing and Inspection, Inc., Joliet, Illinois
Supplement VI, EA 92-102

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$15,000 was issued October 7, 1992, to emphasize the need for the licensee's effective oversight of NRC-licensed activities. The action was based on violations involving (1) repeat failure to notify the NRC when performing radiography in Indiana and Michigan, (2) performance of radiography in Indiana and Michigan on more than 180 days within a calendar year, and (3) failure to comply with the provisions of an Order Modifying License dated November 30, 1989. The licensee responded in a letter November 30, 1992, admitting the violations but requesting that the civil penalty be vacated due to the fact that the licensee had

gone into Chapter 7 bankruptcy. A Confirmatory Order signed for the Commission on March 24, 1993, restricts the licensee from the performance of licensed activities for a period of three years and withdraws the civil penalty.

Chestnut Hill Hospital, Philadelphia, Pennsylvania
Supplements IV and VI, EA 93-086

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$6,250 was issued May 24, 1993, to emphasize (1) the importance of aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected, and (2) the need for ensuring that the Licensee's corrective actions are long-lasting. The action was based on several violations of the radiation safety program which represent a breakdown in the control of licensed activities. The licensee responded and paid the civil penalty on June 8, 1993.

Cleveland Clinic Foundation, Cleveland, Ohio
Supplement VI, EA 92-110

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 was issued March 29, 1993, to emphasize that willful violations of NRC requirements cannot be tolerated. The action was based on a violation of NRC requirements and subsequent inspection and investigative findings which detail the deliberate unauthorized repair of a teletherapy unit by an employee of the licensee. The licensee responded and paid the civil penalty on April 27, 1993.

Rhoda H. Cobin, M.D., Midland Park, New Jersey
Supplement VI, EA 92-230

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$3,800 was issued March 10, 1993, to emphasize (1) the importance of strict adherence to the terms and conditions of the license, to ensure that such activities are conducted safely and in accordance with those requirements, and (2) the seriousness with which the NRC views willful violations. The action was based on (1) failure to have on hand a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 mR/hr to 1 R/hr, (2) failure to repair or replace the dose calibrator when the accuracy and constancy error exceeded 10 percent, and (3) administering therapy doses of iodine-131 to patients even though the dose as determined by the reading on the dose calibrator exceeded the prescribed dose by more than 10 percent.

The licensee responded in letters dated March 11 and 16, 1993. After consideration of the licensee's responses, an Order Imposing Civil Monetary Penalties in the amount of \$3,800 was issued June 4, 1993. The licensee paid the civil penalties on June 8, 1993.

Jersey Technology Laboratories, Incorporated
Newark, New Jersey, Supplements IV and VI, EA 93-049

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$250 was issued April 5, 1993, to emphasize the need to maintain adequate control over licensed material at all times, and to assure that the licensee's corrective actions are long lasting. The action was based on two examples of failure to control licensed material. A moisture density gauge was left unattended at a field site in New Jersey, and was damaged by a construction vehicle; however, the radioactive source was not damaged. In addition, during the NRC inspection at the licensee's facility, the storage area for the gauges was not adequately secured. The licensee responded and paid the civil penalty on April 22, 1993.

Memorial Hospital of Laramie County, Cheyenne, Wyoming
Supplement VI, EA 93-011

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 was issued March 22, 1993, to emphasize the significance NRC places on (1) proper instruction and training in quality management (QM) program procedures for individuals with responsibilities for administering or verifying radiation therapy treatment, and (2) failure to follow a procedure in the licensee's QM program, which caused a therapeutic misadministration. The licensee responded and paid the civil penalty on April 20, 1993.

Mercy Catholic Medical Center, Darby, Pennsylvania
Supplements IV and VI, EA 93-052

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$12,500 was issued April 20, 1993, to emphasize (1) the importance of aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected, and (2) the need for ensuring that the licensee's corrective actions are longlasting. The action was based on: (1) the failure to implement the Quality Management Program, in that written directives signed and dated by the authorized user were not prepared prior to administration of certain radioactive

materials to patients; and (2) a large number of violations identified in the radiation safety program that collectively represented a breakdown in the control of licensed activities. The licensee responded and paid the civil penalty on May 14, 1993.

Metropolitan Hospital, Inc., Richmond, Virginia
Supplement VI, EA 93-076

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 was issued May 12, 1993, to emphasize the importance of maintaining effective control over the radiation safety program and complying with regulatory requirements and license conditions. The action was based on a violation that involved the failure to secure licensed material from unauthorized removal and to maintain constant surveillance and control over licensed material. The licensee responded and paid the civil penalty on June 9, 1993.

Michigan State University, East Lansing, Michigan
Supplement IV, EA 93-062

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$3,750 was issued May 3, 1993, to emphasize the importance the NRC places on adequate oversight of the authorized users, and adequate labeling, control and accountability of licensed material. The action was based on two violations involving failure to keep licensed material under constant surveillance and immediate control, and failure to label radioactive material. The licensee responded and paid the civil penalty on May 26, 1993.

Northern Virginia Endocrinologists, Annandale, Virginia
Supplement VI, EA 93-061

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$500 was issued May 7, 1993, to emphasize the importance of full implementation of the licensee's Quality Management Program (QMP). The action was based on two violations for failure to provide a written directive and to verify the patient's identity by more than one method for medical administrations of iodine-131, and instruct individuals using licensed materials under the supervision of an authorized user in the licensee's written QMP. The licensee responded and paid the civil penalty on May 28, 1993.

Randall C. Orem, D. O., Dayton, Ohio
EA 91-154

An Order Revoking License (Effective Immediately) was issued November 29, 1991. The action was based on the

licensee having submitted an application for a license with inaccurate statements as to the description, status of completion, and location of the facility at which licensed material would be used. The address contained in the license application was a residence and the licensee did not have the capability to receive and use licensed material at that site. The licensee requested a hearing on December 3, 1991. A Settlement Agreement was entered into by the staff and licensee July 28, 1992; the Commission approved the Settlement June 4, 1993.

Overhoff Technology Corporation, Milford, Ohio
Supplements VI and V, EA 92-219

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,200 and Demand for Information was issued April 2, 1993, to emphasize the need for adhering to NRC regulations, the license conditions and commitments, and to ensure effective management of the radiation safety program. The action was based on 10 violations and the licensee's demonstration of careless disregard. The licensee responded and paid the civil penalty on April 27, 1993.

Professional Service Industries, Inc., Lombard, Illinois
Supplement VI, EA 93-021

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$7,500 and Demand for Information was issued March 29, 1993, to emphasize the importance of maintaining direct surveillance and access control over the high radiation area generated as a result of a radiographic operation, so as to prevent entry to these areas. The action was based on a violation that occurred at a field site in Wampum, Pennsylvania, where a radiographer and radiographer's assistant from the licensee's Pittsburgh, Pennsylvania office did not maintain direct surveillance over the high radiation area created during the radiography operations. This action resulted in two individuals entering the high radiation area and receiving unnecessary radiation exposure. The licensee responded and paid the civil penalty on April 8, 1993.

Radiation Oncology Center at Marlton, Marlton, New Jersey
EA 93-041

A Confirmatory Order Modifying License (Effective Immediately) was issued March 9, 1992. Under the terms of the Order, the licensee may not receive or use any NRC-licensed material pending further action by the NRC. The action was based on an NRC inspection that identified a lack of oversight of the radiation safety

program by the radiation safety officer. The RSO and the staff demonstrated a lack of knowledge of the license conditions and routine and emergency operating procedures for high dose rate after-loader brachytherapy.

Sequoyah Fuels Corporation, Gore, Oklahoma
Supplements VI and VIII, EA 93-010

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$18,000 was issued March 25, 1993, to emphasize the importance of ensuring compliance with requirements that are designed to protect the safety of facility employees and the general public. The action was based on a number of violations related to the November 11, 1992, offsite release of nitrogen dioxide. The violations were categorized as a Severity Level II problem because of the potential for significant injury or loss of life to site personnel or the general public. The licensee responded and paid the civil penalty on April 26, 1993.

Southwest X-Ray Corporation, Rock Springs, Wyoming
Supplement VI, EA 93-001

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$2,500 was issued April 9, 1993, to emphasize the importance of maintaining an awareness of and complying with all NRC requirements, particularly those that are designed to ensure safety of radiography personnel and the public. The action was based on the failure of the licensee to comply with the requirement that radiography personnel wear alarm ratemeters at all times during radiographic operations. The licensee responded and paid the civil penalty May 8, 1993.

Standard Nuclear Consultants, Ltd., Elburn, Illinois
Supplement VI, EA 93-048

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$500 was issued March 30, 1993, to emphasize the need for the importance of appropriate management attention to ensure adherence to all regulatory requirements. The action was based on the failure of Standard Nuclear to notify the NRC on at least 75 occasions when work was performed in NRC regulated states under the reciprocity provisions of 10 CFR 150.20. The licensee responded and paid the civil penalty on April 22, 1993.

Wahiawa General Hospital, Wahiawa, Hawaii
Supplement V, EA 92-259

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 was issued February 19, 1993, to emphasize the need for effective management oversight of the licensee's radiation safety program. The action was based on a significant breakdown in the control of licensed activities involving four violations of radioactive material transportation regulations. The licensee responded March 17, 1993, admitting the violations but requesting remission of the civil penalty. After consideration of the licensee's response, the staff concluded that remission of the civil penalty was not warranted but some mitigation was appropriate. An Order Imposing Civil Monetary Penalty in the amount of \$750 was issued June 2, 1993. The licensee paid the civil penalty on June 22, 1993.

Wayne General Hospital, Wayne, New Jersey
Supplements IV and VI, EA 93-093

A Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$6,250 was issued June 1, 1993, to emphasize the importance of (1) adequate implementation of the QM program, and (2) aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected. The action was based on: (1) substantial failure to implement the Quality Management Program, in that written directives signed and dated by the authorized user were not prepared prior to administration of certain radioactive materials to patients; and (2) an aggregate of 12 violations of the radiation safety program which represented a breakdown in the control of licensed activities. The licensee responded and paid the civil penalties on June 25, 1993.

Western Technologies, Inc., Phoenix, Arizona
Supplement VI, EA 92-216

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$8,000 was issued December 28, 1992, to emphasize the seriousness of willful violations, the importance of strict compliance with safety requirements, and the importance of developing mechanisms to ensure that company personnel are complying with such requirements. The action was based on the willful failure to wear alarm rate meters when performing radiography in NRC jurisdiction. Although the Licensee's radiographers acknowledged that they were aware of the requirement to wear an alarm rate meter,

they began the radiographic operation even though they did not have alarm rate meters with them at the site. The licensee responded January 26, 1993, admitting the violation but requesting full mitigation of the civil penalty. After consideration of the licensee's response, the staff concluded that the violation occurred as stated and an Order Imposing Civil Monetary Penalty in the amount of \$8,000 was issued March 22, 1993. The licensee paid the civil penalty on April 5, 1993.

Westinghouse Electric Corporation, Columbia, South Carolina
Supplement VI, EA 93-044

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$18,750 was issued April 23, 1993, to emphasize the importance of ensuring that appropriate nuclear criticality safety (NCS) analyses are performed to ensure that operational activities are conducted safely and in accordance with requirements. The action was based on the licensee's failure to perform a criticality safety analysis prior to using numerous non-favorable geometry containers in various plant locations that handle special nuclear material. The licensee responded and paid the civil penalty on May 24, 1993.

Winchester Medical Center, Winchester, Virginia
Supplement VI, EA 93-090

A Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 was issued May 14, 1993, to emphasize the importance of ensuring the implementation of an adequate quality management program and complying with regulatory requirements and license conditions. The action was based on a violation that involved the failure to establish a written quality management program that included written policies and procedures to cover the administration of sodium iodide I-125 or I-131 in quantities between 30 microcuries and 30 millicuries. The licensee responded and paid the civil penalty on June 2, 1993.

B. Severity Level III Violation. No Civil Penalty

C&R Laboratories, Pearl City, Hawaii
Supplement VI, EA 93-084

A Notice of Violation was issued May 7, 1993, based on violation involving the failure to wear an alarm ratemeter preset to alarm at 500 mR/hr between December 5, 1992, and March 18, 1993. A civil penalty was not issued because of the licensee's prompt

corrective action to remove the GS-15 chirper from service, training radiographic personnel in the correct use of alarm ratemeters, and purchasing an additional RA-500 alarm ratemeter. The licensee also had a good performance record for last two NRC inspections.

Albert Einstein Medical Center, Philadelphia, Pennsylvania
Supplement VI, EA 93-083

A Notice of Violation was issued May 4, 1993, based on three violations of NRC requirements. A violation categorized at Severity Level III involved the failure to prepare a written directive prior to the administration of 5.43 millicuries of iodine-131 to a patient in January 1993, as well as the failure to properly prepare other written directives for brachytherapy implants on other occasions (for example, on two occasions, the respective target organ, as well as the isotope to be used, were not specified). Two other violations categorized at Severity Level IV involved the failure to measure the thyroid burden of individuals involved in the administration of radioactive material to a patient; and the failure to test the licensee's dose calibrator for linearity over the entire range of use of material. A civil penalty was not proposed because of the licensee's prior good enforcement history and because the licensee took prompt and comprehensive corrective actions, which included: (1) counseling staff, including authorized users, on the licensee's written quality management (QM) procedures and requirements; (2) revising the brachytherapy patient treatment forms to include all written information; (3) revising QM audit procedures to require cross checking written directives with dose administration records; (4) initiating an audit of the licensee's brachytherapy program, and (5) revising the QM program to require audits at least every 12 months for brachytherapy.

Froehling and Robertson, Inc., Richmond, Virginia
Supplement IV, EA 93-080

A Notice of Violation was issued April 22, 1993, based on a violation involving the failure to maintain constant surveillance and immediate control of licensed material at a temporary job-site on or about October 1, 1992. Because the material contained in a gauge was not under constant surveillance and immediate control of the licensee at the temporary job-site, a bulldozer hit and damaged the gauge. A civil penalty was not proposed because of the licensee's prompt and extensive corrective actions and the licensee's good prior performance.

Ivinson Memorial Hospital, Laramie, Wyoming
Supplement VI, EA 93-163

A Notice of Violation was issued June 25, 1993, based on violations involving the failure to establish and maintain a quality management program that ensured that a written directive was prepared prior to the administration of sodium iodide I-131 in quantities greater than 30 microcuries, and the failure of an individual working under the supervision of the authorized user to verify that a written directive was made prior to administering two doses of sodium iodide I-131 to patients in quantities greater than 30 microcuries. A civil penalty was not proposed because the licensee's radiation safety officer identified the failure to use written directives for diagnostic whole body scans using iodine-131 and the licensee took prompt action to restore compliance following the identification of the apparent violations.

Riverside Methodist Hospital, Columbus, Ohio
Supplement VI, EA 93-113

A Notice of Violation was issued June 4, 1993, based on violations which resulted in a misadministration. The violations involved: (1) the failure to adequately verify that the radioisotope to be used agreed with the written directive and treatment plan, as required by the licensee's Quality Management Program, and (2) the failure to independently verify treatment time calculations as required by a license condition and the licensee's operating procedures. A civil penalty was not issued because of the licensee's good prior performance and extensive corrective actions, which included: (1) modifying the treatment planning computer, (2) requiring independent checks of treatment calculations, (3) reviewing the independent verification procedures with all four physicists and thoroughly training a new employee on each of the steps required, (4) changing procedures so that independent verifications would be required, and (5) training all personnel on the revised operating procedures.

III. INDIVIDUAL ACTIONS

Richard J. Gardecki IA 93-001

An Order Prohibiting Involvement in Certain NRC-Licensed Activities was issued May 4, 1993 to the above individual. The Order was based on the deliberate submittal of false information to former employers to obtain employment in licensed activities and to NRC investigators. The Order prohibits the individual for a period of five years from being named on an NRC license

as a Radiation Safety Officer or supervising licensed activities for an NRC licensee or an Agreement State licensee while conducting activities within NRC jurisdiction. It also requires for the same period notice by copy of the Order to prospective employers engaged in licensed activities and notice to the NRC on acceptance of employment in licensed activities.

I.A. REACTOR LICENSEES, CIVIL PENALTIES AND ORDERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
700 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-9027

MAY 21, 1993

Docket No. 50-457
License No. NPF-77
EA 93-063

Commonwealth Edison Company
ATTN: Mr. L. O. DelGeorge, Vice President
Nuclear Oversight
and Regulatory Services
Executive Towers West III
1400 Opus Place, Suite 300
Downers Grove, Illinois 60515

Dear Mr. DelGeorge:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$50,000
(INSPECTION REPORT NO. 50-457/93006)

This refers to the routine safety inspection conducted on March 18, 1993, at the Braidwood Generating Station to review the circumstances under which the Unit 2 reactor vessel head vent system was rendered inoperable. The report documenting this inspection was mailed to you by letter dated April 2, 1993. A significant violation of NRC requirements was identified during the inspection, and on April 16, 1993, an enforcement conference was held in the Region III office. A copy of the enforcement conference report was mailed to you on April 23, 1993.

To summarize the events, on March 11, 1993, Unit 2 was in a refueling outage (Mode 5) when plant personnel while performing reactor coolant system (RCS) draining evolution discovered that the manual reactor vessel head vent isolation valve (2RC8070) was in the closed and locked position. This valve is common to both reactor vessel head vent paths and is required to be in the open and locked position during reactor operations in Modes 1-4. The closure of the valve caused both reactor vessel head vent paths to be inoperable. Your review of the event indicated that the valve was locked shut on or about November 15, 1991. The unit was changed to Mode 4 on November 17, 1991, and continued to operate until March 6, 1993, when the unit was changed to Mode 5 for refueling.

The root causes of the violation and the subsequent corrective actions were discussed during the April 16, 1993, enforcement

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

conference. The major factors contributing to the violations appeared to be: 1) the reactor head vent path locked valve 18 month surveillance and the RCS venting activities were not sequenced to allow for verification of proper configuration before entering Mode 4; 2) the reactor vessel fill and vent, and the safety injection system check valve stroke test procedures did not describe the operation of 2RC8070 and although the valve was commonly used in those procedures, its use was not proceduralized; and 3) the abnormal position log was not used to track the position of 2RC8070.

The NRC recognizes that immediate corrective actions were taken to restore system operability when the violation was identified. Additionally, the NRC notes the numerous longer term actions that have been undertaken including various procedural changes, surveys of the locked valve control procedures of other licensees, and a number of training initiatives.

The violation, described in the enclosed Notice of Violation, concerns the failure to place the operating unit in hot standby within six hours and in cold shutdown within the following 30 hours when the inoperable reactor vessel head vent path was not repaired within 30 days. The violation represents a significant failure to comply with the Action Statement for a Technical Specification Limiting Condition for Operation where the appropriate action was not taken within the required time. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III. Because the closed valve rendered both trains of the reactor vessel head vent system inoperable, classification of this violation at Severity Level II was considered. However, given that a number of alternate methods were available to remove voids in the reactor vessel head, had that been necessary, such a classification was determined not to be appropriate.

To emphasize the importance of maintaining proper control of the valve alignment of important plant systems, especially for valves that could render multiple flow paths inoperable, I have decided, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$50,000 for the violation set forth in the Notice.

The base value of a civil penalty for a Severity Level III violation is \$50,000. After considering the civil penalty adjustment factors set forth in the NRC Enforcement Policy no adjustment of the civil penalty was found to be appropriate. This determination was made after applying mitigation for your

MAY 21 1980

identification of the root cause of this self-disclosing event and your corrective actions as well as escalation for the amount of time the system was inoperable.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
S. Berg, Site Vice President
K. Kofron, Station Manager
A. Haeger, Regulatory
Assurance Supervisor
D. Farrar, Nuclear Regulatory
Services Manager
Resident Inspectors, Byron,
Braidwood & Zion
D. W. Cassel, Jr., Esq.

cc w/encl: See Next Page

Commonwealth Edison Company - 4 -

MAY 21 1993

cc w/encl: (Con't)
Richard Hubbard
J. McCaffrey, Chief, Public
Utilities Division
Licensing Project Manager, NRR
R. Newmann, Office of Public Counsel
State Liaison Officer
Chairman, Illinois Commerce Commission

NOTICE OF VIOLATION

Commonwealth Edison Company
Braidwood Station Unit 2

Docket No. 50-457
License No. NPF-77
EA 93-063

During an NRC inspection conducted on March 18, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

Technical Specification 3.4.11 requires, in part, that at least one reactor vessel head vent path be operable during reactor operations in modes 1-4. With one reactor vessel head vent path inoperable, startup and/or power operation in modes 1-4 may continue provided, in part, that the inoperable vent path is restored to operable status within 30 days. Otherwise, the plant must be in hot standby within 6 hours and in cold shutdown within the following 30 hours.

Contrary to the above, from November 17, 1991, to March 6, 1993, a period in excess of 30 days, Unit 2 was operated in Modes 1-4 and both reactor vessel head vent paths were inoperable, and the unit was not brought to hot standby within 6 hours and placed in cold shutdown within the following 30 hours.

This is a Severity Level III violation (Supplement I).
Civil Penalty - \$50,000

Pursuant to the provisions of 10 CFR 2.201, Commonwealth Edison Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Notice of Violation

- 2 -

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional

Notice of Violation

- 3 -

Administrator, U.S. Nuclear Regulatory Commission, Region III,
799 Roosevelt Road, Glen Ellyn, Illinois 60137, a copy to the NRC
Resident Inspector at the Braidwood Station.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
the 21st day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

10-28-92

Docket Nos. 50-269, 50-270
 and 50-287
License Nos. DPR-38, DPR-47
 and DPR-55
EA 92-211

Duke Power Company
ATTN: Mr. J. W. Hampton
 Vice President
 Oconee Site
Post Office Box 1439
Seneca, South Carolina 29679

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
 PENALTY - \$100,000 (NRC INSPECTION REPORT
 NOS. 50-269/92-24, 50-270/92-24 AND 50-287/92-24)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. P. Harmon on September 26 - November 3, 1992, at the Oconee Nuclear Station. The inspection included a review of the facts and circumstances related to the degraded low pressure service water (LPSW) system flow condition through a Unit 3 low pressure injection (LPI) cooler. This condition was identified by the plant staff as a result of a system review performed by the NRC Resident Inspector. The report documenting this inspection was sent to you by letter dated November 16, 1992. As a result of this inspection, a violation of NRC requirements was identified.

An enforcement conference was held on November 24, 1992, in the NRC Region II office to discuss the violation, its cause, and your corrective actions to preclude recurrence. This enforcement conference was open for public observation in accordance with the Commission's trial program for conducting open enforcement conferences as discussed in the Federal Register, 57 FR 30762, July 10, 1992. A summary of the enforcement conference was sent to you by letter dated December 9, 1992.

The violation in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to take adequate corrective action to resolve a reduced LPSW flow condition through the 3B LPI cooler. On September 14, 1992, with Unit 3 in a refueling outage and preparation underway to resume full-power operation, plant personnel initiated LPSW flow testing to verify LPSW system operability. At the start of the flow test for the 3B LPI cooler, LPSW flow to the 3A LPI cooler and the

DEC 28 1992

main turbine oil cooler were isolated, and selected air operated valves were placed in their failed position. In this system configuration, the required flow of 5200 gpm through the 3B LPI cooler could not be achieved using a single LPSW pump and a subsequent investigation identified that valve 3LPSW-78, a manual isolation valve downstream of the cooler flow control valve, was not fully open due to an actuator problem. This valve is a butterfly valve and the pin connecting the actuator to the stem had dislodged resulting in the valve being in a throttled position with the handwheel indicating full open.

Prior to Unit 3 shutting down for the scheduled refueling outage, the NRC questioned whether the 3B LPI cooler was capable of achieving a LPSW flowrate of 5200 gpm using a single pump, which is necessary for single LPI cooler operation following the transfer of the LPI system's suction to the containment sump during postulated loss of coolant accident. The LPSW portion of periodic test PT/3/0150/22A, "Operational Valve Stroke Test," which had been performed on June 9, 1992, while Unit 3 was operating at full power, required that a flowrate of 5200 gpm be attained through the applicable LPI cooler. NRC review noted that during the performance of the test of June 9, 1992, 5200 gpm could not be achieved through the 3B LPI cooler with only one LPSW pump running, so the operators in the control room started a second LPSW pump to achieve the required flow. Further review showed that this potential flow deficiency had been evident as early as June 1991.

In response to NRC questions, your plant personnel (including operators, operations staff, and performance engineering staff) explained that the 3B LPI cooler had "always" exhibited lower flow than the 3A LPI cooler, which consistently met the required flow of 5200 gpm with one pump. The operational practice of starting a second pump was not viewed as unusual by the operators given the variable nature of non-safety loads also being supplied during the test and the fact that this practice was not prohibited by the procedure. In addition, your staff indicated that the purpose of this procedure was to test the valves and not to perform a system-flow verification test. During the enforcement conference, your staff maintained that the judgements made by the plant operators were reasonable given the procedure objective and the changing nature of flow demands in the LPSW system.

The NRC is concerned with several aspects of this event that contributed to both the event's safety and regulatory significance. The first concern is the 3B LPI cooler's inability to meet the 5200 gpm flow requirement with a single pump, assumed in the plant design basis and specified in the emergency

DEC 28 1992

operating procedures, for a period of over one year. At the enforcement conference your staff stated that further analysis indicated the degraded condition would not have impacted plant safety. In our view, the limited impact of this event was only fortuitous given that valve 3LPSW-78 could have failed to any partially open position. However, a more significant concern is the operational practice of routinely starting a second LPSW pump to meet the flow requirements of the periodic test. Your explanation of why this practice went unchallenged is not entirely persuasive.

The operators assumed that variations in non-safety loads necessitated the starting of the second pump, but no effort was made to verify this assumption through calculations and flow measurements. Additionally, even if the variation in non-safety loads is assumed to be a reasonable rationale for starting a second pump, your plant staff never resolved why variations in the B train non-safety loads routinely necessitated starting a second pump and variations in the A train non-safety loads never necessitated a similar action. In summary, our concern is not only that your staff failed to recognize the potential for a degraded condition after a single performance of the periodic test; but, that your staff failed to adequately resolve the trend indicated by several performances of the periodic test which had been accomplished on both trains under varying plant conditions.

Historically, some problems related to the Oconee LPSW system have been addressed while others remained unresolved. For example, a Self-Initiated Technical Audit (SITA) conducted in 1987 identified several problems related to the LPSW system that included a lack of LPSW testing and engineering calculations, yet there was no prompt action to address those problems. If adequate actions had been taken on those issues, it is likely that the plant staff would have been in a much better position to have identified the flow degradation caused by valve 3LPSW-78. At the enforcement conference, your staff seemed satisfied in relying on calculations without the benefit of sufficient system testing as a followup verification. This is of concern because, as illustrated by the degraded flow condition at issue, calculations alone can describe the best estimate condition for a particular system, but not its actual operating condition.

Operating the LPSW system from June 9 until September 14, 1992, without investigating and correcting the inadequate 3B LPI cooler flow is viewed as a significant safety issue which required immediate resolution. The root cause of this problem was a deficiency for which prompt corrective action was not implemented, as well as a lack of management oversight relative to development and implementation of corrective actions.

DEC 28 1992

Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," Enforcement Policy 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), this violation has been categorized at Severity Level III.

The staff recognizes that your staff initiated immediate corrective action to correct the hardware problem associated with the 3B LPI cooler by repairing the affected valve and installing mechanical stops on certain LPSW valves to limit flow. In addition, similar LPI valves in Units 1 and 2 were also verified to be fully functional.

To emphasize the importance of ensuring that corrective actions for conditions adverse to quality are promptly developed and implemented, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$100,000 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is \$50,000.

The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty was escalated by 50 percent for identification because the problem involving the inadequate flow in the 3B LPI cooler and the necessity of using two LPSW pumps to obtain the required flow was identified by the NRC. Neither escalation nor mitigation was warranted for corrective action because your immediate corrective actions to address specific hardware problems such as the installation of mechanical stops on the valves and verification of the operability of valves in the other units were offset by your failure to develop and implement appropriate management processes to improve the overall corrective action program in the long term.

Escalation of 50 percent was warranted for licensee performance based on previous enforcement history. For example, on February 3, 1992, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalties (EA 91-167) as a result of an Augmented Inspection Team inspection that reviewed the facts and circumstances associated with the degradation of decay heat removal on September 7, 1991, and the over-pressurization of the low pressure injection system piping on September 19 and 20, 1991. The letter transmitting the Notice with a proposed civil penalty of \$125,000, placed emphasis on the need for effective implementation of corrective action and management oversight. Additional escalation for this factor was offset by the overall SALP history for the past two SALP periods that reflects a better

DEC 28 1992

than average overall SALP score. The other adjustment factors were considered, and no further adjustment to the base civil penalty is considered appropriate. Therefore, the base civil penalty has been increased by 100 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence including actions you plan to take regarding your overall corrective action program which allowed this violation to occur. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
M. E. Patrick
Compliance
Duke Power Company
P. O. Box 1439
Seneca, SC 29679

cc w/encl con't: (See next page)

Duke Power Company

- 6 -

DEC 28 1992

cc w/encl con't:
A. V. Carr, Esq.
Duke Power Company
422 South Church Street
Charlotte, NC 28242-0001

County Supervisor of
Oconee County
Walhalla, SC 29621

Robert B. Borsum, B&W Company
Nuclear Power Generation Division
1700 Rockville Pike, Suite 525
Rockville, MD 20852

J. Michael McGarry, III, Esq.
Winston and Strawn
1400 L Street, NW
Washington, D. C. 20005

Office of Intergovernmental Relations
116 West Jones Street
Raleigh, NC 27603

Keyward G. Shealy, Chief, B/RH
South Carolina Department of Health
and Environmental Control
2600 Bull Street
Columbia, SC 29201

Manager, LIS
NUS Corporation
2650 McCormick Drive
Clearwater, FL 34619-1035

R. L. Gill
Nuclear Generation Department
Mail Stop EC050
Duke Power Company
P. O. Box 1006
Charlotte, NC 28201-1006

Karen E. Long
Assistant Attorney General
N. C. Department of Justice
P. O. Box 629
Raleigh, NC 27602

State of South Carolina

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Duke Power Company
Oconee Nuclear Station
Unit 3

Docket No. 50-287
License No. DPR-55
EA 92-211

During an NRC inspection conducted on September 26 - November 3, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action," and the licensee's Quality Assurance Program (Duke-1-A, Section 17.3.2.13) require that measures be established to assure that conditions adverse to quality are promptly identified and corrected.

Contrary to the above, a condition adverse to quality was indicated during the performance of procedure PT/3/0150/22A, "Operational Valve Stroke Test," and the licensee failed to identify and correct the condition. Specifically, although the plant operators identified on June 9, 1992, that one low pressure service water (LPSW) system pump failed to provide the required flowrate (i.e., 5200 gpm) through the 3B low pressure injection (LPI) cooler for single LPI cooler operation, they did not recognize this as a condition adverse to quality. During subsequent testing on September 14, 1992, while the unit was shutdown for a refueling outage, the licensee determined that the reduced LPSW flow was due to valve 3LPSW-78 (the LPSW cooler outlet manual isolation valve) remaining in a throttled position due to an actuator problem.

This is a Severity Level III violation (Supplement I).
Civil Penalty \$100,000

Pursuant to the provisions of 10 CFR 2.201, Duke Power Company (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid

further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the civil penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

Notice of Violation

- 3 -

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, and a copy to the NRC Resident Inspector at the Oconee Nuclear Station.

Dated at Atlanta, Georgia
this 28 day of December, 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MAY 14 1993

Docket Nos. 50-269, 50-270, and 50-287
License Nos. DPR-38, DPR-47, and DPR-55
EA 92-211

Duke Power Company
ATTN: Mr. J. W. Hampton
Vice President
Oconee Site
Post Office Box 1439
Seneca, South Carolina 29679

Gentlemen:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$100,000
OCONEE NUCLEAR STATION

This refers to your letter dated February 25, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated December 28, 1992. Our letter and Notice described one violation, identified during an inspection conducted on September 26 - November 3, 1992, at the Oconee Nuclear Station.

To emphasize the importance of ensuring that corrective actions for conditions adverse to quality are promptly developed and implemented, a civil penalty of \$100,000 was proposed.

In your response, you requested that the civil penalty be mitigated because the cited violation was not safety significant and by itself does not warrant significant regulatory concern and that the particular example cited does not adequately consider all of the related information that accompanied the discovery and identification of the degraded Low Pressure Service Water System flow condition.

After consideration of your response, we have concluded for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty that a sufficient basis was not provided for mitigation of the assessed civil penalty. Accordingly, we hereby serve the enclosed Order on Duke Power Company imposing a civil monetary penalty in the amount of \$100,000. We will review the effectiveness of your corrective actions during a subsequent inspection.

Duke Power Company

- 2 -

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

James H. Sniezek
Deputy Executive Director for
Nuclear Reactor Regulation,
Regional Operations and Research

Enclosure:
Order Imposing Civil Monetary
Penalty w/Appendix

cc w/encl:
M. E. Patrick
Compliance
Duke Power Company
P. O. Box 1439
Seneca, SC 29679

A. V. Carr, Esq.
Duke Power Company
422 South Church Street
Charlotte, NC 28242-0001

County Supervisor of
Oconee County
Walhalla, SC 29621

Robert B. Borsum
Babcock and Wilcox Company
Nuclear Power Generation Division
1700 Rockville Pike, Suite 525
Rockville, MD 20852

J. Michael McGarry, III, Esq.
Winston and Strawn
1400 L Street, NW
Washington, D.C. 20005

Office of Intergovernmental Relations
116 West Jones Street
Raleigh, NC 27603

cc w/encl con't: (see next page)

Duke Power Company

- 3 -

cc w/encl con't:
Heyward G. Shealy, Chief
Bureau of Radiological Health
South Carolina Department of Health
and Environmental Control
2600 Bull Street
Columbia, SC 29201

Manager, LIS
NUS Corporation
2650 McCormick Drive
Clearwater, FL 34619-1035

G. A. Copp
Licensing - EC050
Duke Power Company
P. O. Box 1006
Charlotte, NC 28201-1006

Karen E. Long
Assistant Attorney General
N. C. Department of Justice
P. O. Box 629
Raleigh, NC 27602

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of
DUKE POWER COMPANY
Oconee Nuclear Station

)
)
)
)
)
)

Docket Nos. 50-269, 50-270,
and 50-287
License Nos. DPR-38, DPR-47,
and DPR-55
EA 92-211

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Duke Power Company (Licensee) is the holder of License Nos. DPR-38, DPR-47, and DPR-55 issued by the Nuclear Regulatory Commission (NRC or Commission) on February 6, 1973, October 6, 1973, and July 19, 1974, respectively. The licenses authorize the Licensee to operate the Oconee Nuclear Station in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on September 26 - November 3, 1992. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated December 28, 1992. The Notice stated the nature of the violation, the provision of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violation. The Licensee responded to the Notice by letter dated February 25, 1993. In its response, the Licensee requested that the civil penalty be

mitigated because the violation was not safety significant and by itself does not warrant significant regulatory concern and that the particular example cited does not adequately consider all of the related information that accompanied the discovery and identification of the degraded Low Pressure Service Water System flow condition.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of \$100,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director,

Office of Enforcement, U.S. Nuclear Regulatory Commission,
ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region II, 101 Marietta Street N.W., Suite 2900, Atlanta, Georgia 30323.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

- (a) whether the Licensee was in violation of the Commission's requirements as set forth in the Notice referenced in Section II above, and
- (b) whether, on the basis of such violation, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James H. Snieszek
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

Dated at Rockville, Maryland
this 4th day of May 1993

APPENDIX

EVALUATION AND CONCLUSION

On December 28, 1992, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for a violation identified during an NRC inspection. Duke Power Company (licensee) responded to the Notice on February 25, 1993. The licensee requests that the civil penalty assessed for the violation be mitigated because the violation was not safety significant and by itself did not warrant significant regulatory concern. The NRC staff's evaluation and conclusion regarding the licensee's requests are as follows:

Restatement of the Violation

10 CFR 50, Appendix B, Criterion XVI, Corrective Action, and the licensee's Quality Assurance Program (Duke 1-A, Section 17.3.2.13), require that measures be established to assure that conditions adverse to quality are promptly identified and corrected.

Contrary to the above, a condition adverse to quality was indicated during the performance of procedure PT/J/0150/22A, "Operational Valve Stroke Test", and the licensee failed to identify and correct the condition. Specifically, although the plant operators identified on June 9, 1992, that one low pressure service water (LPSW) system pump failed to provide the required flowrate (i.e., 5200 gpm) through the JB low pressure injection (LPI) cooler for single LPI cooler operation, they did not recognize this as a condition adverse to quality. During subsequent testing on September 14, 1992, while the unit was shutdown for a refueling outage, the licensee determined that the reduced LPSW flow was due to valve JLPW-78 (the LPSW cooler outlet manual isolation valve) remaining in a throttled position due to an actuator problem.

Summary of Licensee's Response

While not denying that a condition adverse to quality existed, the licensee, in both the body of the letter and the corrective actions listed, in effect, disputes that the violation occurred as written. The licensee also contends that the NRC staff, in assessing the violation, did not adequately consider all pertinent information concerning discovery and identification of the problem. The licensee also stated that mitigation factors used in assessing the civil penalty were not fully considered.

1. Although the licensee's response does not deny the violation as cited, the licensee disputes that the operators were at fault in not recognizing that a problem existed in the LPSW system. The licensee contends that an undocumented evaluation had been performed by engineering and operating

staff personnel when the anomalous flow indication first occurred. Operating crews who witnessed the questionable indications during subsequent tests were told that the issue had been evaluated and a problem did not exist. The licensee does admit that the evaluation was in error, but does not think that the operators were to blame. Rather, the licensee argues that the initial evaluation adequately addressed the practice of starting two LPSW pumps to perform the valve stroke test. The licensee contends that the actions taken were reasonable because the indications available at the time were not sufficient to reasonably expect the degraded condition to have been identified. The licensee further contends that only after actual flow testing was performed in September 1992, was information disputing the evaluation available.

2. Since the test was not specifically designed to evaluate system performance, the observed flow indication did not immediately alert the operating crews to the possibility that a problem existed. Operators should not, therefore, be blamed for not immediately pursuing the issue.
3. The licensee does not believe that the problem presented by the failed valve was safety significant because the valve disc would have always failed such that the disc would present the smallest cross section to the system flow. The observed flow reduction was a result of some amount of flutter in the disc's position. As a result, the LPSW system was continuously capable of supplying sufficient flow in the affected loop.
4. The licensee recognizes that previous findings regarding a lack of flow testing had been identified in a Self-Initiated Technical Audit (SITA) performed on the LPSW system in 1987. The flow testing which uncovered the problem with the valve was being performed to validate the engineering flow calculations and to resolve concerns expressed by the inspector following his review of those calculations. The licensee does not, however, concede that the problem definitely would have been discovered earlier even if the flow testing had been performed. This is primarily due to the nature of the interconnected system, which does not allow testing in all alignments.
5. In addressing the escalation factors, the licensee has taken issue with the contention that the violation was primarily identified by the NRC resident staff. The licensee states that when the resident inspector questioned the need to start a second pump during the June 1992 test, the inspector was given the same explanation the operators had been given, and he did not express additional concerns at that time. The licensee contends that its conclusion is supported by

NRC Inspection Report 92-13, which covers the time period in which the NRC inspector first raised the concern. The licensee points out that while the report addresses the valve stroke testing it does not contain any concerns relating to that testing. The licensee further states that after the inspectors found mistakes in the flow calculations which were performed to resolve some of the questions about the LPSW system, the concerns were promptly addressed. Plant management then agreed that system testing would be beneficial and performed tests on Unit 3 prior to its scheduled startup. During that test the failed valve was found.

6. In assessing the application of prior enforcement history, the licensee states that the root cause of the violation was the lack of system performance testing which could have more promptly identified the problem with the system. Since the previous enforcement action had identified different root causes, the previous enforcement actions should not be linked to the present enforcement action.

NRC Staff Evaluation

1. The violation as written describes a condition observed by the operators which should have been further investigated by the plant staff. The licensee's position appears to be that it is acceptable for the operators and plant management to be reassured by, and in fact to rely only on, a seemingly plausible explanation without a formal analysis or testing supporting such a position. Instead of requiring a formal response the first time the problem was observed, in July of 1991, operators accepted the system engineer's explanation which was provided informally on the spot without any documentation. The next two times the test was run and the same problem was indicated, operators were assured that the problem had already been evaluated.

The operators and plant management knew that the LPSW system is cross-connected at the discharge of the two pumps. Given that fact, the explanation that non-essential loads would have an effect on the "B" train and not the "A" train does not appear to be persuasive, and should have been challenged. In addition, the LPSW system alignment for the valve stroke test (service to a single cooler and non-essential loads) was actually less demanding than the alignment for a full system performance test (service to two coolers, multiple reactor building cooling units, and non-essential loads). Therefore, if the 5200 gpm could not be achieved under the alignment used for the valve stroke test, a question should have been raised about the system's

ability to meet the more demanding requirements that full system performance required. Finally, in the past there had been instances of cooler outlet flow control valves failing in the full open position which resulted in flow rates through the coolers high enough to peg the flow indicators (greater than 8000 gpm). Operators were therefore well aware of the LPSW pump excess capability and the potential for high flow rates through the coolers should an outlet flow control valve malfunction. However, when subsequently confronted with a low flow condition through one of the coolers, they accepted an explanation that was in apparent conflict with their past experience. In summary, the NRC staff concludes that operations personnel had ample reasons to challenge and question the explanations given. In addition, the NRC staff concludes that licensee management given the above, had reason to question the engineering staff's conclusions, and failed to require a thorough evaluation of conditions, such as the one encountered in this situation.

2. The licensee's position that the tests were not designed to evaluate system performance does not relieve the licensee of the responsibility to investigate and resolve any observed problems. It is essential that anomalies or discrepancies be aggressively pursued regardless of the context in which they occur. This is the essence of the inquisitive, questioning attitude expected of all licensee personnel. Additionally, the fact remains that the flow anomaly was pursued by an NRC inspector rather than a member of the plant staff and that anomaly did, in fact, indicate a condition adverse to quality. That the anomaly would have been more aggressively pursued, if it had occurred during a test which stipulated that 5200 gpm was required with only one LPSW pump operating, goes without saying. In that circumstance, the acceptance criteria would have required meeting the flow rate or declaring the system inoperable. If the acceptance criteria of the observed test had, in fact, required that 5200 gpm could be achieved with one pump, the violation would have been cited in that context. What is at issue in this case is that a problem was indicated during a flow test. While not of a level to require action to be taken, (i.e., not meeting an acceptance criteria for operability), there was, as discussed above, certainly enough reason for the issue to have been pursued. Neither NRC staff nor the licensee should accept a position that only when acceptance criteria are not met should problems be thoroughly investigated.
3. The NRC staff does not agree with the licensee's contention that the valve failure was not safety significant. While

the potential safety consequences of the valve's failure in the as found condition were fortuitously minimal, other issues need to be considered when assessing safety significance. First, there is the significance of the failure of licensee personnel to identify this problem which has been discussed above. In addition, the potential for the valve to have failed in a more limiting condition needs to be considered and is discussed below. During the system's performance testing which finally identified that the valve had failed, the flow rate through the valve decreased each time the valve was operated in the shut direction, and flow did not return to the same value when the valve operator was returned to the full open position. The fact that flow did not return to the previous value when the valve was partially cycled was the method used to determine that the valve was not operating properly. This also indicates that the valve disc's position was not exclusively a function of system flow. Rather, it indicates that the valve disc could have changed to less conservative positions when operated. While an evaluation performed after the fact may indicate that the observed flow was adequate, there is no assurance that the flow through the failed valve would not have changed significantly in the non-conservative direction under accident conditions or by operator action if the problem had not been identified and corrected.

4. A lack of adequate flow testing was indeed a finding of the 1987 SITA on the LPSW system. However, contrary to the implication in paragraph 2.C of the licensee's response, the NRC staff did not state or imply, in either the Notice or the accompanying letter, that had the SITA findings been followed up it was certain that the degraded condition of 3LPSW-78 would have been discovered. Rather, the NRC stated in its letter that "it is likely that the plant staff would have been in a much better position to have identified the flow degradation caused by 3LPSW-78" if adequate actions had been taken to address the SITA findings.

The calculations presented to the inspectors in September 1992 represented the licensee's assurance that the LPSW system was operable and were provided in response to the initial concern expressed by the inspector witnessing the test in June 1992. Prior to September, the inspectors had repeatedly requested either that flow testing be performed or a formal, documented evaluation be performed to resolve the concerns with LPSW flow indications during valve stroke testing in general and specifically the June 1992 test. When the calculations were presented to the inspectors, the licensee contended that the calculations proved that the

system was able to meet its design objectives and obviated the need for actual flow testing. The inspectors reviewed the calculations and found numerous errors in the calculations and the assumptions used. When the inspectors pointed out the errors, the licensee still did not agree that testing was required. Rather, licensee management informed the inspectors that the Unit 3 startup would continue without such testing being performed. The inspectors then informed the site management that the issue was of such a level of concern that it would necessitate contacting senior NRC Region II management for help in resolving the issue. The licensee only then agreed to perform actual system flow testing.

The licensee's point that, because of possible restrictions on testing, the problem may not have been identified even if the licensee had agreed to the testing earlier, is not well supported. The plant conditions that existed at the time the licensee is referring to did not present great difficulty in testing and would not have precluded detection of the problem. The Unit 3 LPSW system is independent of the shared Unit 1 and Unit 2 LPSW system. A system flow test could have been performed on the Unit 3 LPSW system during any refueling outage without any impact on the safety of the unit and without any effect on Units 1 and 2. When the licensee finally decided to perform the testing, the requisite procedures were written without significant problems, the system aligned in a fairly expeditious manner, and there was not an extreme degree of difficulty in performing this test. Testing of the Unit 3 LPSW system at power was also feasible. In fact, a flow test was performed by the licensee at power to benchmark the system flow model calculations performed by design engineering.

5. The NRC staff does not agree with the licensee's position that it was equally responsible for identifying the problem. As discussed above, the licensee did not concede that a problem existed, or that flow testing was necessary until NRC staff forced the issue. The licensee should have been more responsive to the issue. The response to the SITA findings regarding a lack of flow testing, the response to the problems initially identified by the operators, and the initial response to the NRC staff concerns all support the conclusion that, absent NRC staff involvement, the problem would likely not have been identified. The testing which identified the failed valve was, in effect, performed reluctantly, and does not warrant consideration as licensee identification of the problem. While the licensee is correct that NRC Inspection Report 92-13 does not document the inspectors' concerns about the LPSW system, licensee

management was well aware of the concerns. As early as June 10, 1992 (the day after the concern was identified) the inspectors met with the plant staff to attempt to resolve the issue. The concern was periodically discussed in subsequent meetings with the licensee in which plant personnel maintained that they could demonstrate the acceptability of the flow indications. Finally, after giving the licensee ample opportunity to make its case and only after the licensee was unable to demonstrate through the use of calculations that the condition was not a problem, did the inspectors document the issue in an inspection report.

6. The NRC staff disagrees with the licensee's contention that the root cause of the violation was a lack of system performance testing. The violation is based on the fact that a condition adverse to quality was not actively and aggressively pursued. Therefore, the primary root cause of the violation was the inadequate response of the plant operations and engineering staffs to a potential problem. In addition, a lack of flow testing and other deficiencies in the LPSW system had been identified as early as 1987 in the licensee's SITA evaluation. The failure of licensee management to follow up on those findings, as well as management's acceptance of the informal and undocumented method of analysis used to resolve the identified LPSW flow reduction, make inadequate management oversight of the resolution of LPSW deficiencies a very significant contributing root cause.

The licensee's argument that escalation of the civil penalty should not be applied for licensee performance because the violation at issue is not similar to previous violations and the root cause of this violation differs from that of previous enforcement actions reflects a misunderstanding of the application of that factor. Assessment of the licensee performance factor is based on a broad view of performance, including all enforcement actions over a two-year period, and is not limited to similar violations or violations with similar root causes.

NRC Staff Conclusion

NRC staff concludes that the violation occurred as written. The NRC staff also concludes that the licensee has not provided an adequate basis for its request for mitigation of the proposed civil penalty and that the civil penalty adjustment factors were appropriately applied. Consequently, the NRC staff concludes that the proposed civil penalty in the amount of \$100,000 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

APR 30 1993

Docket Nos. 50-413 and 50-414
License Nos. NPF-35 and NPF-52
EA 93-054

Duke Power Company
ATTN: Mr. M. S. Tuckman
Vice President
Catawba Site
4800 Concord Road
York, South Carolina 29745-9635

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY
\$75,000 (NRC INSPECTION REPORT NO. 50-413/93-07 AND 50-414/93-07)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. William T. Orders on February 7 - March 13, 1993, at the Catawba Nuclear Station. The inspection included a review of the facts and circumstances related to your staff's discovery that the Nuclear Service Water (NSW) system had been degraded for seven years and inoperable for about six months. The report documenting the NRC inspection was sent to you by letter dated April 2, 1993. An enforcement conference was conducted in the NRC Region II office on April 14, 1993, to discuss the violation, its cause, and your corrective actions to preclude recurrence. This enforcement conference was open for public observation in accordance with the Commission's trial program for conducting open enforcement conferences as discussed in the **Federal Register**, 57 FR 30762, July 10, 1992.

The violation is described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Both loops of the Nuclear Service Water system were inoperable from August 15, 1992 through February 25, 1993, due to improper torque switch settings on the pump discharge valve motors. As a result of the improper torque switch settings, three of the four pump discharge valves would not have been able to open against the system design differential pressure (encountered during a loss of offsite power event after restoration of emergency power when full pump discharge pressure is applied to the upstream side of the closed valve with the downstream side essentially depressurized). Additionally, although you contend that subsequent differential pressure testing demonstrated the "operability" of the fourth valve (see LER 93-002-00, page 10), the NRC remains unconvinced because the actuator tripped and reset several times, and the valve took an additional 25 seconds to open. At a minimum, this valve was seriously degraded and of questionable reliability.

The cause of this violation was due to your staff's failure to take comprehensive corrective actions following similar Nuclear Service Water system valve failures that occurred between November 1985 and December 1989.

APR 30 1993

Following the 1985 discovery that one of the Nuclear Service Water System valves would not open against pump discharge pressure, your corrective actions were limited to adjusting that valve's torque switch. No adjustments were made to the other valve actuators. After the 1989 discovery that seat hardening problems had degraded the performance of the valves, your staff misadjusted the required torque switch settings on two of the four valves (2RN28A and 2RN38B). A contributing cause of this misadjustment was the ambiguous nature of the procedure which did not specifically identify the open and close torque switch set screws. Similarly, in August 1992, your staff failed to perform an adequate engineering analysis to generate the torque switch settings for the other two valves (1RN28A and 1RN38B). This resulted in both of those valves being inoperable from August 1992 through February 1993.

The failure to identify and correct the root cause of these valve failures resulted in the Nuclear Service Water system, the ultimate heat sink for the Catawba Nuclear Station, being unable to perform its intended function under certain conditions from August 1992 to February 1993. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

The NRC recognizes that corrective actions have been taken to assure the current operability of similar valves and that actions have been planned to develop a long-term disposition for the RN pump discharge valves, that extensive studies are planned to examine various technical problems associated with these particular type of valves, and that the dynamic testing plan for butterfly valves related to Generic Letter 89-10 will be reevaluated.

To emphasize the importance of ensuring that an important safety system is maintained in an operable state for all expected design bases conditions, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$75,000 for the Severity Level III violation. The base value of a civil penalty for a Severity Level III violation is \$50,000. The escalation and mitigation factors in the Enforcement Policy were considered as discussed below.

The base civil penalty was mitigated by 50 percent because you identified the problem during a surveillance test of RN pumps 1B and 2B. An additional 50 percent mitigation was deemed warranted for your corrective actions, as discussed above. Furthermore, an additional 50 percent mitigation was warranted for licensee performance. In considering this factor, your Systematic Assessment of Licensee Performance (SALP) rating of 2 in Maintenance/Surveillance and Engineering/Technical Support as well as your previous enforcement history that included three previous enforcement actions (resulting in Severity Level IV violations) over the last two years offset full mitigation when balanced with your good performance in advancing MOV testing in the industry and your generally good overall performance relative to NRC Generic Letter 89-10.

APR 30 1993

Escalation of 100 percent was warranted for your prior opportunity to identify this problem. For example, in November 1985, valves 1RN28A and 1RN69B failed to fully open during testing and the torque switch settings (TSS) were reset, but the TSS for the other valves in the RN system were not evaluated for possible similar problems. In October 1988, valves 1/2RN148A failed to open under high differential pressure because of a seat hardening problem that was corrected by changing the TSS to the maximum setting. In July 1989, the TSS for valve 1RN38B was changed from 1.5 to 3.0, but the TSS for valves 2RN28A and 2RN38B were inadvertently left at 1.5 instead of also being changed to 3.0. In August 1992, the TSS for valves 1RN28A and 1RN38B were changed from 3.0 to 2.0 for the open position, but the TSS for valves 2RN28A and 2RN38B were not changed and remained at TSS 1.5. Had more engineering evaluation and testing been applied to these incidents, it is likely that the valve problems would have been identified and corrected sooner. During the enforcement conference, you said that Duke Power Company's actions were consistent with the state of knowledge and sensitivity within the industry at the time these issues were addressed. While that may have been the case in 1985, the subsequent three years yielded more understanding of the problem and more sensitivity should have been applied in 1989. An additional escalation of 100 percent was warranted for the factor of duration because of the length of time valves 1RN28A, 1RN38B and 2RN38B were inoperable. The factor of multiple occurrences was not applicable in this case. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: (see next page)

APR 30 1983

cc w/encl:
R. C. Futrell
Compliance
Duke Power Company
4800 Concord Road
York, SC 29745-9635

A. V. Carr, Esq.
Duke Power Company
422 South Church Street
Charlotte, NC 28242-0001

J. Michael McGarry, III, Esq.
Winston and Strawn
1400 L Street, NW
Washington, D. C. 20005

North Carolina MPA-1
Suite 600
P. O. Box 29513
Raleigh, NC 27626-0513

Heyward G. Shealy, Chief
Bureau of Radiological Health
S. C. Department of Health
and Environmental Control
2600 Bull Street
Columbia, SC 29201

Richard P. Wilson, Esq.
Assistant Attorney General
S. C. Attorney General's Office
P. O. Box 11549
Columbia, SC 29211

Michael Hirsch
Federal Emergency Management Agency
500 C Street, SW, Room 840
Washington, D. C. 20472

North Carolina Electric
Membership Corporation
P. O. Box 27306
Raleigh, NC 27611

Saluda River Electric
Cooperative, Inc.
P. O. Box 929
Laurens, SC 29360

cc w/encl con't: (see next page)

Duke Power Company

5 -

APR 30 1983

cc w/encl con't:
Karen E. Long
Assistant Attorney General
N. C. Department of Justice
P. O. Box 629
Raleigh, NC 27602

T. Richard Puryear
Nuclear Technical Services Manager
Carolinas District
Westinghouse Electric Corporation
P. O. Box 32817
Charlotte, NC 28232

County Manager of York County
York County Courthouse
York, SC 29745

Piedmont Municipal Power Agency
121 Village Drive
Greer, SC 29651

G. A. Copp
Licensing - EC050
Duke Power Company
P. O. Box 1006
Charlotte, NC 28201-1006

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Duke Power Company
Catawba Nuclear Station
Units 1 and 2

Docket Nos. 50-413 and 50-414
License Nos. NPF-35 and NPF-52
EA 93-054

During an NRC inspection conducted on February 7, 1993 - March 13, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

Technical Specification 3.7.4, Nuclear Service Water System, requires, in part, that at least two independent Nuclear Service Water (RN) System loops shall be operable when both units are in Modes 1, 2, 3, or 4, with each loop containing two operable Nuclear Service Water pumps, associated diesel generators and flowpaths.

Contrary to the above, both loops of the Nuclear Service Water system were inoperable from August 1992 through February 25, 1993, due to three of the four RN pump discharge valves being unable to open against the pump discharge pressure. RN pump discharge valves 1RN28A, 1RN38A and 1RN38B were unable to open against the pump discharge pressure due to incorrect torque switch settings. This resulted in both units being operated for an extended period of time in Modes 1, 2, 3, or 4 without the required two operable flowpaths.

This is a Severity Level III Violation (Supplement I).
Civil Penalty - \$75,000.

Pursuant to the provisions of 10 CFR 2.201, Duke Power Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to

the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia, and a copy to the NRC Resident Inspector at the Catawba Nuclear Station.

Dated at Atlanta, Georgia
this 30th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MAY 17 1993

Docket No. 50-219
License No. DPR-16
EA 93-055

Mr. John J. Barton
Vice President and Director
GPU Nuclear Corporation
Oyster Creek Nuclear Generating Station
Post Office Box 388
Forked River, New Jersey 08731

Dear Mr. Barton:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$50,000
(NRC Inspection Report No. 50-219/93-80)

This letter refers to the NRC Augmented Inspection Team conducted on January 26 through February 2, 1993, at the Oyster Creek Nuclear Generating Station, Forked River, New Jersey. The inspection report was sent to you on February 23, 1993. The inspection was conducted to review the circumstances associated with an event that occurred at Oyster Creek between January 23 and 25, 1993. Specifically, the temperature of the reactor water increased to levels above 212 degrees F, resulting in the plant being in a condition prohibited by the technical specifications (TS). This event was identified and reported to the NRC by your staff on January 25, 1993. On April 2, 1993, an enforcement conference was conducted with you and members of your staff to discuss the event, its causes, your corrective actions, and the potential violations.

On January 25, 1993, while the facility was in a refueling outage with fuel in the reactor vessel, the reactor vessel metal temperature was found to be above 212 degrees F indicating that reactor water temperature may have inadvertently increased above that temperature. This condition was detected by your staff following performance of a main steam line isolation valve (MSIV) local leak rate test (LLRT). Your staff also subsequently confirmed that reactor water temperature had exceeded 212 degrees F. When reactor water temperature exceeds that level, the plant TS require that specific safety systems be operable, primary containment integrity be maintained, and a Shift Technical Advisor (STA) be on duty. These requirements were not met. After identification of this condition, the operators promptly increased shutdown cooling flow through the core, and reduced the temperature to less than 212 degrees F.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MAY 17 1993

A temporary procedure change (TPC) to the shutdown cooling system operating procedure led to this condition. The revised procedure, when implemented on January 23, 1993, allowed performance of the MSIV LLRT simultaneously with reactor recirculation pump maintenance based on a draft engineering analysis for shutdown cooling. To allow the recirculation pump maintenance, all of the recirculation pumps were secured, and to create a post-MSIV LLRT vent path, the reactor water level was lowered to 165 inches above the top of the active fuel (a level below the normally required level of 185 inches). One recirculation loop was kept open to ensure communication between the water in the reactor vessel annulus and the water within the core shroud. This configuration contributed to the increase in water temperature by allowing some of the shutdown cooling flow to bypass the active fuel. This was not accounted for in the TPC which, rather than requiring the minimum shutdown cooling flow rate specified in the engineering analysis, only required that both shutdown cooling pumps be in operation.

The NRC is concerned that the TPC was approved for use without ensuring that adequate shutdown cooling system flow existed to prevent reactor coolant "heat up". Although the procedure change was being implemented for the first time based on a draft engineering analysis, no precautions or monitoring criteria, such as requiring a minimum shutdown cooling flow rate or the monitoring of reactor vessel metal temperatures, were specified in the TPC to ensure adequate shutdown cooling and decay heat removal. Implementation of the TPC with these process deficiencies constituted a violation of the 10 CFR Part 50, Appendix B, Criterion V, which requires that the activities affecting quality be prescribed by procedures appropriate to the circumstances.

Although your Licensee Event Report (LER 93-002) identified personnel error to be the root cause of the violation, as discussed at the enforcement conference, the NRC determined that the inadequate procedure was not solely attributable to an individual personnel error. A significant contributing factor was a programmatic weakness in the TPC process that allowed this TPC to be implemented without technical and safety reviews commensurate with the scope of the change. That weakness stems from the failure to have comprehensive guidance available as to what constitutes a "change of intent" which is the threshold for in-depth review prior to the approval of a TPC. The NRC recognizes that there are differences across the industry as to the definition of "change of intent." However, evaluating the intent of specific procedural steps against the overall procedure purpose, as presented by your staff at the enforcement conference, is such a broad approach that very few, of even the most significant, procedural changes would ever be changes of intent using that standard. The NRC notes that as part of your corrective actions you intend to address this issue. Given its potential effect on every plant procedure, it is expected that this issue will be resolved in a careful and expeditious manner.

MAY 17 1993

Mr. John J. Barton

3

NRC IE Circular No. 81-11 and General Electric (GE) Service Information Letter (SIL) No. 357, issued in June 1981, identified the possibility of reactor coolant temperature stratification if recirculation was secured and shutdown cooling was insufficient. The SIL recommended monitoring of reactor vessel temperature. You had identified before that a reactor level of 185 inches should be maintained when no recirculation pumps were running, but the TPC revised this requirement without any compensating measures as recommended in the SIL. This industry information, if followed, would have provided a prior opportunity to prevent the increase in reactor coolant temperature.

The NRC recognizes that the safety impact of the plant "heat up" was low in that the reactor core remained adequately cooled throughout the event and there was no fuel damage or release of radioactivity. Nevertheless, a programmatic weakness in your TPC process allowed implementation of this substantive TPC after minimal review and led to your failure to maintain the plant within TS limits. This weakness is safety-significant and is a regulatory concern because it permits limited and perhaps inadequate technical and safety reviews before a substantive change is implemented. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

The NRC also recognizes that subsequent to the identification of the violation, you took immediate corrective actions to restore adequate core cooling and initiated three separate reviews of the event. In addition, you implemented interim changes to the TPC process to prevent recurrence. These corrective actions, which were described either during the inspection or at the enforcement conference, included, but were not limited to: (1) establishing an interim requirement to complete a technical review, and independent safety review (if required) prior to implementation of a TPC; (2) requiring the Group Shift Supervisors to challenge the need for specific TPCs so as to minimize their use; (3) requiring that the STA review all TPCs prior to implementation; (4) establishing guidance on what constitutes a change of the intent of a procedure; (5) providing additional guidance on the safety review/determination process to help determine the potential impact of a proposed change on nuclear safety; (6) determining the need for long term revisions to the TPC process; and (7) revising the shutdown cooling procedure to address all prior concerns. While the proposed corrective actions were acceptable, the completion status for the longer term actions noted at the time of the enforcement conference did not reflect an aggressive schedule and some of these actions were not yet defined.

MAY 17 1993

Mr. John J. Barton

4

To emphasize the importance of (1) maintaining proper control of activities affecting quality so as to ensure the plant is operated and maintained in accordance with the TS limits, and (2) ensuring that changes to approved plant procedures receive a level of review commensurate with their significance, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$50,000 for the violation set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is \$50,000. The escalation and mitigation factors set forth in the Enforcement Policy were considered and, on balance, the base civil penalty was neither escalated nor mitigated. The violation was identified by your staff, and therefore, 50 percent mitigation of the base civil penalty on this factor was appropriate. In addition, mitigation in the amount of 50 percent of the base penalty was appropriate based on your good performance in shutdown risk management. Full mitigation under licensee performance factor was not applied because it was not supported by your overall performance, as represented by SALP Category 2 ratings in the areas of operations and engineering/technical support. The civil penalty was also escalated by 100 percent of the base civil penalty based on the prior opportunity to prevent the violation which was provided to you by NRC IE Circular No. 81-11 and GE SIL No. 357. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

MAY 17 1993

Mr. John J. Barton

5

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

A handwritten signature in black ink, appearing to read "Thomas T. Martin". The signature is stylized with a large, sweeping initial "T" and a long, horizontal stroke at the end.

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition
of Civil Penalty

MAY 17 1993

Mr. John J. Barton

6

cc w/encl:

M. Laggart, Manager, Corporate Licensing

P. Czaya, Acting Licensing Manager, Oyster Creek

Public Document Room (PDR)

Local Public Document Room (LPDR)

Nuclear Safety Information Center (NSIC)

NRC Resident Inspector

State of New Jersey

ENCLOSURE

NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY

GPU Nuclear Corporation
Oyster Creek Nuclear Generating Station

Docket No. 50-219
License No. DPR-16
EA 93-055

Based on the NRC review of an NRC Augmented Inspection Team inspection conducted between January 26 and February 2, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR Part 50, Appendix B, Criterion V, states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances. Instructions, procedures, or drawings shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to the above, between January 23 and 25, 1993, a procedure for an activity affecting quality, namely, Procedure No. 305, Shutdown Cooling System Operations, was neither appropriate to the circumstances nor contained quantitative or qualitative acceptance criteria for determining that an important activity, maintaining reactor water temperature less than 212 degrees F, had been satisfactorily accomplished. A Temporary Procedure Change (TPC) was made to Step No. 4.2.5 of Procedure No. 305 to allow stopping of all reactor recirculation pumps when reactor water level was less than 185 inches above top of the active fuel without providing acceptance criteria (i.e., precautions or monitoring criteria) in the TPC to ensure adequate shutdown cooling was maintained. Specifically, the TPC failed to specify an adequate shutdown cooling flow rate to compensate for the change to Step No. 4.2.5, which resulted in reactor water temperature exceeding 212 degrees F for about six hours.

This is a Severity Level III violation (Supplement I).
Civil Penalty - \$50,000.

Pursuant to the provisions of 10 CFR 2.201, GPU Nuclear (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

Enclosure

3

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pa 19406, and a copy to the NRC Resident Inspector at the Oyster Creek Nuclear Generating Station.

Dated at King of Prussia, Pennsylvania
this ~~17~~¹⁸ day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8084

MAY 21 1993

Docket: 50-458
License: NPF-47
EA 93-060

Gulf States Utilities
ATTN: P. D. Graham
Vice President (RBNG)
P.O. Box 220
St. Francisville, Louisiana 70775

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$50,000 (NRC INSPECTION REPORT NO. 50-458/93-11)

This is in reference to the inspection conducted February 25-March 30, 1993, at the River Bend Station nuclear power plant, St. Francisville, Louisiana. This inspection was conducted specifically to review the circumstances surrounding two events that occurred on February 25 involving the operation of interlock mechanisms on the containment personnel airlock. A report documenting the results of this inspection was issued on April 12, 1993. On April 21, 1993, you and other Gulf States Utilities (GSU) representatives attended an enforcement conference in the NRC's Arlington, Texas office to discuss NRC's preliminary conclusion that potentially significant violations of NRC requirements and plant Technical Specifications had occurred. This conference was open to public observation in accordance with the terms of a pilot program begun by the NRC in July 1992.

The violations described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved: 1) the failure to perform an adequate evaluation to determine whether an unreviewed safety question existed prior to permanently modifying the containment and drywell airlock interlock mechanisms described in the River Bend Station safety analysis report on October 25, 1991 (the NRC notes that the interlock mechanisms were effectively modified a year earlier, in October 1990, when power was removed from the electrical portion); 2) the failure to maintain the containment airlock interlock mechanisms in an operable condition per Technical Specification 3.6.1.4 between October 1990 and March 1993; and 3) the failure to perform an adequate containment airlock surveillance test to ensure that only one airlock door could be opened at one time.

The circumstances surrounding these violations are described in more detail in the inspection report. From the NRC's perspective, the most significant failure on the part of GSU is its failure to understand the design bases for the containment and drywell airlock interlock mechanisms. This appears to be the root cause of these violations. Because GSU did not recognize the necessity of maintaining the electrical portion of the interlock system, plant staff proceeded to disable the electrical portion of both the containment and drywell airlock mechanisms. This created a potential for breaching the integrity of the containment structure when personnel were passing through the

airlock. Modifying the design of the facility, as described in the plant safety analysis report, and not conducting an adequate safety analysis to determine whether the modification created an unreviewed safety question are of significant regulatory concern to the NRC. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem.

Although the NRC considers these violations significant from a regulatory perspective and from an overall safety perspective -- because they created a potential threat to the safety of licensed activities -- we acknowledge, as GSU pointed out during the enforcement conference, that the actual effect on the safety of the facility was minimal because there are only three documented instances in which the integrity of the containment structure was breached (two in February 1993 and an additional instance in 1986 that GSU brought to the NRC's attention at the conference), each involving very brief periods of time and each having been promptly recognized and corrected. The NRC also recognizes that GSU has taken corrective action to enhance its procedures for conducting safety analyses when facility modifications are made, to ensure the proper operation of the containment and drywell airlock interlock mechanisms and to conduct a routine surveillance test that ensures that the interlock mechanisms work as designed and as described in design documents.

To emphasize the importance of understanding the plant design bases and ensuring that modifications do not result in a reduction of the intended level of safety, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$50,000 for the Severity Level III problem described above and in the Notice. The base value of a civil penalty for a Severity Level III problem is \$50,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in no net adjustment to the base value. In considering the "Identification" factor, the NRC determined that a 50-percent increase was warranted because the electrical interlock unreviewed safety question was identified by the NRC inspectors and would not have been discovered had it not been for the pursuit of the inspectors. This increase was balanced against a 50-percent decrease based on GSU's corrective actions, discussed above. The remaining adjustment factors were considered but no further adjustments were determined to be appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken, and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

Gulf States Utilities
ATTN: J. E. Booker, Manager-
Nuclear Industry Relations
P.O. Box 2951
Beaumont, Texas 77704

Winston & Strawn
ATTN: Mark J. Wetterhahn, Esq.
1401 L Street, N.W.
Washington, D.C. 20005-3502

Gulf States Utilities
ATTN: Les England, Director
Nuclear Licensing
P.O. Box 220
St. Francisville, Louisiana 70775

Mr. J. David McNeill, III
William G. Davis, Esq.
Department of Justice
Attorney General's Office
P.O. Box 94095
Baton Rouge, Louisiana 70804-9095

H. Anne Plettinger
3456 Villa Rose Drive
Baton Rouge, Louisiana 70800

President of West Feliciana
Police Jury
P.O. Box 1921
St. Francisville, Louisiana 70775

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Gulf States Utilities
River Bend Station

Docket No. 50-458
License No. NPF-47
EA 93-060

During an NRC inspection conducted February 25 - March 30, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. 10 CFR Section 50.59 states, in part, that the holder of a license authorizing operation of a production or utilization facility may make changes in the facility as described in the safety analysis report, without prior commission approval, unless the proposed change involves an unreviewed safety question. A change is deemed to involve an unreviewed safety question if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased.

The River Bend Station Updated Safety Analysis Report, Section 3.8.2.1.3.1, Personnel Air Lock, states in part, that the air lock doors are electrically coupled and mechanically interlocked, so that one door cannot be opened unless the other door is closed and sealed.

Contrary to the above, on October 25, 1991, the licensee failed to perform an adequate safety evaluation prior to the permanent removal of the electrical interlock on the drywell and containment airlock doors. The removal of the electrical interlock was a change to the facility as described in the Updated Safety Analysis Report and involved an unreviewed safety question, i.e., an increase in the probability of a malfunction of the airlock. The change was made without prior Commission approval.

- B. Technical Specification 3.6.1.4 states, in part, that each primary containment air lock shall be operable in Operational Conditions 1, 2, 3, and when irradiated fuel is being handled in the primary containment and during core alterations and operations with a potential for draining the reactor vessel. Technical Specification 3.6.1.4 Action Statement b. requires, in part, with the interlock mechanism inoperable, that the licensee maintain at least one operable air lock door closed and either return the interlock to service within 24 hours or lock one operable air lock door closed; and, that personnel entry and exit through the air lock is permitted provided one operable air lock door remains locked at all times and an individual is dedicated to assure that two doors are not open simultaneously.

Contrary to the above, from October 1990 to March 11, 1993, with the plant in Operational Conditions 1, 2, or 3 at various times, the interlock mechanism on both containment airlock doors was inoperable because the licensee had removed power from the electrical portion, and the licensee did not return the interlock to service within 24 hours or lock one operable airlock door closed or control personnel entry and exit through the containment airlock with an individual who was dedicated to assure that two doors were not open simultaneously.

- C. Technical Specification 4.6.1.4 states, in part, that each primary airlock shall be demonstrated operable at least once per 6 months by verifying that only one door in each airlock can be opened at a time.

Contrary to the above, from October 1990 to April 1993, the licensee did not perform a surveillance test that was adequate to verify that only one door in each airlock could be opened at a time. Surveillance Test STP-057-0401, which was used to test the safety-related containment airlock interlocks, was inadequate because the electrical portion of the interlock was identified as optional and was not tested when de-energized.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - \$50,000

Pursuant to the provisions of 10 CFR 2.201, Gulf States Utilities (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the

cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at River Bend Station.

Dated at Arlington, Texas,
this 21st day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8084

APR 19 1993

Dockets: 50-498; 50-499
Licenses: NPF-76; NPF-80
EA 92-175

Houston Lighting & Power Company
ATTN: William T. Cottle, Group
Vice President, Nuclear
P.O. Box 1700
Houston, Texas 77251

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$75,000 (NRC INSPECTION REPORT 92-17)

This is in reference to the special inspection conducted May 26-29 and August 28-September 15, 1992. The results of this inspection were documented in a report issued on January 15, 1993. The inspection report described five apparent violations of requirements associated with the South Texas Project Electric Generating Station (STP). These apparent violations were discussed with you and other Houston Lighting & Power Company (HL&P) representatives at an enforcement conference in the NRC's Region IV office in Arlington, Texas on March 8, 1993.

The violations in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) include: 1) a failure on May 19, 1992, to promptly inform the control room shift supervisors, either verbally or via a written Station Problem Report, of a manual reactor trip surveillance deficiency; and 2) failures on June 8, 1992 and September 3, 1992, to follow procedural requirements for issuing clarification or interpretation of plant Technical Specifications. A detailed description of the events surrounding these violations appears in the January 15, 1993 inspection report.

The May 19, 1992 event involved a violation of STP procedures governing Station Problem Reporting. On that day, with STP Units 1 and 2 operating at full power, plant officials concluded after extensive review that a problem existed with respect to a required surveillance test of the reactor trip system. The potential surveillance test deficiency had been identified on the previous day. Despite the involvement of approximately 26 plant employees in the process of reviewing the surveillance deficiency that led to the plant manager declaring the reactor trip system inoperable for both units and placing the units in Technical Specification 3.0.3 (requiring that steps be taken to shut both units down), the unit shift supervisors were not informed until two and one-half hours after the decision was made to enter Technical Specification 3.0.3. In fact, the unit shift supervisors were not informed

APR | 9 1993

until NRC regional officials prompted the licensee during a telephone conference call that HL&P had requested to seek a temporary waiver of compliance from the Technical Specifications. This delay in informing shift supervisors prevented them from taking steps to prepare for or initiate a plant shutdown and also prevented them from making required notifications.

The June 8 and September 3, 1992 events involved a violation of STP procedures governing the issuance of Technical Specification clarification or interpretation. On both June 8 and September 3, 1992, guidance was issued to control room operators which clarified their responsibilities for implementing Technical Specification 3.0.3 and the process established by Procedures OPGP03-ZO-0018 and OPGP03-ZO-0040 for routing and approving such guidance was not followed. The September 3rd event is specifically noteworthy for two reasons. First, control room operators were in the process of implementing Technical Specification 3.0.3 and were two minutes from beginning a facility shutdown when revised guidance on implementing Technical Specification 3.0.3 was electronically transmitted to the control room. The revised guidance, which was provided without explanation, caused confusion on the part of control room personnel. Because of the confusion and their proper understanding of what had to be done, control room personnel did not follow the guidance, which would have permitted additional time for emergency repair or troubleshooting prior to taking required actions. Second, it was extremely poor judgement on the part of the manager involved to transmit guidance to the control room without explanation especially when he could have simply gone to the control room and conveyed his expectations, eliminating the potential for confusion.

The NRC's concerns about these violations include: 1) weaknesses in the process for identifying potentially significant problems to the control room; and 2) STP management's failure to properly convey its expectations to NRC-licensed operators in the control room in a timely and unambiguous manner. In the first instance (May 19) the process for informing shift supervisors of a potentially significant failure to comply with plant Technical Specifications apparently broke down because: 1) the plant manager believed that informing the shift supervisors would cause them to initiate a shutdown of both units; and 2) the plant manager felt the problem was of low significance and believed that the NRC would grant a waiver of compliance, thus permitting the continued operation of the facility. Although the NRC did ultimately grant a waiver of compliance, the NRC considers plant management's actions inappropriate because licensed personnel were not informed in a timely manner of plant management's decision to declare safety related equipment inoperable. In the September 3rd event, the NRC considers plant management's actions inappropriate because licensed personnel were provided guidance on compliance with an important license condition (Technical Specification 3.0.3) moments before operators were required to take actions to comply with existing procedures for implementing Technical Specification 3.0.3. Furthermore, despite the fact that the guidance conflicted with training provided to operators on compliance with this technical specification and the guidance had not been subjected to the formal reviews required by plant procedures, the involved manager did not

April 15, 1993

go to the control room and explain either the meaning of the revised guidance or the reason for it.

The NRC recognizes that plant management is ultimately responsible for the safe operation of the plant and, provided that compliance with license and other NRC requirements is assured, has the latitude to modify procedures governing plant operations. However, the NRC expects that in non-emergency situations such changes will be made by following established procedures and when appropriate, as it was in these cases, such changes will be made in consultation with NRC licensed operators. In the NRC's view, the violations discussed above are of significant regulatory concern because plant management's actions could have interfered with the ability of licensed personnel to carry out their assigned responsibility and plant management's actions violated established procedures. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

The corrective actions that HL&P has taken to address these violations include: 1) revisions to Station Problem Reporting instructions; 2) revisions to policies to emphasize the role of the shift supervisors; 3) revisions to policies regarding Technical Specification required shutdowns and the handling of unresolved problems; 4) the issuance of procedures governing temporary waivers of compliance; 5) lessons learned briefings for licensed operators; 6) the conduct of an organizational interface assessment; and 7) revisions to the Corrective Action Group charter to address timeliness and effectiveness of corrective actions. As HL&P indicated during the enforcement conference, there are examples of these corrective actions already having been effective in resolving the NRC's concerns about the flow of information to control room operators.

To emphasize the need for managers, when necessary, to promptly and properly interface with the NRC-licensed personnel in the control room and the importance of plant management personnel following or properly modifying established procedures, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$75,000 for the Severity Level III problem described above and in the Notice.

The base value of a civil penalty for a Severity Level III problem is \$50,000. The civil penalty adjustment factors in Section VI.B. of the Enforcement Policy were considered and resulted in a net increase of \$25,000. In making this adjustment, the NRC considered HL&P's corrective actions worthy of a reduction equivalent to 50 percent of the base value. However, this was offset by increases because NRC identified these violations and because HL&P had prior opportunities to take action to prevent the procedural violations that occurred on May 19, 1992. With specific regard to the prior

opportunities, given that the potential issue had been raised on the previous day and given the number of plant personnel involved in the event the plant staff had more than enough time to prepare the SPR in case it would be required as well as many opportunities to ensure it was submitted once the decision was made that a problem existed. Each of these increases was equivalent to 50 percent of the base value. The other adjustment factors were considered and no further adjustment to the civil penalty was considered appropriate.

Based on the NRC's review of the information in the inspection report; information provided by HL&P in writing on September 12, 1992, January 12, 1993, and February 24, 1993; and the information provided during the enforcement conference, the NRC has decided that three of the apparent violations identified during this inspection will not be cited. These include: 1) a violation of Technical Specification requirements regarding the performance of surveillances (tests) of manual reactor trip circuits; 2) an apparent failure to take adequate corrective actions to address a condition adverse to quality as well as to address an identified reluctance on the part of plant personnel to initiate Station Problem Reports; and 3) an apparent failure to provide complete and accurate information to the NRC.

The violation of Technical Specification surveillance requirement 4.3.1.1, for the manual reactor trip circuits, is not being cited because it was identified by HL&P personnel, was of relatively low safety significance, was reported to the NRC and was not a problem which could have been prevented by corrective action for a previous similar violation. The efforts of HL&P personnel in discovering and pursuing this surveillance deficiency are to be commended. The apparent violation involving inaccurate information is not being cited because the information in question was provided orally in response to NRC questions, HL&P promptly provided clarification of the information when it was questioned, and the information at issue was ultimately determined to be of low significance. The apparent violation involving the failure to take adequate corrective action for a condition adverse to quality is not being cited because at the time of occurrence HL&P was implementing corrective actions for past similar problems and a citation is being made for other issues related to the May 19, 1992 event.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

APR 1993

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

cc w/enclosure:

Houston Lighting & Power Company
ATTN: William J. Jump, Manager
Nuclear Licensing
P.O. Box 289
Wadsworth, Texas 77483

City of Austin
Electric Utility Department
ATTN: J. C. Lanier/M. B. Lee
P.O. Box 1088
Austin, Texas 78767

City Public Service Board
ATTN: R. J. Costello/M. T. Hardt
P.O. Box 1771
San Antonio, Texas 78296

Newman & Holtzinger, P. C.
ATTN: Jack R. Newman, Esq.
1615 L Street, NW
Washington, D.C. 20036

Central Power and Light Company
ATTN: D. E. Ward/T. M. Puckett
P.O. Box 2121
Corpus Christi, Texas 78403

INPO
Records Center
1100 Circle 75 Parkway
Atlanta, Georgia 30339-3064

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Houston Lighting & Power Company
South Texas Project Electric
Generating Station (STP)

Docket Nos. 50-498; 50-499
License Nos. NPF-76; NPF-80
EA 92-175

During an NRC inspection conducted between May 26 and September 15, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. 10 CFR Part 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings," requires, in part, that activities affecting quality shall be prescribed by documented procedures of a type appropriate to the circumstances and shall be accomplished in accordance with these procedures.

STP Interdepartmental Procedure IP-1.45Q, "Station Problem Reporting," Step 6.1.1, states, in part, that any person who discovers a condition that may impact the safe and reliable operation of the plant shall originate a Station Problem Report (SPR) and if the condition appears to require immediate response, the originator shall report (i.e., call) the condition immediately to the Shift Supervisor followed by documenting the condition on a SPR.

Contrary to the above, on May 19, 1992, after declaring the reactor trip system inoperable for STP Units 1 and 2 and placing both units in Technical Specification 3.0.3 based on this condition, thus requiring immediate response, licensee personnel did not report the condition immediately to the Shift Supervisor. The condition was not reported to the Shift Supervisors until approximately two and one-half hours after the plant manager declared the plant to be in Technical Specification 3.0.3. In addition, the condition was not promptly documented in a Station Problem Report.

- B. 10 CFR Part 50, Appendix B, Criterion V, "Instructions, Procedures, and Drawings," requires, in part, that activities affecting quality shall be prescribed by documented procedures of a type appropriate to the circumstances and shall be accomplished in accordance with these procedures.

STP Procedure OPGP03-ZO-0018, Revision 4, "Technical Specification Interpretation Control," Step 1.2, requires, in part, that this procedure be used for those situations which are not clearly or specifically addressed by wording in the Technical Specifications.

STP Procedure OPGP03-ZO-0040, Revision 0, "Maintenance of the Operations Policies and Practices Manual," Step 3.2.2, states, in part, that

memoranda from whatever source that are potentially "Tech Spec Interpretations" should be formally routed by the initiating authority through the formal evaluation process in accordance with OPGP03-ZO-0018, "Technical Specification Interpretation Control".

Contrary to the above, on June 8, 1992, and again on September 3, 1992, Office Memoranda from the Operations Manager to the Policies and Practices Manual were issued which provided clarification of a situation which was not clearly addressed by the wording of Technical Specification 3.0.3 and other Technical Specifications. These memoranda were not formally routed through the formal evaluation process in accordance with OPGP03-ZO-0018.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - \$75,000

Pursuant to the provisions of 10 CFR 2.201, Houston Lighting & Power Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating

circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at the South Texas Project.

Dated at Arlington, Texas
this 19th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

APR 19 1993

Dockets: 50-498; 50-499
Licenses: NPF-76; NPF-80
EA 93-023

Houston Lighting & Power Company
ATTN: William T. Cottle, Group
Vice President, Nuclear
P.O. Box 1700
Houston, Texas 77251

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$25,000 (NRC INSPECTION REPORTS 92-29, 92-32 AND 93-03)

This is in reference to NRC inspections conducted between September 13, 1992, and February 1, 1993. These inspections reviewed eight instances in which South Texas Project Electric Generating Station (STP) personnel failed to follow procedures requiring self-verification. Each of these was discovered by Houston Lighting & Power Company (HL&P) and described in a written Station Problem Report. The inspection reports describing the events that resulted in these apparent violations were issued on November 25, 1992; January 19, 1993; and February 18, 1993. These apparent violations were discussed with you and other HL&P representatives at an enforcement conference in the NRC's Arlington, Texas office on March 8, 1993.

The violations in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) include eight examples of failures of STP personnel to adhere to procedural requirements regarding self-verification. STP Procedure OPGP03-ZA-0010, "Plant Procedure Adherence and Implementation and Independent Verification," requires plant personnel to follow a seven-step self-verification process in performing any procedure that requires the manipulation of plant equipment. The seven steps are: 1) stop and think about the task; 2) locate the device to be operated; 3) touch the device; 4) verify the correctness of the device; 5) anticipate the expected and unexpected responses and the actions to be taken; 6) manipulate the component; and 7) observe for expected and unexpected responses. Step 2 of the self-verification process requires individuals to ensure they are on the correct unit, correct train and correct device.

The eight violations of this procedural requirement occurred between September 28, 1992, and January 9, 1993, and primarily involved the failure to verify the correct unit, correct train or correct device before conducting testing or maintenance activities. The specific examples are described in more detail in the inspection reports and included: 1) maintenance work begun on the wrong condenser waterbox before the error was discovered; 2) maintenance performed on the wrong pipe support in the Essential Cooling Water

APR 19 1993

system; 3) operational test performed on the wrong reactor cooling pump underfrequency trip actuating device; 4) local leak rate test performed on the wrong containment isolation valves; 5) lifting of wrong leads during the performance of accumulator pressure surveillance test; 6) maintenance performed on the Qualified Display Parameter system in the wrong unit; 7) service request written for the wrong feedwater heater drain valve (although work was performed on the correct valve); and 8) high neutron flux trip setpoint set incorrectly.

The NRC acknowledges that these particular errors did not result in any operational events and did not have any immediate impact on the safety of the plant or plant personnel. The NRC's concerns about these errors, and similar errors HL&P identified subsequent to the issuance of the inspection reports include: 1) the potential for errors of this type to result in plant transients or cause injury to personnel; 2) the recurring nature of personnel errors at STP despite the NRC's having expressed concern about such errors on numerous occasions and despite plant management's efforts to correct previous, similar problems involving the failure of personnel to pay attention to detail; and 3) because a number of these errors involved contract personnel, the extent to which contract employees are being trained in procedural adherence requirements. When viewed collectively, these violations represent a significant regulatory concern in the area of personnel performance and more specifically attention to detail. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem.

In its presentation at the enforcement conference, HL&P presented additional examples of the issues discussed above and identified two broad causes of all of these recent errors: 1) personal accountability and responsibility, which HL&P said encompassed both the failure of individuals to perform the self-verification procedure and a lack of attention to detail; and 2) organizational/programmatic support, which HL&P said encompassed a lack of clear written instructions, poor oral briefings/instructions, inadequate equipment design/labeling, and the repetitive nature of some tasks. While HL&P has developed a long list of short-term and long-term corrective actions to address these root causes, the likely effectiveness of these actions is difficult to gauge at this time since many of the more important actions are planned but have not been implemented or completed. The NRC notes that four additional examples of individuals failing to follow self-identification procedures or pay attention to detail were reviewed during an inspection completed on April 12, 1993. These examples, which will be discussed in Inspection Report 93-11, indicate that HL&P's efforts to correct these problems have not yet been effective.

HL&P's completed corrective actions to address these problems include: meeting with plant personnel to discuss these errors, management expectations and lessons learned; issuing a plant bulletin on "Attention to Detail;" conducting additional training on the self-verification process; and modifying

J 1996

work packages and service requests to minimize the opportunity for error. Ongoing and planned corrective actions include, but are not limited to: increasing oversight of field activities by supervisors; discussing self-verification and attention to detail in routine meetings; simplifying the self-verification process and enhancing self-verification training; rotating personnel to avoid desensitization; initiating a plant manager's forum to discuss human performance expectations and employee-identified problems; augmenting work controls for critical plant equipment; upgrading labeling of plant components; and evaluating the results of an ongoing organizational interface assessment for issues which affect human performance.

To emphasize the importance of attention to detail, i.e., doing the job right the first time, and the need for HL&P to be aggressive in implementing corrective actions of a lasting nature, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$25,000 for the Severity Level III problem described above and in the Notice.

The base value of a civil penalty for a Severity Level III problem is \$50,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in a 50-percent decrease in the base value. In assessing these factors, the NRC considered HL&P's identification and documentation of these errors worthy of a decrease equivalent to 50 percent of the base value. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

APR 19 1993

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition
of Civil Penalty

cc w/enclosure:
Houston Lighting & Power Company
ATTN: William J. Jump, Manager
Nuclear Licensing
P.O. Box 289
Wadsworth, Texas 77483

City of Austin
Electric Utility Department
ATTN: J. C. Lanier/M. B. Lee
P.O. Box 1088
Austin, Texas 78767

City Public Service Board
ATTN: R. J. Costello/M. T. Hardt
P.O. Box 1771
San Antonio, Texas 78296

Newman & Holtzinger, P. C.
ATTN: Jack R. Newman, Esq.
1615 L Street, NW
Washington, D.C. 20036

Central Power and Light Company
ATTN: D. E. Ward/T. M. Puckett
P.O. Box 2121
Corpus Christi, Texas 78403

INPO
Records Center
1100 Circle 75 Parkway
Atlanta, Georgia 30339-3064

Houston Lighting & Power Company - 5 -

APP 15 1992

Mr. Joseph M. Hendrie
50 Bellport Lane
Bellport, New York 11713

Bureau of Radiation Control
State of Texas
1101 West 49th Street
Austin, Texas 78756

Judge, Matagorda County
Matagorda County Courthouse
1700 Seventh Street
Bay City, Texas 77414

Licensing Representative
Houston Lighting & Power Company
Suite 610
Three Metro Center
Bethesda, Maryland 20814

Houston Lighting & Power Company
ATTN: Rufus S. Scott, Associate
General Counsel
P.O. Box 61867
Houston, Texas 77208

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Houston Lighting & Power Company
South Texas Project Electric
Generating Station

Dockets 50-498; 50-499
Licenses NPF-76; NPF 80
EA 93-023

During NRC inspections conducted between September 13, 1992, and February 1, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

Technical Specification 6.8.1.a requires that written procedures shall be established, implemented, and maintained for those activities recommended in Appendix A of Regulatory Guide (RG) 1.33, Revision 2, February 1978. RG 1.33, Appendix A, Item 1.d recommends operating procedures for procedure adherence.

STP Procedure OPGP03-ZA-0010, Revision 15, "Plant Procedure Adherence and Implementation and Independent Verification," Step 4.2.1, states, "For performance of procedures which require manipulation of plant equipment, prior to performing any step or group of steps of a procedure, the individual performing that step SHALL first implement the seven step Self Verification program..."

The Self Verification program is defined in the procedure and requires that an employee stop and think about the task, locate the device to be operated, touch the device, verify the correct device, anticipate the expected and unexpected responses and the actions to be taken, manipulate the component, and observe for expected and unexpected responses.

Step 4.2.1.2 of the Self Verification program states "LOCATE device to be operated" and includes the following directions: a) Ensure you are on the correct UNIT; b) Ensure you are on the correct TRAIN; and c) Ensure you are on the correct DEVICE.

Contrary to the above, from September 28, 1992, through January 9, 1993, licensee personnel did not verify the correct device, did not ensure they were on the correct unit, did not ensure they were on the correct train or otherwise complete the self-verification program required by procedure OPGP03-ZA-0010 in the following eight instances:

- A. On September 28, 1992, Equipment Clearance Order 1-92-8030 was issued to allow chemical cleaning of Condenser Waterbox 12N. Seven of 64 Waterbox outlet bolts for Condenser Waterbox 12S were removed before water leakage revealed that work was being conducted on the wrong component.

- B. On October 12, 1992, work specified by Work Package 116446-EP01 for Essential Cooling Water Pipe Support EW-1107-HL5006 was performed on Essential Cooling Water Pipe Support EW-1128-HL5003.
- C. On October 19, 1992, an underfrequency trip actuating device operational test was performed on Reactor Coolant Pump 2A whereas work permission had only been given to perform the test on Reactor Coolant Pump 2C.
- D. On October 29, 1992, a local leak rate test was performed on Containment Isolation Valves CV0033A, B, and C whereas the procedure was written for performing the test on Containment Isolation Valves CV0034A, B, and C.
- E. On November 2, 1992, while performing Procedure OPSP02-SI-0964, "Accumulator C Pressure Group 3 ACOT (P-0964)," a technician incorrectly lifted wire TB-J from terminal 7 and wire TB-J from terminal 8 when the procedure called for lifting wire TB-J from terminal 10 and wire TB-J from terminal 11.
- F. On November 5, 1992, during final review of Unit 1 Qualified Display Parameter System work packages, it was determined that Service Requests AM-164610 and AM-164611 were performed in Unit 1 on October 30, 1992, whereas the service requests were written for and intended to be performed in Unit 2.
- G. On November 7, 1992, Service Request 173475 was written to repair a steam leak on Heater Drip System Valve N2HDLC7222 whereas the leak was actually on valve N2HDLC7223; this resulted in repairs being made to the leaking valve but not the valve identified on the service request.
- H. On January 9, 1993, a technician failed to implement the seven step Self Verification program while attempting to adjust the high neutron flux setpoint for channel N-0041 from 84.5 to 109 percent. As a consequence, the setpoint was erroneously set at 99 percent.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - \$25,000.

Pursuant to the provisions of 10 CFR 2.201, Houston Lighting & Power Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps

that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at the South Texas Project.

Dated at Arlington, Texas
this 19th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-6064

APR 19 1993

Dockets: 50-498; 50-499
Licenses: NPF-76; NPF-80
EA 93-047

Houston Lighting & Power Company
ATTN: William T. Cottle, Group
Vice President, Nuclear
P.O. Box 1700
Houston, Texas 77251

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$75,000 (NRC INSPECTION REPORT NO. 93-08)

This is in reference to the inspection conducted on February 17-26, 1993, at Houston Lighting & Power Company's (HL&P) South Texas Project Electric Generating Station (STP). A report documenting the results of this inspection was issued on March 17, 1993. As indicated in the report, this inspection found apparent violations of requirements associated with HL&P's maintenance and operation of motor-operated valves (MOV) in safety-related systems. These violations were discussed with you and other HL&P representatives during an enforcement conference in the NRC's Arlington, Texas office on March 25, 1993.

The violations identified during this inspection include: 1) a failure to repair a failed motor on an MOV in the Low Head Safety Injection system for some 18 months, as well as a failure to determine the cause of the motor failure to prevent a recurrence; 2) as a consequence of the above violation, a failure to operate STP Unit 2 in accordance with the Technical Specification requirements related to the Low Head Safety Injection system; and 3) a failure to take prompt action to determine the cause of and correct an over-torque condition that was affecting five MOVs in the STP Unit 1 Residual Heat Removal system.

On February 9, 1993, STP Unit 2 MOV SI-31A failed to open on demand from the control room. During the subsequent investigation, HL&P determined that the valve motor had burned up while attempting to lift the valve disc off the closed seat. The area between the actuator springpack washers was found to have been thoroughly packed with partially hardened and slightly discolored grease, which was the most likely cause of the valve motor failure.

As a result of its investigation, HL&P discovered that the valve motor for MOV SI-31A had previously burned up during an attempt to open the valve in April 1989. Although a work request was issued to replace the motor, no

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

APR 19 1993

station problem report was issued; consequently, no effort was undertaken to determine the root cause of the failure. In addition, even though the motor failed in April 1989 and was again checked and determined to be shorted in November 1989, for reasons not fully understood by HL&P at the time of the enforcement conference, the valve motor was not replaced until October 1990.

STP Unit 2 was operated for a full fuel cycle with the motor to SI-31A inoperable. Although operations personnel placed the valve in its normal operating position for reactor operation, i.e., fully open with power removed from the motor, SI-31A was unable to perform its safety function. Specifically, the design basis for SI-31A is to close approximately 13 hours following a loss-of-coolant accident to establish hot leg recirculation for Train A of the Low Head Safety Injection System. The valve is inaccessible in a post-accident environment.

The NRC recognizes that HL&P's after-the-fact analysis of this condition concludes that operators would have been able to take action to overcome the SI-31A failure and that the full safety function of the Low Head Safety Injection system would have been retained, due to the robust design of the STP emergency core cooling system (three 100% ECCS trains). Nonetheless, the NRC considers Violations I.A and B of the enclosed Notice to be a significant regulatory concern because (1) a safety-related MOV went unrepaired for 18 months, despite multiple opportunities to recognize the significance of the deficiency and take corrective action, and (2) operations personnel did not recognize the technical specification implications of operating the reactor with SI-31A inoperable.

During the enforcement conference HL&P asserted that its initial corrective actions in 1989 were reasonable in light of industry information available in that timeframe. The NRC does not agree, but rather views HL&P's inaction in 1989 to be the result of a passive corrective action program in which potentially significant equipment problems were not aggressively pursued. In fact, current inspection findings indicate that there have been other situations in which HL&P has not taken prompt action to determine the causes of safety-related MOV failures and deficiencies (as discussed during an NRC exit meeting for Inspection Report 93-13, held on March 26, 1993); thus, the issues surrounding SI-31A do not appear to be isolated concerns. It appears that HL&P's corrective actions continue to often focus on only the symptoms of the problem and not the root cause. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, Violations I.A and B have been categorized as a Severity Level III problem.

HL&P has taken or has plans to take a number of necessary corrective actions aimed primarily at equipment operability and repair issues. These actions included: 1) repair of SI-31A; 2) modifications to the valve to prevent similar failures; 3) plans to review the operability tracking log and open service requests on Unit 1 prior to start-up; and 4) plans to enhance programmatic controls over operability determinations and equipment failure

APR 19 1993

trending. With regard to its corrective action program, HL&P acknowledged past weaknesses in its program, but contends that significant enhancements have been made to it since the occurrence of the events described above. While the NRC agrees that programmatic enhancements have been made, those enhancements have not been completely effective. Specifically, a number of recent violations were cited in Inspection Report 92-35 that involved inadequate corrective actions for known hardware or programmatic deficiencies.

As discussed in the inspection report and during the enforcement conference, the NRC believes that HL&P's long-term corrective actions should include definitive plans for reviewing MOV lubrication issues, particularly since hardened grease was determined to be the apparent cause of the SI-31A motor failure. The grease that had migrated into the springpack of Valve SI-31A was approximately five years in age. In HL&P's MOV program, each springpack is inspected approximately once every five years. Thus, it would be prudent to examine the frequency of grease inspections in light of your experience and, as warranted, adjust the inspection intervals.

To emphasize the importance of ensuring that identified problems that have the potential to affect the operability of safety systems are resolved in a timely manner, and are resolved commensurate with their relevance to ensuring compliance with plant Technical Specifications, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$75,000 for the Severity Level III problem described above and in the Notice. The base value of a civil penalty for a Severity Level III problem is \$50,000. The civil penalty adjustment factors in the Enforcement Policy were considered as discussed below.

Although the valve failure is considered a self-identifying event, the base civil penalty was mitigated by 25 percent in recognition of HL&P's having discovered the violations associated with the 1989 SI-31A failure while investigating the 1993 event. However, the base civil penalty was escalated by 25 percent for the corrective action factor because the NRC identified the broad concerns with the adequacy of HL&P's lubrication program. In addition, the civil penalty amount was escalated a further 50 percent for the added significance of the duration that SI-31A remained inoperable without the Operation Department's recognition of its technical specification impact. The full 100 percent escalation was not applied for this factor in recognition of the extra margin that you incorporated into your emergency core cooling system. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

The remaining violation, addressed in Section II of the Notice, involved the failure to take prompt corrective action to address an over-torque condition for five motor-operated valves in the Residual Heat Removal system, and has been classified at Severity Level IV. Although an after-the-fact examination and limited testing performed by a third party indicated that these valves may

APR 10 1992

have been capable of performing their safety function for a limited number of cycles, the NRC is concerned that HL&P made an initial operability determination without performing an analysis, test, or a specific inspection of the load bearing components that were subjected to the over-torque condition. This condition is of more than minor concern because it reduces the number of cycles that the valve actuator can perform before failure and, if left uncorrected, could lead to a more serious safety concern.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

Houston Lighting & Power Company
ATTN: William J. Jump, Manager
Nuclear Licensing
P.O. Box 289
Wadsworth, Texas 77483

City of Austin
Electric Utility Department
ATTN: J. C. Lanier/M. B. Lee
P.O. Box 1088
Austin, Texas 78767

APR 19 1993

City Public Service Board
ATTN: R. J. Costello/M. T. Hardt
P.O. Box 1771
San Antonio, Texas 78296

Newman & Holtzinger, P. C.
ATTN: Jack R. Newman, Esq.
1615 L Street, NW
Washington, D.C. 20036

Central Power and Light Company
ATTN: D. E. Ward/T. M. Puckett
P.O. Box 2121
Corpus Christi, Texas 78403

INPO
Records Center
1100 Circle 75 Parkway
Atlanta, Georgia 30339-3064

Mr. Joseph M. Hendrie
50 Bellport Lane
Bellport, New York 11713

Bureau of Radiation Control
State of Texas
1101 West 49th Street
Austin, Texas 78756

Judge, Matagorda County
Matagorda County Courthouse
1700 Seventh Street
Bay City, Texas 77414

Licensing Representative
Houston Lighting & Power Company
Suite 610
Three Metro Center
Bethesda, Maryland 20814

Houston Lighting & Power Company
ATTN: Rufus S. Scott, Associate
General Counsel
P.O. Box 61867
Houston, Texas 77208

••

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Houston Lighting & Power Company
South Texas Project Electric
Generating Station

Dockets 50-498; 50-499
Licenses NPF-76; NPF 80
EA 93-047

During an NRC inspection conducted February 17-19 and February 23-26, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 50, Appendix B, Criterion XVI, states that "measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management."

Contrary to the above, in April 1989 and November 1989, the licensee identified a significant condition adverse to quality related to an inoperable motor on Unit 2 safety-related valve SI-31A, but did not replace the motor until October 1990. Further, the licensee did not determine the cause of the failure and take action to preclude recurrence, or document and report the condition to appropriate levels of management until the motor failed again under similar circumstances on February 9, 1993.

- B. Technical Specification 3.5.2 requires for operation in Modes 1, 2, and 3, that three independent Emergency Core Cooling System (ECCS) subsystems shall be operable with each subsystem comprised of, in part, one operable Low Head Safety Injection (LHSI) pump and an operable flowpath capable of taking suction from the containment sump during the recirculation phase of operation through a LHSI pump and its respective RHR heat exchanger into the Reactor Coolant System. An inoperable ECCS subsystem must be restored to an operable status within 72 hours or the unit must be placed in hot standby within the next 6 hours and in hot shutdown within the following 6 hours.

Contrary to the above, from April 1989 to October 1990, Unit 2 was operated for one fuel cycle, predominantly in Mode 1, with the Train A ECCS LHSI subsystem inoperable. Motor-operated valve

SI-31A, cold leg injection isolation for the Train A LHSI pump, was inoperable during this period of time because of a failed motor; consequently, the valve, normally open, could not have been closed electrically or manually following a loss of coolant accident to enable initiation of hot leg recirculation, a safety function assumed in the updated safety analysis report.

Violations I.A and B are a Severity Level III problem (Supplement I).
Civil Penalty - \$75,000

II. Violation Not Assessed a Civil Penalty

10 CFR 50, Appendix B, Criterion XVI, states, in part, that measures shall be established to assure that conditions adverse to quality are promptly identified and corrected.

Contrary to the above, on February 2, 1993, the licensee determined that five STP Unit 1 Residual Heat Removal suction isolation motor-operated valves had incurred torque loadings of up to 253% of the actuator qualified limit for up to 50 cycles, a condition adverse to quality, but failed to identify the full scope of the deficiency and take adequate corrective action. Specifically, the licensee concluded that the valves were operable based on valve internal inspections conducted during the previous outage, which recorded "excessive" wear on the worm gear (a component vulnerable to the effects of high torque). The licensee developed no justification or basis consistent with the recommendations of the actuator vendor or information published by or for the users of motor-operated valves in the nuclear power industry for the continued application of torque values in excess of the qualified limit.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Houston Lighting & Power Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the

response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at the facility that is the subject of this Notice.

Dated at Arlington, Texas
this 19th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

MAY 28 1993

Docket Nos. 50-498 and 50-499
License Nos. NPF-76 and NPF-80
EA 93-057

Houston Lighting & Power Company
ATTN: William Cottle, Group
Vice President, Nuclear
Post Office Box 1700
Houston, Texas 77251

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -
\$325,000 (NRC INSPECTION REPORT NO. 93-05)

This is in reference to an NRC inspection conducted March 8-12, 1993, at the South Texas Project (STP) Electric Generating Station. This inspection was conducted to review the circumstances surrounding: 1) equipment problems with turbine-driven auxiliary feedwater pumps in STP Units 1 and 2 that culminated in a shutdown of Unit 1 in February 1993; and 2) the disabling of a Unit 1 emergency diesel generator in December 1992. The inspection disclosed eight apparent violations of NRC requirements associated with these events. These violations were described in an inspection report (50-498 and 499/93-05) issued on April 8, 1993, and were discussed with you and other HL&P representatives at an enforcement conference in the NRC's Arlington, Texas office on April 22, 1993.

On February 4, 1993, HL&P informed the NRC Operations Center in Bethesda, Maryland, of a Technical Specification-required shutdown of STP Unit 1 based on HL&P's inability to return the unit's turbine-driven auxiliary feedwater (TDAFW) pump to an operable status within the allowable time (72 hours). The NRC dispatched an Augmented Inspection Team (AIT) on the same date to review the circumstances leading up to this event and to determine the causes of a history of TDAFW pump overspeed trips at the STP facility. The AIT inspection report (Inspection Report 93-07), which described the results of this evaluation, was issued on March 24, 1993. HL&P's investigation of these issues was described in Licensee Event Report 93-007, issued on March 5, 1993.

As a result of the AIT inspection, the follow-up inspection described in Inspection Report 93-05, and the information gained during the enforcement conference, the NRC has determined that the STP Unit 1 TDAFW pump was effectively inoperable from December 26, 1992, until February 4, 1993, a period of 33 days. The NRC concludes that during this period the pump would have tripped on overspeed if it had received an automatic start signal. In addition, the NRC has determined that a cause of this condition was an improper adjustment to the TDAFW pump governor valve, which affected the operation of the turbine, contributing to its tripping on overspeed when started from a normal standby condition. In all, the NRC's inspection identified five violations of requirements relative to the maintenance and testing of the STP TDAFW pumps in Units 1 and 2.

MAY 28 1993

The circumstances surrounding these violations are described in the referenced inspection reports. The violations include: 1) the Unit 1 TDAFW pump remaining in an inoperable condition for a period in excess of that permitted by the plant Technical Specifications; 2) a failure to perform adequate TDAFW pump surveillance testing to ensure that the pumps would operate when called upon to do so (both units) in light of the recurring overspeed trips; 3) a failure to provide adequate instructions for conducting preventive maintenance on the Unit 1 TDAFW pump governor valve; 4) a failure to follow procedures regarding the positioning of a steam trap valve associated with the Unit 2 TDAFW pump; and 5) the performance of maintenance on the Unit 2 TDAFW pump throttle valve linkage by an unauthorized individual.

Water intrusion was determined to have been the primary cause of the TDAFW pumps tripping on overspeed. In the case of Unit 1, this was caused primarily by leakage past MOV 514 and an improperly adjusted governor valve. These two causes effectively rendered the Unit 1 pump inoperable. In the case of Unit 2, the overspeed trips were caused by an improper adjustment to a steam trap bypass valve. Of broader significance, however, are: 1) the failure of HL&P's TDAFW pump surveillance test program to detect overspeed trip problems; 2) the failure of HL&P's corrective action program to capture recurring TDAFW pump trips as a problem in need of resolution; and 3) the failure of HL&P's work control processes to prevent the improper valve adjustments that permitted water intrusion.

During the enforcement conference, you asserted that the surveillance testing performed on the TDAFW pumps was consistent with industry practice. While the normal plant surveillance testing program is sufficient to demonstrate that operability is maintained, absent some known deficiency or problem, such testing may not envelope all conditions that impact operability. In this particular case, after several start attempts, the pumps would perform their operability tests satisfactorily, only to subsequently trip on overspeed when started in their normal standby mode. It is our view that you should have recognized that the repetitive trips were indicative of a continuing problem for which you had not identified the root cause. In addition, as discussed during the enforcement conference, the NRC is also concerned about the violations that involved unauthorized adjustments to a steam trap drain valve and to the Unit 2 TDAFW pump throttle valve linkage. The latter incident is of particular concern because the maintenance performed by a senior reactor operator was observed by the duty plant manager and general maintenance supervisor, and was not recognized as being an unauthorized activity.

The majority of these violations resulted in, or had the potential to result in, preventing the TDAFW pumps from performing their intended safety function, that of operating automatically to provide emergency feedwater to the plant's steam generators in the event of a loss of normal feedwater. This condition is made more serious by the fact, as discussed below, that for a period of 61 hours at least two of the three emergency diesel generators associated with Unit 1 were out of service at the same time, a situation which created the potential, under certain accident conditions that neither the steam-driven Unit 1 TDAFW pump nor two of the three Unit 1 motor-driven AFW pumps would

MAY 28 1993

have been available to provide auxiliary feedwater. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations related to STP's TDAFW pumps are classified in the aggregate as a Severity Level III problem.

With regard to the events surrounding the disabling of emergency diesel generator (EDG) 13, HL&P informed the NRC's Operations Center on January 20, 1993, that EDG 13, one of three STP Unit 1 EDGs, had failed to start during a routine periodic surveillance test earlier on the same day. HL&P's investigation of this event, which was documented in Licensee Event Report 93-005, issued on February 19, 1993, determined the failure of the EDG to start to have been caused by paint dripping into fuel metering rod ports. The painting of the EDG began on December 29, 1992, and was completed on December 31, 1992. Thus, the EDG appears to have been inoperable from the date painting began until January 22, 1993, when it was restored to operability, a period of 24 days. STP Technical Specifications permit one diesel to remain inoperable for only 72 hours before action must be taken to shut down the facility.

As a result of the NRC's inspection of the circumstances surrounding this event, and the information gained during the enforcement conference, the NRC has determined that three violations of requirements occurred. The circumstances surrounding these violations are described in more detail in Inspection Report 93-05. The violations include: 1) EDG 13 remaining in an inoperable condition for a period in excess of that permitted by the plant Technical Specifications; 2) a failure to ensure that maintenance activities that could affect safety-related equipment were carried out in accordance with procedures appropriate to the circumstances, resulting in a failure to test EDG 13 following painting to ensure its operability; and 3) EDGs 13 and 12 remaining in an inoperable condition for a period of 61 hours, when the Technical Specifications permit such a condition to exist for only two hours. The NRC notes that the second violation has been revised from that which was described in the inspection report; the NRC agrees with HL&P's stated position at the enforcement conference that Procedure OPGP03-ZA-0090 was not violated in this instance.

Paint dripping into fuel metering rod ports was the obvious cause of the EDG 13 failure. However, other factors contributed to this failure. First, HL&P failed to take advantage of industry experience and information relative to diesel failures. In NRC Information Notice 91-46, for example, the NRC described several incidents that had resulted in rendering EDGs inoperable. Three of the incidents involved painting of fuel injection assemblies, one of which (Palo Verde) appears to have been identical to that which HL&P experienced. Secondly, despite this and other industry information available describing such incidents, HL&P failed to conduct a test of EDG 13 following painting to ensure that it had not been adversely affected. This occurred despite the fact that a post-maintenance test was included in the original maintenance plan (it was deleted by a shift supervisor who mistakenly believed that several operational tests of the diesel would have to be conducted and

441 23 1993

who apparently felt that the necessary controls had been established to prevent the inadvertent disabling of the EDG). Finally, poor communications and poor work control processes appear to have played a role in this event. For example, had the shift supervisor been involved in the maintenance planning discussions and understood that only one operability test was planned and the reasons for that operability test, it is unlikely that he would have eliminated the test.

These violations resulted in an important piece of safety equipment being incapable of performing its intended safety function. In addition, based on HL&P not being aware of the condition of EDG 13, a second Unit 1 EDG was taken out of service for maintenance for some 61 hours, 56 hours of which it was actually incapable of operating. As indicated above, this period coincided with the inoperable Unit 1 TDAFW pump, significantly reducing the safety margin associated with the design assumptions relative to the auxiliary feedwater system. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations related to STP Unit 1's EDGs are classified in the aggregate as a Severity Level III problem.

The staff recognizes that immediate corrective action was taken when these problems were identified to restore compliance with all Technical Specification requirements, and that considerable corrective action has been taken to improve the reliability of the TDAFW pumps, to enhance TDAFW pump surveillance testing, and to prevent problems similar to that which resulted in EDG 13 being inoperable. However, at the time of the enforcement conference, HL&P had not developed with specificity the broader corrective actions needed to eliminate the contributing causes of these problems, which included poor work control processes, poor communications, ineffective use of industry experience and information, and the failure of the corrective action program to capture repetitive equipment problems.

To emphasize the importance of ensuring the operability of safety equipment through proper maintenance, adequate testing and the correction of recurring problems, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of \$325,000 for the two Severity Level III problems described above and in the Notice. The base value of a civil penalty for a Severity Level III problem is \$50,000. However, both penalties were increased based on the following.

The civil penalty adjustment factors in Section VI.B.2 of the Enforcement Policy were considered and resulted in the following adjustments: 1) for the Severity Level III problem related to STP's TDAFW pumps, the penalty was increased 50 percent based on the NRC's identification of the inadequacies in HL&P's surveillance test program, 100 percent for the multiple opportunities that HL&P had to identify and correct the cause of TDAFW pump overspeed trips, and 100 percent for the duration of the inoperable Unit 1 TDAFW pump, resulting in a total penalty of \$175,000; and 2) for the Severity Level III problem related to the EDGs, the penalty was increased 100 percent based on the specific notice given with regard to EDG problems caused by painting, and

Houston Lighting and
Power Company

- 5 -

MAY 2 1997

100 percent for the duration of the inoperable EDG 13, resulting in a total penalty of \$150,000. The remaining adjustment factors in the Enforcement Policy were considered and no further adjustments to the civil penalties were considered appropriate.

HL&P is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing its response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In particular, the NRC requests that HL&P address the actions it is taking or plans to take to improve work control processes, eliminate communications problems, improve its corrective action program, and use industry experience more effectively. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalties

cc w/encl:

Houston Lighting & Power Company
ATTN: William J. Jump, Manager
Nuclear Licensing
P.O. Box 289
Wadsworth, Texas 77483

City of Austin
Electric Utility Department
ATTN: J. C. Lanier/M. B. Lee
P.O. Box 1088
Austin, Texas 78767

MAI 28 1993

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Houston Lighting & Power Company Docket Nos. 50-498 and 50-499
South Texas Project Electric Licenses Nos. NPF-76; NPF 80
Generating Station EA 93-057

During an NRC inspection conducted March 8-12, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.201. The particular violations and associated civil penalties are set forth below:

I. Violations related to turbine-driven auxiliary feedwater pumps

- A. Technical Specification 3.7.1.2 requires, in part, that at least four independent steam generator auxiliary feedwater pumps and associated flow paths shall be OPERABLE, with one steam turbine-driven auxiliary feedwater (TDAFW) pump capable of being powered from an OPERABLE steam supply system in Modes 1-3. Action b.4 states, in part, that with the TDAFW pump inoperable, restore the affected turbine-driven auxiliary feedwater pump to operable status within 72 hours or place the reactor in at least HOT STANDBY within the next 6 hours and HOT SHUTDOWN within the following 6 hours.

Contrary to the above, from December 26, 1992, to February 4, 1993, a period of 33 days, and with STP Unit 1 in Modes 1-3, the Unit 1 TDAFW pump was inoperable and the licensee did not take the actions described above to place the reactor in hot standby or hot shutdown.

- B. 10 CFR Part 50, Appendix B, Criterion XVI, states, in part, that measures shall be taken to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action is taken to preclude repetition.

10 CFR Part 50, Appendix B, Criterion XI, states, in part, that all testing required to demonstrate that structures, systems and components will perform satisfactorily in service is identified and performed in accordance with written test procedures which incorporate appropriate requirements and acceptance limits. The test procedures shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and used, and that the test is performed under suitable environmental conditions.

MAY 28 1993

Contrary to the above, the licensee failed to assure that the cause(s) of the turbine driven auxiliary feedwater pump (TDAFW pump) overspeed trips, a significant condition adverse to quality, were identified and adequate corrective action taken to preclude repetition. Specifically, following maintenance troubleshooting, the licensee performed procedures OPSP03-SO-0019D, Revision 0, "Turbine Driven Auxiliary Feedwater Pump Actuation And Response Time Test," and OPSP03-AF-0007, Revision 7, "Auxiliary Feedwater Pump 14 Inservice Testing," to demonstrate TDAFW pump operability on June 11, 1990, December 27, 1992, and January 30, 1993, for the Unit 1 TDAFW pump; and on December 11, 1991, for the Unit 2 TDAFW pump. The successful completion of these test procedures was not sufficient to assure that the TDAFW pumps would perform satisfactorily in service because the TDAFW pumps were not returned to their normal standby condition prior to retest after the initial test failed.

- C. Technical Specification 6.8.1.a requires, in part, that written procedures be established, implemented, and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide (RG) 1.33, Revision 2, February 1978. RG 1.33, Appendix A, Item 9a, recommends, in part, that maintenance that can affect the performance of safety-related equipment be properly pre-planned and performed in accordance with written procedures appropriate to the circumstances.

Contrary to the above, in November 1992, maintenance on the STP Unit 1 TDAFW pump governor valve was not performed in accordance with written procedures that were appropriate to the circumstances. Preventative Maintenance Work Instruction MM 1-AF-89003576, the document that provided the guidance to adjust the governor valve, did not contain sufficient quantitative and qualitative acceptance criteria to ensure that the governor valve would perform satisfactorily in service, resulting in an improper adjustment that contributed to overspeed trips of the pump on December 27, 1992, and January 28, 1993.

- D. Technical Specification 6.8.1.a requires, in part, that written procedures be established, implemented, and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide (RG) 1.33, Revision 2, February 1978. RG 1.33, Appendix A, Item 1.d recommends operating procedures for procedure adherence. STP Procedure OPGP03-ZA-0010, Section 4.2.3, states that activities affecting quality-related structures, systems and components SHALL be conducted in accordance with written, approved procedures.

STP Procedure 2POP02-AF-0001, "Auxiliary Feedwater," was modified by Field Change Request 92-0220 on April 15, 1992, to align Valve MS-517, the bypass valve for the Unit 2 TDAFW pump steam admission line drain line steam trap, in the open position.

Contrary to the above, in January 1993, the licensee did not assure that activities affecting quality-related components were conducted in accordance with written, approved procedures. Specifically, Valve MS-

MAY 28 1993

517 was fully closed on January 24, 1993, and remained closed through February 3, 1993. As a result of this condition, the Unit 2 TDAFW pump tripped on overspeed due to water buildup in the steam admission line when the pump was called upon to perform its safety-related function on February 3, 1993.

- E. Technical Specification 6.8.1.a requires that written procedures be established, implemented, and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide (RG) 1.33, Revision 2, February 1978. RG 1.33, Appendix A, Item 9a, recommends, in part, that maintenance that can affect the performance of safety-related equipment should be properly pre-planned and performed in accordance with written procedures appropriate to the circumstances.

STP Procedure OPGP03-ZA-0090, Revision 5, "Work Process Program," Section 4.2.1.1 lists work activities that may be performed immediately by personnel reporting to the Issuing Authority without originating a Service Request. In addition, a note in Section 4.2.1.1 states, in part, that personnel performing these work activities should have appropriate prior training consisting of completion of qualification per job task analysis.

Contrary to the above, on January, 25, 1993, the licensee failed to pre-plan or conduct maintenance on the Unit 2 TDAFW pump overspeed trip linkage in accordance with written procedures appropriate to the circumstances. The maintenance activity was performed without a required Service Request by an individual who had not satisfactorily completed the requisite maintenance job task analysis training requirements.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - \$175,000

II. Violations related to emergency diesel generators

- A. Technical Specification 3.8.1.1.b requires, in part, that three separate and independent standby (emergency) diesel generators be operable in Modes 1-4. Technical Specification 3.8.1.1, Action b, requires, in part, that an inoperable emergency diesel generator be restored to operable status within 72 hours or (that the reactor) be in at least HOT SHUTDOWN within the next 12 hours and in COLD SHUTDOWN within the following 24 hours.

Contrary to the above, from December 29, 1992, until January 22, 1993, a period of 24 days, and with STP Unit 1 in Modes 1-4, Emergency Diesel Generator (EDG) 13 was inoperable and the licensee did not take the actions required above to place the reactor in hot shutdown or cold shutdown. Specifically, EDG 13 would not have run if it had received a start signal due to paint having dripped into fuel metering rod ports.

MAY 28 1993

- B. 10 CFR 50, Appendix B, Criterion V, states, in part, that activities affecting quality shall be prescribed by documented procedures, and that these procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Technical Specification 6.8.1.a requires, in part, that written procedures be established, implemented, and maintained covering the applicable procedures recommended in Appendix A of Regulatory Guide (RG) 1.33, Revision 2, February 1978. RG 1.33, Appendix A, Item 9a, recommends, in part, that maintenance that can affect the performance of safety-related equipment should be properly pre-planned and performed in accordance with written procedures appropriate to the circumstances.

Contrary to the above, on December 29-31, 1992, maintenance that could affect safety-related equipment (painting of an EDG) was not performed in accordance with written procedures appropriate to the circumstances. Specifically, Work Request XG-116382 did not provide for a post-maintenance test to assure the operability of Emergency Diesel Generator 13 following the painting of the machine. As a result of the painting evolution, Emergency Diesel Generator 13 was later determined to have been inoperable from December 29, 1992, until January 22, 1993.

- C. Technical Specification 3.8.1.1.b requires that three separate and independent standby (emergency) diesel generators be operable in Modes 1-4. Technical Specification 3.8.1.1, Action f, requires, in part, that with two or three emergency diesel generators inoperable, restore at least two emergency diesel generators to operable within 2 hours or (that the reactor) be in at least HOT STANDBY within the next 6 hours and COLD SHUTDOWN within the following 30 hours.

Contrary to the above, from January 12-14, 1993, a period 61 hours, Emergency Diesel Generators 12 and 13 were inoperable and the licensee did not take the actions described above to place the reactor in hot standby or cold shutdown. This condition occurred when EDG 12 was taken out of service for maintenance concurrent with EDG 13 being inoperable due to paint having dripped into fuel metering rod ports.

These violations represent a Severity Level III problem (Supplement I).
Civil Penalty - \$150,000

Pursuant to the provisions of 10 CFR 2.201, Houston Lighting & Power Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation:

4. 1. 1990

(1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the cumulative amount of the civil penalties proposed, or may protest imposition of the civil penalties, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties, in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

MAY 28 1993

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011 and a copy to the NRC Resident Inspector at the South Texas Project Electric Generating Station.

Dated at Arlington, Texas
this 28th day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D C 20555-0001

May 4, 1993

Docket No. 50-423
License No. NPF-49
EA 92-212

Northeast Nuclear Energy Company
ATTN: W. Ellis
Chairman of the Board and
Chief Executive Officer
Post Office Box 270
Hartford, Connecticut 06141-0270

Dear Mr. Ellis:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$100,000 AND DEMAND FOR INFORMATION
(NRC INVESTIGATION REPORT 1-90-001)

This letter refers to the NRC investigation conducted from December 18, 1989, through August 31, 1992, into allegations of (1) harassment, intimidation, and discrimination (HI&D) against the Supervisor, Instrumentation and Control (I&C) Special Projects, employed by Northeast Utilities Service Company (NUSCo) of Northeast Utilities (NU), and (2) the destruction of an original safety evaluation and modification of a document in order to conceal safety concerns. A copy of the OI Investigation Report Synopsis is attached. As a result of that investigation, significant violations of NRC requirements were identified.

Violation I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) concerns subjecting Mr. Paul Blanch to HI&D for raising safety issues. Specifically, from late 1988 through March 1989, Mr. Blanch, Supervisor, I&C Special Projects, was involved in raising a potentially significant generic safety issue related to an undetectable failure mechanism for Rosemount level transmitters used in the reactor protection system. As a result of his continuing efforts to have this generic safety concern addressed, Mr. Blanch was subjected by his immediate management chain to a number of discrete acts of HI&D that, taken together, comprised a hostile work environment. Knowledgeable senior utility management did not take effective action to terminate this treatment of Mr. Blanch.

These acts started in April, 1989, when Mr. Johnson wrote a memorandum to Mr. Roby in which he stated that Mr. Blanch had acted in an unprofessional manner during a meeting with the NRC on March 30, 1989, that concerned the Rosemount issues. Mr. Roby had not attended the meeting but, based in part on this information from Mr. Johnson, he held a counseling session on

April 3, 1989, during which he accused Mr. Blanch of unprofessional conduct during the March 30th meeting. Mr. Johnson subsequently sent a memorandum to file, dated April 12, 1989, noting that the NRC Senior Resident Inspector felt that all attendees at the March 30th meeting had acted in a professional manner and that he (Mr. Johnson) agreed. However, he never retracted this accusation nor did he notify Mr. Roby that he had apparently changed his position. Thus, the inappropriate admonition was never rectified. This failure to retract the accusation had a chilling effect on the raising of safety concerns by Mr. Blanch, as he testified to OI that he viewed the April 3rd meeting as an attempt to get him to back off the Rosemount issue. This failure to retract the accusation also had a potential chilling effect on other employees, since other employees were aware that Mr. Blanch had raised a safety issue and subsequently was criticized for unprofessional conduct at the NRC meeting.

On May 5, 1989, Mr. Mroczka, Senior Vice President, issued a memorandum to Mr. Werner with a copy to Mr. Johnson, stating that (1) Mr. Blanch would be responsible for developing NU's position on programmatic aspects of the Rosemount transmitter issue, and (2) any retaliation by those in Mr. Blanch's management chain for his raising of safety concerns would be inappropriate. Notwithstanding this memorandum, in June, 1989, Mr. Johnson attempted to keep Mr. Blanch from serving as the chairman for the Boiling Water Reactor Owners Group (BWROG) Committee reviewing the Rosemount transmitter issue. In a handwritten memorandum to Mr. Mroczka, Mr. Johnson recommended that Mr. Blanch not be allowed to serve as chairman, based in part on discussions with Rosemount, the entity whose product was being questioned. Mr. Mroczka subsequently overruled Mr. Johnson's recommendation. Nevertheless, Mr. Johnson's actions demonstrated his hostility towards Mr. Blanch's efforts to have the Rosemount safety issue addressed.

The Internal Audit Department (IAD) initiated an audit on September 14, 1989, into allegations of time and expense abuses in Mr. Blanch's group. This action was not consistent with the treatment of similar concerns regarding others which were raised during the audit. Specifically, during the audit of Mr. Blanch's group, IAD received allegations of similar time and expense problems in the I&C Engineering Department, which, like Mr. Blanch's section, also reported to Mr. Roby; however, IAD did not investigate those allegations. Additionally, although the draft IAD report did note that similar time and expense reporting abuses might have been occurring in other GEC groups, no audit was initiated.

In addition to the initiation of the audit, the manner in which the IAD audit was conducted also contributed to the creation of

the hostile work environment. Certain of the auditors raised concerns as to whether the audit was being used in a retaliatory manner against Mr. Blanch for raising safety concerns. The audit relied on data that Generation Engineering & Construction personnel knew were not reliable, IAD investigators did not appropriately review or follow up on the explanations for identified discrepancies offered by those audited in Mr. Blanch's group, and IAD applied a lower level of inquiry to other individuals selected as a comparison sample but who were not in Mr. Blanch's group.

Furthermore, the IAD auditors met with Messrs. Werner, Johnson and Roby to allow them to review and comment on the initial draft report, even though (1) they were not interviewed as part of the audit, (2) senior corporate management had intended for the audit to be independent of Mr. Blanch's management chain, and (3) Messrs. Werner, Johnson and Roby had been issued letters of reprimand (for their handling of Mr. Blanch) just eleven days before being provided a draft IAD report for comment. Messrs. Werner, Johnson and Roby improperly attempted to influence the audit findings by providing comments negative of Mr. Blanch's supervisory ability, although this was not the subject of the audit. Further, Mr. Werner drafted a letter of reprimand to Mr. Blanch dated November 3, 1989, which discussed the possibility of termination and referenced the draft audit report, even though the audit report had not yet been issued.

Mr. Mroccka, Senior Vice President, issued letters of reprimand to Messrs. Werner, Johnson, Roby and Mr. Thomas Shaffer, Manager, I&C Engineering, on October 16, 1989, for their respective part in handling the issues raised by Mr. Blanch. This action was taken by Mr. Mroccka based, in part, on the findings of LRS (Lapp, Rice and Staker, an independent consultant to NU, who had been specifically tasked with assessing the Rosemount transmitter issue, including possible incidents of harassment and intimidation). The LRS Report, dated August 28, 1989, concluded, in part, that: Mr. Blanch had exhibited superior technical insight, commendable initiative, and unusual courage in tenaciously pressing for recognition of the Rosemount transmitter issue as a significant nuclear safety concern; that Mr. Blanch was subjected to harassment and attempts at intimidation by his management, and such actions might have been continuing; and that the acts of harassment were sometimes apparently made with intent. However, the licensee subsequently withdrew those letters of reprimand based upon the decisions of non-nuclear corporate managers during a grievance appeal process. One of the managers in the third level of review, Mr. George D. Uhl, concluded that there was not an environment that was free from harassment and intimidation, and that he believed it more proper to address this issue in the managers' annual performance appraisals.

The NRC is especially concerned that in light of the LRS report and reprimand issue, senior utility management still did not take action to terminate the hostile work environment to which Mr. Blanch was subjected. In addition, various workers testified that they knew of the Blanch matter and, as a result, would not raise safety concerns with their management.

Mr. Ellis, Chief Executive Officer (CEO), raised a concern in a note to file, dated September 1, 1989, that some members of management might have a poor attitude about personnel who raise safety issues. Mr. Opeka, Executive Vice President, subsequently responded to Mr. Ellis' concerns in a memorandum dated December 20, 1989, which stated that the LRS Report supported that view and that letters of reprimand were issued to address the performance of the individuals (Messrs. Werner, Johnson, Roby and Shaffer).

A further indication of certain utility officials attitude toward resolving issues concerning harassment and intimidation was the initial response of some management personnel toward the OI investigation. Specifically, Mr. Shaffer, who was a supervisor, and Mr. Richters, who was corporate counsel, threatened several individuals with letters of reprimand if they did not talk with licensee attorneys prior to being interviewed by OI. It was only after an employee complained to LRS, who in turn brought it to the attention of Mr. Ellis, that the position was changed.

In light of the above, it appears that Mr. Blanch was placed in a work environment that was not conducive to the identification of potential safety issues by workers. It is recognized, as indicated in NRC Combined Inspection Nos. 50-245/90-81, 50-336/90-81, 50-423/90-82, and 50-213/90-82, that this environment may not exist throughout the licensee's organization. Nevertheless, the aforementioned activities indicate that not all of NU's supervisors and managers appreciate the importance of maintaining an environment that permits individuals to raise safety concerns without fear of retribution.

Violation I is particularly significant to the NRC because officers of the company were either directly participating in the discrimination (Mr. Werner, Vice President - Generation Engineering and Construction), or aware of it, but failed to act in an effective manner to correct the situation (Mr. Ellis, CEO; Mr. Fox, President; Mr. Opeka, Executive Vice President; and Mr. Mroczka, Senior Vice President). Therefore, in accordance with the guidance contained in Supplement VII of the Enforcement Policy, this violation has been categorized at Severity Level II because it involved the actions of management above first-line supervision.

To emphasize the importance of licensees providing a work environment that is free of harassment, intimidation and discrimination against those who raise safety issues, I have been authorized, after consultation with the Commission, to issue the enclosed Notice in the amount of \$100,000 for this violation. The base civil penalty for a Severity Level II violation is \$80,000. The civil penalty has been increased to \$100,000 because of the significant management involvement in the violation.

In addition, pursuant to sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, 10 CFR 2.204 and 50.54(f), in order for the Commission to determine whether your license should be modified or other actions taken, you are required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the date of this Demand for Information, in writing and under oath or affirmation, an explanation as to:

(1) why the NRC can have confidence that the licensee will ensure an environment that is free from harassment, intimidation and discrimination, both in general throughout its organization, and in particular with Messrs. Roby and Johnson involved with safety related activities at NU; especially in light of their actions related to Mr. Blanch in 1989, and

(2) why, after Messrs. Ellis, Fox, Opeka and Mroczka became aware of the harassment and intimidation concerns involving Mr. Blanch, NU was ineffective in promptly terminating the hostile work environment to which Mr. Blanch was subjected.

Copies of the response to this Demand for Information should be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406-1415.

Violation II concerns the failure of Mr. Thomas Shaffer, Manager, Instrument and Controls Engineering, to implement the requirements of NEO Procedure 2.01, "Implementation of 10 CFR 21: Reporting of Defects and Noncompliance," after five of twelve Rosemount flow transmitters failed on the Unit 3 Reactor Protection System during the November 1986 to November 1987 fuel cycle. The original evaluation determined that a substantial safety hazard (SSH) existed. Mr. Shaffer did not agree with that evaluation and attempted to persuade the evaluator to change the SSH determination. After the evaluator refused, Mr. Shaffer subsequently persuaded the evaluator's supervisor to change the SSH determination to a non-SSH call. However, this action was not completed within the timeframe recommended in the procedure and Mr. Shaffer failed to notify the Manager - Generation

Facility Licensing, in order to obtain a required time extension. Finally, it is noteworthy that the original evaluation which indicated that a SSH existed, was misplaced and the licensee was not able to recover it until July 31, 1990. The Nuclear Review Board later determined the issue to be an SSH.

Of particular concern to the NRC on this matter is that a positive SSH determination is a significant safety concern that has possible generic implications which could involve the safety of other nuclear power plants. Mr. Shaffer failed to act on this issue within the timeframe outlined in the approved procedure. During that period of time, the only evidence of activity by Mr. Shaffer was his attempt to get a literal interpretation of the definitions used in the procedure. There is no indication that Mr. Shaffer pursued the safety matter from a technical standpoint. Though there is testimony that SSH issues are uncommon and dissension regarding determinations that an SSH exists rare, Mr. Shaffer failed to bring the differing view of the original evaluator to the attention of Mr. Miller, who was acting for the vice president of nuclear operations at the time. As a result, although the original SSH determination was made on December 8, 1987, it was not until March 25, 1988, that NU made the required 10 CFR Part 21 report, after the Unit 3 Nuclear Review Board independently reviewed the issue and changed the determination back to a SSH. The circumstances resulting in the delay in making the notification demonstrated a careless disregard on the part of Mr. Shaffer for the Commission's reporting requirements.

In accordance with the guidance provided in Supplement VII of the Enforcement Policy, this violation has been classified at a Severity Level III. A civil penalty is not being proposed for this violation because the licensee did eventually report the matter and a "director or responsible officer", as defined in 10 CFR Part 21, was not involved in the violation.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

Northeast Nuclear Energy Co. 7

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James H. Sniezek
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations & Research

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty
OI Synopsis
cc w/encl:
Board of Directors
R. Werner
E. Mroczka
G. Johnson
A. Roby
T. Shaffer
P. Blanch

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Northeast Nuclear Energy Company
Berlin, Connecticut

Docket No. 50-423
License No. NPF-49
EA 92-212

Based on an NRC investigation conducted from December 18, 1989, to August 31, 1992, the NRC has determined that a violation of its regulations occurred. In accordance with the "General Statement of Policy and Procedures for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 50.7, Employee Protection, subsection (a), prohibits discrimination by a Commission licensee against an employee for engaging in certain protected activities. Discrimination includes discharge and other actions that relate to compensation, terms, conditions, and privileges of employment. Protected activities include, but are not limited to, providing information to the NRC on potential violations or other matters within the NRC's regulatory responsibilities.

Contrary to the above, the licensee discriminated against an employee for engaging in protected activities. The employee, Paul Blanch, Supervisor, Instrument and Controls Special Projects Section, was engaged in a protected activity in that he raised safety concerns related to an undetectable failure mechanism in certain Rosemount transmitter models with his management and the NRC. Beginning on April 3, 1989, the licensee subjected Mr. Blanch to a hostile work environment, as evidenced by the following:

1. In April, 1989, Mr. Johnson wrote a memorandum to Mr. Roby in which he stated that Mr. Blanch had acted in an unprofessional manner during a meeting with the NRC on March 30, 1989, that concerned the Rosemount issues. Mr. Roby had not attended the meeting but, based in part on this information from Mr. Johnson, he held a counseling session with Mr. Blanch on April 3, 1989, during which he accused Mr. Blanch of unprofessional conduct during the March 30th meeting. Mr. Johnson subsequently sent a memorandum to file, dated April 12, 1989, noting that the NRC Senior Resident Inspector felt that all attendees at the

March 30th meeting had acted in a professional manner and that he (Mr. Johnson) agreed. However, he never retracted the accusation nor did he notify Mr. Roby that he had apparently changed his position regarding Mr. Blanch's conduct, so that this admonition was never rectified. The failure to retract this accusation contributed to a hostile work environment directed toward Mr. Blanch, because he viewed the April 3rd meeting as an attempt to get him to back off the Rosemount issue. This failure to retract also had a chilling effect on the raising of safety concerns by other employees in the GEE section, since other employees were aware that Mr. Blanch had raised a safety issue and subsequently was criticized for unprofessional conduct at the NRC meeting.

2. In June, 1989, Mr. Johnson attempted to preclude Mr. Blanch from serving as chairman of the Boiling Water Reactor Owner's Group (BWROG) committee concerning the Rosemount issue by recommending in a memorandum to Mr. Mroczka that Mr. Blanch not be allowed to serve as chairman of that group. Mr. Johnson based his recommendation in large part on negative input about Mr. Blanch from Rosemount, the company whose product was under scrutiny, which raises an inference that Mr. Johnson's actions were a result of Mr. Blanch's attempting to raise safety issues, and were discriminatory.
3. Messrs. Roby, Johnson, and Werner improperly attempted to influence an audit report being prepared by NU's Internal Audit Department (IAD) between September and November, 1989, of an audit that was conducted of time and expense reporting in Mr. Blanch's group. Specifically, Messrs. Roby, Johnson, and Werner reviewed the first draft of the report, dated October 27, 1989, and attempted to have negative comments concerning Mr. Blanch's supervisory performance, which was not the subject of the audit, inserted into the audit report. This is significant because: (1) Messrs. Roby, Johnson and Werner had not been interviewed as part of the audit, (2) senior corporate management intended the audit to be independent of Mr. Blanch's line management, and (3) Messrs. Roby, Johnson and Werner had earlier received letters of reprimand from Mr. Mroczka on October 16, 1989, concerning their dealings with Mr. Blanch. The timing of these attempts (i.e., during the period when Mr. Blanch had been raising

the Rosemount safety issue) supports an inference that the attempts were the result of Mr. Blanch's attempting to raise the Rosemount issue. Furthermore, the IAD audit contributed to the creation of a hostile work environment. The audit (the conduct of which was known to other people in the work group) was biased by its reliance on data which should have been known to be unreliable. The data consisted of unofficial signout logs which were not required or controlled documents, were not required to be accurately maintained, and which had known errors. In addition, the key card records for the Berlin office did not accurately reflect all entrances to the building in that the card readers were not reliable or always used. The report was further biased because IAD investigators did not appropriately review or follow up on all of the explanations offered by those audited in Mr. Blanch's group. IAD applied a lower level of inquiry to those individuals who were selected by the auditors for a comparison sample but were not in Mr. Blanch's group. Further, the licensee did not initiate an audit into allegations of other similar potential abuses of time and expense reporting in the Instrument and Controls Engineering Department (such as long lunches, as well as drinking and golfing on company time). Mr. Blanch testified to OI that he viewed the audit as a vehicle to discredit him.

These actions constitute an environment which Mr. Blanch personally believed, as described above, stifled his ability to raise safety concerns or work effectively. Also a reasonable nuclear power plant employee would believe that these actions stifled his or her ability to raise safety concerns or work effectively. With regard to the belief of a reasonable nuclear power plant employee, several employees within the GEE section testified to OI that Mr. Blanch was retaliated against for raising a safety issue and that this resulted in a chilling effect on the raising of safety concerns. A Licensee consultant also observed similar indications of a hostile work environment.

This is a Severity Level II Violation (Supplement VII).
Civil Penalty - \$100,000.

II. Violation Not Assessed a Civil Penalty

10 CFR 21.21 (a) requires that each individual, corporation, partnership or other entity subject to the regulations in

this part shall adopt procedures to provide for the evaluation of deviations, and to assure that a director or responsible officer is informed if a basic component supplied for such facility fails to comply with any particular rule, regulation, order, or license of the Commission relating to a substantial safety hazard.

Nuclear Engineering and Operations (NEO) Procedure NEO 2.01, Revision 2, dated July 24, 1987, entitled "Implementation of 10 CFR 21: Reporting of Defects and Noncompliance," defines, in Section 4.2, a Substantial Safety Hazard (SSH) as a loss or potential loss of a safety function due to a defect or noncompliance to the extent that there is a major reduction in the degree of protection provided to the public health and safety of the facility or activity.

Section 6.1.1.1 of NEO 2.01 requires that an SSH evaluation shall be initiated when any employee has knowledge of a suspected defect or demonstrated deviation or defect. Section 6.5 of NEO 2.01 requires that the evaluation be pursued in a timely manner, in accordance with the suggested processing time on the SSH Evaluation Form of ten working days for the technical evaluation, or for the Manager, Generation Facility Licensing (GFL), to be notified if the suggested processing time cannot be met.

Contrary to the above, between December 8, 1987 and February 11, 1988, Mr. Thomas Shaffer, Manager, Instrument and Controls Engineering, violated the requirement for identification, evaluation and processing of a SSH in a timely manner, in that the suggested processing time of 10 days was exceeded by approximately 35 days, and the Manager, GFL was not notified. The specific SSH involved the potential for a generic problem with the operation of the Rosemount transmitters used in safety related systems at the facility due to undetectable failure of the transmitters as a result of slow fill-oil loss.

This is a Severity Level III Violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Northeast Nuclear Energy Company (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken

to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 82 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the civil penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of

Notice of Violation

6

Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, and a copy to the NRC Resident Inspector at the Millstone facility.

Dated at Rockville, Maryland
this 4th day of May 1993

SYNOPSIS

On December 18, 1989, the Regional Administrator (RA), Region I, U.S. Nuclear Regulatory Commission (NRC), requested that an investigation be initiated concerning allegations of harassment, intimidation, and discrimination (HI&D) of a corporate level supervisor employed by Northeast Utilities Service Company (NUSCo) of Northeast Utilities (NU), Berlin, Connecticut. The HI&D was allegedly carried out with the knowledge of senior line management of the licensee, the Northeast Nuclear Energy Company (NNECo), in order to restrict the free flow of information related to the technical resolution of a significant nuclear safety issue involving undetected failures of Rosemount transmitters. Furthermore, the RA requested that the Office of Investigations (OI) determine if the licensee failed to address legitimate safety concerns by modifying documents and/or destroying original evaluations to conceal those concerns. One set of the documents in question pertained to the Rosemount transmitter issue.

The OI investigation substantiated that an instrumentation & controls (I&C) engineering manager (since reorganization, the manager of Component Test Services) deliberately caused the processing of the Rosemount significant/substantial safety hazard (SSH) form, which determines reportability to the NRC, to be delayed for approximately six weeks. This delay resulted in NU's "suggested maximum processing time" for the SSH form being exceeded. OI determined, as did an independent consultant retained by the licensee, that the manager successfully pressured a supervisory subordinate into changing the original finding of "is" a SSH, to "is not" a SSH. OI concluded that, although the licensee was not in violation of 10 CFR 21 reporting requirements, the manager deliberately violated the intent of the NU internal procedure for the SSH evaluation, as well as measures established in 10 CFR 50, Appendix B designed to assure the prompt identification and correction of deficiencies adverse to quality. The investigation disclosed that the SSH form and corresponding technical evaluation were not destroyed; however, the SSH form had been modified.

The OI investigation also substantiated that the I&C Special Studies and programs supervisor who raised the Rosemount transmitter safety concern, but was not involved in the original SSH evaluation, was the victim of various incidents of HI&D and attempted HI&D as a result of his stand on the issue. OI identified those responsible in Nuclear Engineering and Operations (NE&O), either directly or indirectly, as the supervisor's manager (the systems manager of Electrical Engineering; since reorganization, the manager of Engineering and I&C); the director of the supervisor's department (the director of Engineering; since reorganization, the manager of Field Services); the vice president of that department (Generation Engineering & Construction; since retired), the vice president of Nuclear and Environmental Engineering (since reorganization, the vice president of Environmental Engineering), and the then senior vice president of NE&O (since resigned).

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

MAR 23 1993

Docket Nos. 50-327 and 50-328
License Nos. DPR-77 and DPR-79
EA 92-257 and EA 93-034

Tennessee Valley Authority
ATTN: Dr. Mark O. Medford
Vice President, Nuclear
Assurance, Licensing & Fuels
3B Lookout Place
1101 Market Street
Chattanooga, Tennessee 37402-2801

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTIES -
\$225,000 (NRC INSPECTION REPORT NOS. 50-327/92-36, 50-328/92-36,
50-327/92-38, 50-328/92-38, 50-327/93-02 and 50-328/93-02)

This refers to the Nuclear Regulatory Commission (NRC) inspections conducted from November 29, 1992, through January 29, 1993, at the Sequoyah Nuclear Plant (SNP). The inspections included a review of three separate events that were due, in large part, to continuing performance-based problems in the Operations Department. These events involved: (1) several mispositioned safety-system throttle valves, (2) the failure to maintain the Refueling Water Storage Tank (RWST) solution temperature above the minimum limit for approximately 24 hours, and (3) a loss of reactor coolant pump (RCP) seal injection flow during the recovery of SNP Unit 2 from the December 31, 1992, dual unit trip. Individually, each event is viewed as a significant safety concern. Each event also shares a common root cause, namely the poor performance of personnel charged with operating SNP in a safe manner. A particularly disturbing aspect of these events is the fact that the Quality Assurance (QA) Department had previously identified the recurring nature of the performance problems at SNP, yet management has failed to effectively address the situation.

The reports documenting these inspections were sent to you by letters dated January 15 and February 23, 1993. As a result of these inspections, significant failures to comply with NRC regulatory requirements were identified. Enforcement conferences were conducted in the NRC Region II office on February 5, 1993, to discuss the violations associated with events (1) and (2), and on March 3, 1993, to discuss the violations associated with event (3). Summaries of the enforcement conferences were sent to you by letters dated February 17 and March 5, 1993.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice). Section I addresses the failure to adequately control safety-system throttle valve settings. Violation I.A concerns the failure to provide adequate procedural instructions for setting

the Pratt butterfly throttle valves in several safety systems. Specifically, the instructions provided did not adequately account for the slack travel in the valve hand-operators and was not consistent with past operator training on throttle valve positioning. As a consequence, valves in several safety systems in both units were mispositioned for approximately one to two years. Subsequent testing found that the actual cooling water flow rates were only 50-70 percent of the expected flow rates. Violation I.B addresses the failure to ensure that newly established throttle valve position settings were correctly transferred from flow test procedures to operating procedures for seven throttle valves in the Essential Raw Cooling Water (ERCW) system for both units. Though later analysis determined that the flow reductions would not have caused any adverse consequences, the breakdown in procedural controls that allowed these conditions to occur and remain undetected is a significant safety concern.

The violation described in Section II relates to both technical and administrative procedures that either were not followed or were inadequate and resulted in the Unit 2 RWSST solution temperature dropping below the Technical Specification limit for approximately 24 hours on December 23 and 24, 1992. This event involved the recirculation of RWSST water through a containment spray pump and associated heat exchanger, as part of one test, while simultaneously running ERCW cooling water through that heat exchanger as part of another test. A waiver of compliance had been granted to allow SNP extra time to perform the tests without shutting down. A significant aspect of this event was the fact that the Operations Department allowed the two tests to be performed concurrently without adequately evaluating or recognizing the system interactions associated with the test configurations. An additional concern was the fact that three control room operations shift turnovers occurred, but the low RWSST temperature condition was not detected by control room personnel until routine 24-hour logs were recorded. Although later analysis demonstrated that the low RWSST temperature would not have caused any adverse safety consequences, the inadequate procedural controls that allowed this condition to occur and remain undetected are safety significant.

The violations in Section III concern the December 31, 1992, dual unit trip from full power due to an electrical disturbance in the switchyard. During the recovery of Unit 2 after the reactor trip, a series of events occurred that included: several operator errors, inadequate control of the thermal barrier booster pump switches, and confusion caused by charging pump low lube oil alarm indications. This resulted in both high head safety injection pumps being disabled for approximately one minute. As a consequence, the normal RCP seal injection cooling was lost at the same time that the thermal barrier heat exchanger cooling flow was degraded. It is estimated that both RCP seal cooling functions were simultaneously degraded for 21 seconds. Both units were subsequently stabilized in MODE 3 after the event.

Violation III.A involved five examples of procedures that were either not followed or were inadequate. The first three examples involved the control room operators' failure to follow Abnormal Operating Instructions relating to emergency boration and the alignment and restoration of components associated

MAR 23 1993

with the charging pump suction sources. These errors occurred, in part, due to the operators switching from a symptomatic approach to an event based approach for controlling the event and ineffective command and control by the crew. The fourth example involved the adequacy of the procedural guidance related to thermal barrier booster pumps (TBBP) switch position, which resulted in the unavailability of both TBBPs to restart after power was restored to the shutdown boards. The fifth example involved the failure to perform an adequate post trip review prior to the restart of Unit 2. Specifically, the review was inadequate in that it failed to identify that the cause of the second Volume Control Tank (VCT) isolation was due to operator error in reclosing the isolation valves, rather than the low level isolation setpoint. As a result, Unit 2 was shutdown to verify that the isolation logic was functioning properly. After the additional testing, it was concluded that the operators erroneously re-isolated the VCT.

A significant root cause of the poor operator performance during the recovery from the dual unit transient was the practice of training the operating crews at full staffing levels rather than at the minimum levels allowed by SNP Technical Specifications (TS). Crews were at minimum levels when the dual unit transient occurred. Such training practices cannot provide for the added operational responsibilities placed on a "short" crew when both units simultaneously undergo a transient. Review of staffing levels indicated that use of minimum crew levels had become a common practice at SNP.

Violation III.B involved an example of inadequate corrective action related to the TBBP switch position. The TBBP switch position problem was identified during the performance of a test procedure on March 14, 1992, but was not corrected. The improper TBBP switch alignment problem significantly complicated the operator's response while attempting to recover from the Unit 2 trip on December 31, 1992.

The NRC recognizes that specific corrective actions were taken for each violation, as discussed during the enforcement conferences. Those actions included: (1) verification that all Pratt butterfly throttle valves were correctly positioned, as well as retraining of operations personnel in the proper way to position valves in order to preclude the effect of valve hand-operator slack, (2) the RWST solution temperature was restored to within TS limits, the event was reviewed with all operations personnel, and various procedures were revised, and (3) the operator training program is being revised to ensure that operator crew training includes consideration of minimum staffing levels during dual unit transients. In addition, the staff recognizes that as part of your Site Improvement Plan you are taking other longer-term actions which you discussed at the enforcement conference.

The violations cited in Sections I, II and III of the Notice, each represents a significant breakdown in your programs and processes to assure that safety-related activities are properly controlled and conducted in accordance with regulatory requirements. In addition, it is apparent that the management involvement and oversight that you have previously discussed with the NRC have not yet been fully effective in instilling the appropriate sensitivity into

MAR 23 1983

line management and staff as to the importance of procedural adherence and quality in plant operations. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations in each Section have been categorized at Severity Level III.

To emphasize the importance of 1) ensuring procedural adherence during operations important to safety, 2) the adequacy of control room staffing and procedures, and 3) maintaining configuration control, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the amount of \$225,000 for the three Severity Level III problems. The base value of a civil penalty for a Severity Level III problem is \$50,000. The escalation and mitigation factors in the Enforcement Policy were considered.

For the violations in Section I of the Notice, the base civil penalty was mitigated 50 percent because your staff identified the specific hardware problems and subsequently recognized the severe configuration and operations control problems. The civil penalty was mitigated another 50 percent for your corrective actions, which included verification of the correct setting for other butterfly throttle valves and extensive operator training on the correct method of setting throttle valves. However, the civil penalty was escalated by 100 percent for poor licensee performance. Within the past two years, there were several Severity Level IV violations and three escalated enforcement actions (EA 92-065, 92-092, and 92-155) issued which shared the common denominators of configuration control problems and a lack of attention to detail during conduct of operations. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty was considered appropriate. Therefore, based on the above, a civil penalty of \$50,000 is assessed for the violations in Section I.

For the violation in Section II, the base civil penalty was mitigated by 50 percent for your staff's identification. No escalation or mitigation was warranted for your corrective action. Specifically, despite the Quality Assurance (QA) organization's numerous findings in the areas of concern, the long-term plan presented at the first enforcement conference failed to describe the role that QA would have in ensuring proper corrective actions are taken. The base civil penalty was escalated by 100 percent for your poor performance. The other adjustment factors were also considered and no further adjustment to the civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty for the violation in Section II has been increased 50 percent to \$75,000.

For the violations in Section III, the base civil penalty was neither escalated nor mitigated for identification because of the self-disclosing nature of the event and the fact that the NRC raised the issue of not training operator crews at the minimum staffing level allowed. No mitigation nor escalation was warranted for corrective action because of the recurring nature

MAR 23 1983

of the performance problems. As with the previous sections, the base civil penalty was escalated by 100 percent for your poor performance. The other adjustment factors were also considered and no further adjustment to the civil penalty was considered appropriate. Therefore, based on the above, the base civil penalty for the violation in Section III has been increased 100 percent to \$100,000.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In particular, you should address any actions you plan to take to assure that: (1) problems identified by QA receive the appropriate level of management attention and are resolved in a timely manner, (2) there is adequate staff available to safely operate the facility, notwithstanding the minimum level specified in the SNP Technical Specifications, and (3) operating crew training takes into account actual plant staffing practices. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: See Next Page

MAR 23 1993

cc w/encl:
Mr. John B. Waters, Director
Tennessee Valley Authority
ET 12A
400 West Summit Hill Drive
Knoxville, TN 37902

TVA Representative
Tennessee Valley Authority
Rockville Office
11921 Rockville Pike
Suite 402
Rockville, MD 20852

General Counsel
Tennessee Valley Authority
ET 11H
400 West Summit Hill Drive
Knoxville, TN 37902

Mr. J. R. Bynum, Vice President
Nuclear Operations
Tennessee Valley Authority
3B Lookout Place
101 Market Street
Chattanooga, TN 37402-2801

Ms. Marci Cooper, Site
Licensing Manager
Sequoyah Nuclear Plant
Tennessee Valley Authority
P. O. Box 2000
Soddy-Daisy, TN 37379

Mr. Robert Fenech
Vice President Sequoyah Nuclear
Plant
Tennessee Valley Authority
P. O. Box 2000
Soddy-Daisy, TN 37379

Mr. M. J. Burzynski, Manager
Nuclear Licensing and
Regulatory Affairs
Tennessee Valley Authority
5B Lookout Place
Chattanooga, Tennessee 37402-2801

Mr. Michael H. Mobley, Director
Division of Radiological Health
T.E.R.R.A. Building 6th Floor
150 9th Avenue North
Nashville, TN 37219-5404

County Judge
Hamilton County Courthouse
Chattanooga, TN 37402

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Tennessee Valley Authority
Sequoyah Nuclear Plant
Units 1 and 2

Docket Nos. 50-327 and 50-328
License Nos. DPR-77 and DPR-79
EA 92-257 and EA 93-034

During NRC inspections conducted from November 29, 1992 through January 29, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violations Associated With Control of Throttle Valve Position

- A. Technical Specification 6.8.1 requires, in part, that written procedures be established, implemented and maintained for applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Quality Assurance Program Requirements, Revision 2, February 1978. Appendix A to Regulatory Guide 1.33 requires administrative procedures for safe operation of nuclear power plants, and specific procedures for conducting surveillance tests.

Contrary to the above the following procedures were inadequate resulting in the mispositioning of the specified valves for the time periods indicated:

1. Surveillance Instruction O-SI-OPS-067-682.M, ERCW FLOW BALANCE VALVE POSITION VERIFICATION, Revision 2, implements configuration control for the position of throttled valves in the Essential Raw Cooling Water (ERCW) system. The procedure was inadequate in that it did not provide proper instructions for accounting for slack travel in valve hand-operators which resulted in the Containment Spray Heat Exchanger ERCW throttle valves 1-67-537A and B being improperly positioned from November 30, 1991, through December 16, 1992.
2. Surveillance Instruction 2-SI-OPS-070-032.A, COMPONENT COOLING WATER VALVES POSITION VERIFICATION TRAIN A, Revision 1, implements configuration control for the position of throttled valves in the Component Cooling Water System (CCS). The procedure was inadequate in that it did not provide proper instructions for accounting for slack travel in the valve hand-operator which resulted in the Residual Heat Removal (RHR) Heat Exchanger CCS throttle valve 2-70-546A being improperly positioned from approximately March 1, 1989, through December 19, 1992.

- B. Technical Specification 6.8.1 requires, in part, that written procedures be established, implemented and maintained for applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Quality Assurance Program Requirements, Revision 2, February 1978. Appendix A to Regulatory Guide 1.33 requires administrative procedures for safe operation of nuclear power plants, and specific procedures for conducting surveillance tests.

Contrary to the above, procedure SI-566, ERCW FLOW VERIFICATION TEST - UNITS 0, 1, AND 2, Revision 22 was inadequate in that, it did not include a requirement to verify that newly established valve throttle positions were correctly transferred to procedure O-SI-OPS-067-682.M. Seven examples of improperly transferred valve positions were identified.

This is a Severity Level III Problem (Supplement I).
Civil Penalty - \$50,000.

II. Violations Associated With Control of RWST Temperature

- A. Technical Specification 6.8.1 requires, in part, that written procedures be established, implemented and maintained for applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Quality Assurance Program Requirements, Revision 2, February 1978. Appendix A to Regulatory Guide 1.33 requires administrative procedures for safe operation of nuclear power plants, and specific procedures for conducting surveillance tests.

Technical Specification (TS) 3.5.5, requires that the RWST be operable in Modes 1, 2, 3, and 4 and, in part, for the RWST to be operable, solution temperature must be maintained above 60 degrees F. The action requirement for the TS requires that with the RWST inoperable it must be restored to operable status within one hour or be in hot standby within 6 hours.

Contrary to the above, with the Unit 2 in Mode 1 the following procedures were either inadequate or not followed on December 23 and 24, 1992 resulting in the Unit 2 RWST solution temperature being below the TS minimum limit for approximately 24 hours without the plant being placed in hot standby:

1. Surveillance Instruction 2-SI-SXP-072-001.B, CONTAINMENT SPRAY PUMP 2B-B QUARTERLY OPERABILITY TEST, Revision 0, was inadequate in that no precautions or limitations were identified with regard to system interactions. As a result, performance of the Surveillance Instruction on December 23, 1992, in conjunction with coincident ERCW testing cooled the Unit 2 RWST solution below the TS minimum temperature limit.

2. Site Standard Practice SSP-12.1, CONDUCT OF OPERATIONS, Revision 2, establishes requirements for control of equipment and system status, and requires operators to maintain cognizance of operational status of equipment and systems. This procedure was not followed between approximately 5:00 a.m. on December 23, 1992, and 3:00 a.m. on December 24, 1992, in that three operating shifts failed to identify the below minimum required solution temperature for the RWST despite performing shift turnovers and monitoring ongoing test evolutions.

This is a Severity Level III Violation (Supplement I).
Civil Penalty - \$75,000

III. Violations Associated With the December 31, 1992, Dual Unit Trip Recovery

- A. Technical Specification 6.8.1 requires, in part, that written procedures be established, implemented and maintained for applicable procedures recommended in Appendix A of Regulatory Guide 1.33, Quality Assurance Program Requirements, Revision 2, February 1978. Appendix A to Regulatory Guide 1.33 requires administrative procedures for the safe operation of nuclear power plants, and procedures for abnormal, offnormal, or alarm conditions.

Contrary to the above, the following procedures were either not followed or were inadequate in that the following examples resulted in the degradation of the Unit 2 high head safety injection capability for approximately one minute, increasing the probability of a reactor coolant pump seal loss-of-coolant-accident.

1. Abnormal Operating Instruction (AOI) 34, EMERGENCY BORATION, Revision 7, provides the necessary actions to initiate emergency boration when the reactor is shut down and directed by procedure. On December 31, 1992, Unit 2 operators failed to follow the requirements of AOI-34, in that, when reactor coolant system temperature dropped to 537 degrees F, the operators used a normal boration flowpath, rather than the emergency boration flowpath required by the AOI.
2. AOI-34, EMERGENCY BORATION, Revision 7, provides instructions to operators to adequately realign and restore components utilized in normal charging operations and boration flowpaths. These include precise steps to return the centrifugal charging pump (CCP) suction to the volume control tank (VCT) from the RWST source. On December 31, 1992, Unit 2 operators failed to follow the requirements of

AOI-34 during restoration of the VCT as the suction to the operating CCP as described in the following examples.

- a. RWST suction valve handswitches, 2-HS-62-135 and 2-HS-62-136, were not pulled to the A-P AUTO position after manipulation as required. This resulted in the disabling of the process function to automatically open the RWST suction supply valves upon a closure of the VCT suction supply valves.
 - b. During VCT/RWST valve manipulations the operator inadvertently closed the VCT outlet suction supply valves, 2-LCV-62-132 and 2-LCV-62-133. At the time, these valves were providing the suction supply to the operating CCP.
3. Sequoyah Nuclear Plant Final Safety Analysis Report (FSAR) Section 9.2.1.3.3, Thermal Barrier Booster Pumps, states that the purpose of the thermal barrier booster pumps (TBBP) is to provide the additional head necessary to overcome high head loss through the thermal barriers. Each of the four pump motors receives electric power from normal or emergency sources and is connected to one of the four shutdown boards.
- Tennessee Valley Authority Design Criteria for the Component Cooling Water System, SQN-DC-V-13.9.9, specifies that the TBBPs (two per unit) shall be loaded to the diesel generators simultaneously with the Component Cooling System pumps after a loss of offsite power (LOOSP). Placement of the control room TBBP handswitches in the A-P AUTO position ensures the above requirements are met.
- System Operating Instructions (SOI) 1-SO-70-1, Component Cooling Water System - A Train, Revision 3, and 2-SO-70-1, Component Cooling Water System - A Train, Revision 1, provides the procedure requirements for controlling the TBBP control room handswitch positions, but were inadequate, in that, the procedure required the subject handswitches to be in the A-AUTO in lieu of the A-P AUTO position. This resulted in a failure of the TBBPs on both units to automatically restart as required, during the December 31, 1992 LOOSP event.
4. Site Standard Practice Procedure SSP-12.9, Incident Investigations and Root Cause Analysis, provides detailed guidance on post-trip review requirements, including the requirement to assure that plant equipment operated as designed to mitigate the event, and identify the true root cause of the event such that it can be corrected prior to resumption of power operation.

The post trip review performed pertaining to the trip of Sequoyah Unit 2 on December 31, 1992, was inadequate in that the personnel performing the review did not analyze tank level chart recorder traces to verify the cause of the volume control tank outlet valves 2-LCV-62-132 and 133 closing after having been opened by the operators. The personnel assumed the level in the VCT had decreased below the low level isolation setpoint, when in fact, it had not.

- B. 10 CFR Part 50, Appendix B, Criterion XVI, Corrective Action, requires in part, that measures be established to assure that conditions adverse to quality such as failures, malfunctions, and deficiencies be promptly identified and corrected.

Contrary to the above, a condition adverse to quality existed since March 14, 1992, when the hand switch for the 2A-A TBBP was recognized as being misaligned during the performance of test procedure 2-SI-OPS-082-026.A, "Loss of Offsite Power with Safety Injection-DG-2A-A Containment Isolation Test", and the test resolution of the test deficiency did not correct the condition. Consequently, the hand switches for all four of the TBBPs (2 per unit) remained inappropriately aligned, such that the TBBPs would not automatically restart following a momentary loss of offsite power. This condition adverse to quality existed until the December 31, 1992, event.

This is a Severity Level III Problem (Supplement I).
Civil Penalty - \$100,000.

Pursuant to the provisions of 10 CFR 2.201, Tennessee Valley Authority (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to

the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed above, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalties due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia, and a copy to the NRC Resident Inspector at the Sequoyah Nuclear Plant.

Dated at Atlanta, Georgia
this ~~23~~²⁴ day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
798 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

MAY 21, 1993

Docket No. 50-002
License No. R-28
EA 93-069

University of Michigan
ATTN: Dr. Ronald F. Fleming, Director
Michigan Memorial - Phoenix Project
3038 Phoenix Memorial Laboratory
Ann Arbor, Michigan 48109-2100

Dear Dr. Fleming:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$3,750
(NRC INSPECTION REPORT NO. 50-002/93002(DRSS))

This refers to the special safety inspection conducted during the period of March 25-26, 1993, at the Ford Nuclear Reactor. The inspection included a review of your operation of the reactor at a power level which exceeded the licensed maximum power level during a startup on March 24, 1993. You reported this event to the NRC by telephone on March 24, 1993, and subsequently submitted a written report dated April 6, 1993. The report documenting the inspection was sent to you by letter dated April 13, 1993.

During this inspection violations of NRC requirements were identified. An open enforcement conference was held on April 26, 1993, to discuss the proposed violations, their causes, and your corrective actions. The report summarizing the conference was sent to you by letter dated May 10, 1993. At the enforcement conference, you took two exceptions to the sequence of events described in the inspection report. Those exceptions are noted in the enforcement conference report which also contains a revision to page 4 of the inspection report.

On March 24, 1993, the shift crew (two senior reactor operators) was conducting a routine reactor startup. At an indicated 1 megawatt power level (50% of full power), the shift crew conducted a calorimetric determination of power which found that the reactor was actually at 1.15 megawatts.

At that point, the shift crew should have adjusted the linear power level setpoint used for automatic power control to 86% which, while in the automatic rod control mode, would have

CERTIFIED MAIL
RECEIPT REQUESTED

MAY 21 1974

reduced actual power to 1 megawatt. However, the shift crew continued to raise reactor power to 2 megawatts (100% indicated power). That resulted in actual power being 2.3 megawatts, 15% above the licensed limit. Approximately 10 minutes later, the Assistant Reactor Manager for Operations arrived in the control room, reviewed the calorimetric data, and immediately ordered the crew to return the reactor to 1 megawatt indicated power.

One violation is described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) for operation of the reactor at 2.3 megawatts for 10 minutes, a level in excess of the 2 megawatt licensed limit.

There were several root causes for the event. There was a lack of management oversight of operations and poor communication between the shift supervisor and console operator. Additionally, operator knowledge regarding the power level instrumentation was deficient, the operators failed to review or use the startup procedure, and had it been used, the procedural step covering the evolution was unclear.

The NRC recognizes that, in this case, the safety limit of 4.68 megawatts was not challenged. Nevertheless, the violation represents a significant failure to comply with a fundamental safety parameter specified in your license. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

The NRC acknowledges your corrective actions which included, but were not limited to, permanently removing the shift supervisor from licensed activities; requiring that, when neutron channel adjustments are necessary to match thermal power, those adjustments be made at one megawatt prior to proceeding to two megawatts; revising Operating Procedure OP-101, "Reactor Startup," to provide a smooth transition to OP-106, "Power Level Determination," and back to OP-101; conducting an unannounced oral and written examination of the reactor operations staff; and issuing a memorandum to emphasize adequate review of procedures prior to their use.

To emphasize the need for your strict compliance with your license, I have been authorized after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research to issue the enclosed Notice in the amount of \$3,750 for the violation described in the Notice. The base value of a civil penalty for a Severity Level III violation is \$2,500.

MAY 21 1992

The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was not mitigated for identification in that the violation was identified as a result of a self-disclosing event and you did not demonstrate sufficient initiative in identifying its root causes. The proposed civil penalty was mitigated by an amount equal to 50 percent of the base civil penalty in recognition of the corrective actions discussed above.

The proposed civil penalty was escalated by an amount equal to 100 percent of the base civil penalty for your poor past performance. Of particular note is the civil penalty of \$1,250 that was proposed on August 21, 1992 (EA 92-123). That civil penalty was issued for the failure to maintain the reactor subcritical during fuel loading changes, and the failure to ensure that all shim rods were fully inserted prior to the removal or insertion of fuel. Some of the root causes of the violations in that case were similar to those, discussed earlier, which led to this event. The fuel movement event involved poor communications between fuel handlers and the control room operator, the failure to review procedures prior to the fuel move, and the failure to use the procedures during the fuel move.

The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

Section II of the Notice describes two violations, related to exceeding the licensed power level, that were not assessed a civil penalty. The first of these violations involved the failure of the Control Console Operator to review the reactor startup procedure prior to the startup. The second involved the failure to set the corrected linear level setpoint after completion of the calorimetric determination in accordance with the startup procedure.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to take.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

University of Michigan

- 4 -

MAY 21 1983

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/enclosure:
PDR
DCD/DCB (RIDS)
OC/LFDCB
Dr. William Vernetson, Director
of Nuclear Facilities
Michigan Public Service Commission

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

University of Michigan
Ford Nuclear Reactor

Docket No. 50-002
License No. R-28
EA 93-069

During an NRC inspection conducted on March 25-26, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

Operating License No. R-28, Condition 3.C(1), "Maximum Power Level," states that the licensee is authorized to operate the facility at power levels not in excess of two megawatts (thermal).

Contrary to the above, on March 24, 1993, the licensee operated the facility at 2.3 megawatts (thermal) for 10 minutes, a level in excess of 2 megawatts (thermal).

This is a Severity Level III violation (Supplement I).
Civil Penalty - \$3,750.

II. Violations Not Assessed a Civil Penalty

Ford Nuclear Reactor Technical Specification 6.4.1 requires, in part, that written procedures, including applicable check lists shall be followed for startup of the reactor.

- A. Operating Procedure OP-101, Revision 22, "Reactor Startup," Step 5.1, requires the Control Console Operator to review OP-101, Reactor Startup, as part of the startup procedure.

Contrary to the above, the Control Console Operator did not review OP-101 during the reactor startup on March 24, 1993.

This is a Severity Level IV violation (Supplement I).

- B. Operating Procedure OP-101, Revision 22, "Reactor Startup," Step 5.36, states that after completion of the calorimeter, set the corrected Linear Level setpoint.

Contrary to the above, the licensee did not set the

corrected Linear Level setpoint after completion of the calorimeter during the reactor startup on March 24, 1993.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, University of Michigan (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205

should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY
COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 21st day of May 1993

**I.B. REACTOR LICENSEES, SEVERITY LEVEL III VIOLATION,
NO CIVIL PENALTY**

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94598-5368

APR 27 1993

Dockets: 50-528, 50-529, 50-530
Licenses: NPF-41, NPF-51, and NPF-74
EA 93-039

Arizona Public Service Company
ATTN: Mr. William F. Conway
Executive Vice President, Nuclear
P. O. Box 53999, Sta. 9012
Phoenix, Arizona 85072-3999

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT 50-528/93-03, 50-529/93-03, and 50-530/93-03)

This letter refers to our inspection, conducted at your Palo Verde Nuclear Generating Station from January 11 to February 12, 1993, that reviewed an instance of worker radiation exposure that occurred on December 21, 1992. The incident was reported by telephone to NRC as a potential overexposure on December 24, 1992, and in Licensee Event Report 1-92-17, dated January 20, 1993. Several violations related to the incident were identified by your investigation and confirmed by our inspection, as reported in Inspection Report 50-528/93-03, 50-529/93-03, and 50-530/93-03, transmitted by cover letter dated March 1, 1993. These violations, and your subsequent corrective actions, were the topic of an enforcement conference held at our Region V NRC office on March 16, 1993, as reported in Enforcement Conference Report 50-528/93-16, 50-529/93-16, and 50-530/93-16, transmitted by cover letter dated March 24, 1993.

Each of the violations addressed in the enclosed Notice of Violation (Notice) relates to circumstances surrounding the December 21, 1992, incident. Violation A involved the whole-body radiation exposure of 2.445 rems to a contract worker during the fourth quarter of 1992, an exposure in excess of the 10 CFR 20.101(a) limit of 1.25 rems per calendar quarter. Violation B involved your failure to conduct a radiation survey, as required by 10 CFR 20.201(b), in a manner appropriate for evaluating the job-specific radiation hazards incident to removal of a resin fill-head and capping the resin liner. Violation C involved your failure to supply appropriate personnel monitoring equipment as specified in 10 CFR 20.202(a). Violation D involved ten instances of failure to follow procedures for personnel radiation protection, as required by Technical Specification 6.11.1.

Your corrective actions for these violations included a thorough investigation of the circumstances leading to the incident, re-training and discipline for the individuals responsible, restructuring of your ALARA planning organization, and a revision of major aspects of your radiation protection (RP) management controls. We have reviewed both the corrective actions you have already taken and those proposed for the near future, and they should be effective in preventing recurrence of similar incidents involving radiation

exposure. We will continue to monitor your implementation of these corrective actions as well as your efforts to address previous quality assurance audit findings in the radiological controls area.

We recognize that the exposure received by the contract worker would have been within the limits provided by 10 CFR 20.101(b), had certain specified administrative conditions been met prior to the exposure. However, an inadequate pre-job survey, the multiple failures to follow procedures, the lack of proper dosimetry, and apparent less stringent standards for health physics monitoring of activities performed entirely within your RP organization contributed to what we believe was a substantial potential for the worker to have received a significantly higher exposure than was actually incurred. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem. The decision to include the procedural violations as part of the Severity Level III problem was made not only to emphasize the number of such violations but also the fact that those violations were committed by numerous personnel, including a number of supervisors in your RP organization.

In accordance with the Enforcement Policy, a civil penalty is considered for a Severity Level III problem. However, after consultation with the Director, Office of Enforcement and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, and Research, I have decided that a civil penalty will not be proposed in this case.

The base civil penalty was fully mitigated based on your identification of the excessive exposure which resulted from the thoroughness of your investigation of a dosimeter discrepancy, the broad scope and promptness of your corrective actions which addressed multiple aspects of management controls needing improvement, and despite seven violations in radiological controls since the last SALP report, your past overall good performance in Health Physics.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation

cc w/enclosure:

Mr. Steve Olea, Arizona Corporation Commission
James A. Beoletto, Esq., Southern California Edison Company
Mr. Charles B. Brinkman, Manager, ABB Combustion Engineering Nuclear Power
Mr. Aubrey Godwin, Director, Arizona Radiation Regulatory Agency
Chairman, Maricopa County Board of Supervisors
Jack R. Newman, Esq., Newman & Holtzinger, P.C.
Mr. Curtis Hoskins, Executive Vice President and Chief Operating Officer,
Palo Verde Services
Roy P. Lessey, Jr., Esq., Akin, Gump, Strauss, Hauer and Feld
Bradley W. Jones, Esq., Akin, Gump, Strauss, Hauer and Feld

NOTICE OF VIOLATION

Arizona Public Service Company
Palo Verde Unit 1

Docket 50-528
License NPF-41
EA 93-039

During an NRC inspection conducted on January 11 through February 12, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 20.101(a) requires that the licensee limit the whole body radiation dose of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b). 10 CFR 20.101(b) allows a licensee to permit an individual in a restricted area to receive a whole body radiation dose of three rems per calendar quarter provided the dose when added to the individual's accumulated occupational dose to the whole body does not exceed the applicable limit and the individual has a completed Form NRC-4 or equivalent record on file.

Contrary to the above, on December 21, 1992, the licensee did not limit the whole body radiation dose of an individual in the Unit 1 radwaste truck bay, a restricted area, to one and one quarter rems per calendar quarter and the conditions of 10 CFR 20.101(b) were not met. Specifically, the individual received a whole body dose of 2.445 rems during the fourth calendar quarter of 1992 without a completed Form NRC-4 or equivalent record on file.

- B. 10 CFR 20.201(b) requires that each licensee make such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of December 21, 1992, the licensee did not make surveys to assure compliance with the limits of 10 CFR 20.101 for the radiation exposure to the whole body. Specifically, during the fill head removal and capping of the high-integrity container, the radiation hazards incident to removing the resin fill head and the worker putting his hand in the fill hole were not evaluated.

- C. 10 CFR 20.202(a)(3) requires that each licensee supply appropriate personnel monitoring equipment to, and require the use of such equipment by, each individual who enters a high radiation area.

Contrary to the above, on December 21, 1992, the licensee did not supply appropriate personnel monitoring equipment to a contract worker who entered a high radiation area. Specifically, the dosimetry issued to the

worker was not appropriate in that the portion of the worker's body receiving the highest whole body dose, the left upper arm, was not monitored.

- D. Technical Specification 6.11.1 states, "Procedures for personnel radiation protection shall be prepared consistent with the requirements of 10 CFR Part 20 and shall be approved, maintained, and adhered to for all operations involving personnel radiation exposure."

1. Procedure 75PR-ORP03, Revision 2, "ALARA Program," states:

3.8.2 Station modifications or equipment changes which may affect radiation exposure shall receive an ALARA review based on Regulatory Guide 8.8.

Contrary to the above, in January 1992, the licensee changed radwaste disposal containers for high radiation area applications from metal Enviroalloy to polyethylene high-integrity containers (HIC), a modification which could affect radiation exposure, and did not perform an ALARA review of this equipment change.

2. Procedure 75PR-9AL03, Revision 3.00, "ALARA Pre-job Planning," contains instructions for the Radiation Exposure Permit (REP) preparer to follow as part of the pre-job planning process. Section 3.1, "Pre-Job Planning," makes the following statements:

3.1.2 Determination of Job Scope

3.1.2.1 The job scope should be determined such that the REP, when written, adequately addresses specific radiological conditions and protective requirements.

Section 3.1, "Pre-Job Planning," further states:

3.1.6 RP Interface with Planners/Work Group

3.1.6.2 Address aspects of the job that might affect personnel exposures such as body position, special tools, etc.

Contrary to the above, on December 15 - 21, 1992, a work planner did not determine the scope of the work to be performed and did not communicate with the work group so as to address aspects of the job that might affect personnel exposures, when preparing REP 1-92-1059-A. Specifically, the planner was not aware that the job involved working in the prone position on top of the HIC or that the worker would be inserting his hand into the HIC's resin fill hole (the location of the highest exposure rates).

3. Procedure 75RP-9RP02, Revision 2.00, "Radiation Exposure Permits," Section 2.1.1 provides that RP Supervision/Management are

"responsible for required reviews and approvals of REPs [radiation exposure permits] per Appendix F, the Job Hazard Evaluation System (JHES) Category Index."

Appendix F states that Category 1 tasks:

... are considered the most radiologically hazardous work that we encounter. When REP's are written for Category 1 work, the Manager, Unit RP shall sign the approval section of the REP. The Manager, RP Operations shall also review and sign the REP.

Contrary to the above, the Unit RP Manager's approval signature did not appear on REP 1-92-1059-A on December 21, 1992, when the REP was issued, even though the job was classified as JHES Category 1.

4. Section I of the ALARA Review Form states that when an REP meets JHES Category 1 criteria, a Site ALARA review is required.

Contrary to the above, on December 21, 1992, the Acting ALARA/Work Control Supervisor did not forward REP package 1-92-1059-A, a JHES Category 1 REP, to Site ALARA for review.

5. Section I of the ALARA Review Form states that when a REP meets JHES Category 1 criteria, a Site ALARA review is required. Procedure 75RP-9RP02, Revision 2.00, "Radiation Exposure Permits," states in Section 3.2, "REP Preparation," the following:

3.2.21 RPS - The signature in the RPS Block verifies that the controls identified on the REP ensure adequate radiological protection and that the REP is a complete document (e.g., required ALARA Reviews are complete, etc.)

Contrary to the above, on December 18, 1992, the Acting ALARA/Work Control Supervisor signed the RPS block on REP 1-92-1059-A prior to Site ALARA review being completed.

6. Procedure 75RP-9AL03, Revision 3.00, "ALARA Pre-Job Planning," states:

3.4.3 ALARA Reviews (Section 2) require review and approval by the Manager, RP Operations.

Contrary to the above, the RP Operations Manager did not review or approve the Site ALARA review on REP 1-92-1059-A prior to the REP being issued on December 21, 1992.

7. Procedure 76CP-9NP06, Revision 2, "Operating Procedure - Resin Drying (Dewatering) System," requires in Section 5.4.1 that workers "Follow all instructions on the REP." REP 1-92-1059-A included the following instructions to the workers performing the fill head

removal:

- "A/S [air sample] during fill head removal."
- "Remotely install lid w 'T Handle.' [sic]"
- "No work other than described above will be permitted on this REP"

Contrary to the above, on December 21, 1992, workers did not use the "T Handle" to install the HIC lid and no air sample was taken while performing the work authorized by REP 1-92-1059-A. Additionally, RP technicians working under this REP performed a resin sample split, work not authorized under REP 1-92-1059-A.

8. Procedure 75RP-9RP10 Rev. 1.2, "Conduct of Radiation Protection Operations," states the following RP Senior Technician job coverage duties:

- 2.2.4 Be aware of activities in the designated area of responsibility, provide adequate supervision and radiation protection surveillance to ensure the appropriate procedures are followed, planned precautions are observed, and all potential radiation hazards that develop or are recognized during the operation are addressed in a timely and appropriate manner.

Additional RP Senior Technician duties are listed in REP 1-92-1059-A, including the duty to provide "Continuous covg. [coverage] during any HIC/fillhead move and LHRA entry." Continuous coverage is defined in 75RP-9RP02, Revision 2.00, "Radiation Exposure Permits," as:

- 4.1.9.1 A qualified RP technician with a dose rate monitoring device who is responsible for providing positive control over the activities within the area.

The RP Senior Technician is also charged with the authority to stop work as defined in 75RP-9RP02, Revision 2.00, "Radiation Exposure Permits":

- 4.1.12.1 This authority will be exercised by qualified RP representatives when radiological conditions and job practices could endanger the workers or could violate NRC regulations, station procedures, or ALARA controls for the job.

Contrary to the above, on December 21, 1992, the primary RP Senior Technician did not exercise his stop work authority when unexpected radiation hazards were recognized while performing work authorized

by REP 1-92-1059-A. Specifically, the RP Senior Technician did not stop the job when he recognized that radiation readings were higher than expected after the resin fill head was raised above the HIC. The RP Senior Technician also failed to ensure that planned precautions to reduce personnel radiation exposure were followed, in that remote tools were not used and an air sample was not taken.

9. Procedure 76CP-9NP06, Revision 2, "Operating Procedure - Resin Drying (Dewatering) System," contains instructions for the workers performing the resin fill head removal and capping of the HIC under REP 1-92-1059-A. Procedure 76CP-9NP06 states:

6.8.2 Install the container lid in accordance with the container instruction manual or procedure. Insure that the lid is installed to a leak tight seal.

Attachment H, "Resin Drying Process Memo and Process Data Sheet," is an official record that documents the entire resin transfer process from filling the HIC and drying the resin to capping the HIC.

Section VI, "Closure," of Attachment H contains the sign-off check list for closing the HIC and requires the worker's initials verifying that the "Threaded lid [was] torqued to min. 50 ft-lbs (if applicable)" using a calibrated torque wrench.

Contrary to the above, on December 21, 1992, a worker performing work authorized by REP 1-92-1059-A installed the HIC lid for final closure by hand without the use of a torque wrench, which is required for final closure, to determine if the minimum torque required was achieved.

10. Procedure 75RP-ORP03, Revision 3.00, "ALARA Program," Section 2.15 provides in part that Work Group Supervisors are required to supervise jobs "to ensure that maximum benefit is derived from necessary worker radiation exposure" (2.15.1), and "participat[e] in pre-planning of work to be performed in Radiological Controlled Areas and Post-Job Reviews" (2.15.4).

Contrary to the above, on December 15-21, 1992, the supervisor responsible for the work group performing the fill head removal job did not participate in the pre-job planning or pre-job briefing, and was not present to supervise during the actual job performance.

This is a Severity Level III problem (Supplement IV).

Pursuant to the provisions of 10 CFR 2.201, Arizona Public Service Company is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator Region V, and a copy to the NRC Resident Inspector at Palo Verde Nuclear Generating Station within 30 days of the date of this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2)

the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Commission may issue an order or a demand for information as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Walnut Creek, CA
this 27th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5027

June 25, 1993

Dockets No. 50-282 and 50-306
Licenses No. DPR-42 and DPR-60
EA 92-096

Northern States Power Company
ATTN: Mr. Douglas Antony
Vice President
Nuclear Generation
414 Nicollet Mall
Minneapolis, Minnesota 55401

Dear Mr. Antony:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT 50-282/90019; 50-306/90020)
(NRC INVESTIGATION REPORT 3-91-001)

This refers to the routine safety inspection conducted from November 20, 1990, to January 14, 1991, and a subsequent investigation by the NRC Office of Investigations (OI) at the Prairie Island Nuclear Generating Plant. The report documenting the inspection was mailed to Northern States Power Company (NSP) by letter, dated January 28, 1991, and a summary of the OI report was sent to NSP on December 23, 1992. The inspection and investigation identified significant violations of NRC requirements and an enforcement conference was held on February 3, 1993, in the Region III office. The report of the enforcement conference was mailed to NSP on February 12, 1993.

The NRC inspection and subsequent investigation were initiated as a result of an NSP letter dated November 20, 1990, notifying the NRC that a compliance audit had identified a potential violation of NRC requirements (10 CFR Part 26) in the background screening program implemented by the Prairie Island security contractor. The audit found that an individual with a documented history of alcohol abuse, and who had failed to complete a substance abuse rehabilitation program, was granted unescorted access as an armed security guard at the Prairie Island Nuclear Generating Plant.

The violations arising out of this matter are fully described in the enclosed Notice of Violation (Notice) and include:
(a) failure to make a management and medical determination of the fitness for duty of the individual who had been subject to a treatment program for alcohol abuse prior to granting him unescorted access to the plant; and (b) permitting the same individual to act as an armed guard at the Prairie Island Nuclear Generating Plant, even though he had an established medical

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

history of habitual alcoholism and could not demonstrate that he had successfully completed a rehabilitation program. The violations continued for several months before you identified them, notwithstanding several opportunities between May 15, 1990, and October 22, 1990, to either prevent the violations or identify them after they occurred. These opportunities included initial receipt of the individual's Form DD-214, both long and short form, discussions among contractor and licensee employees, and a report concerning the individual's arrest for driving under the influence of alcohol.

As a result of the investigation, the NRC concluded that the violations were caused by the deliberate failure of the regional manager of American Protective Services (APS), the contractor responsible for conducting background investigations of new employees, to report potentially disqualifying information about the individual to the NSP fitness-for-duty coordinator. This contributed to the failure to evaluate the information prior to granting access and/or assigning him to duties as an armed security officer. The NRC recognizes that once the violations were identified and understood by the NSP staff, the NRC was promptly notified, the matter was immediately investigated, and corrective actions were prompt and extensive. Nevertheless, licensees are held responsible for the actions of their contractors. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1990), the violations are collectively categorized at Severity Level III.

Deliberate violations, whether by NSP employees or contractors, are significant and may undermine NSP's ability to ensure compliance. Therefore, consideration was given to increasing the severity level because of the deliberate nature of the violation. However, the severity level was not changed in this case principally because the information was reported to one member of the licensee's security management, although he was not aware that the fitness-for-duty coordinator had not been notified, because there did not appear to be any deliberateness on the part of the licensee, and because the violation was reported to the NRC even though there was no requirement to do so.

A civil penalty was also considered for the violations comprising the Severity Level III problem in accordance with the Enforcement Policy. However, after consultation with the Commission and after considering your corrective actions following your identification of the violations, your voluntary reporting of the matter, and the time that has passed since you notified the NRC of the access issue, a civil penalty will not be proposed for the violations.

Finally, apart from the enforcement action against you, it should be noted that had this event occurred after September 1991, the effective date of the Commission's regulations concerning deliberate misconduct by individuals, this enforcement action may

Northern States Power Company - 3 -

have included action directly against the contractor's regional manager.

Northern States Power Company is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should address not only the failure to consider the potentially disqualifying information available before granting the individual's access authorization but also why subsequent information relating to his arrest did not cause a reconsideration of the access decision. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure: Notice of Violation

cc w/enclo:
DCD/DCB (RIDS)
E. L. Watzl, Site Manager
M. Wadley, Plant Manager
Resident Inspectors, Monticello
and Prairie Island
John W. Ferman, Ph.D.
Nuclear Engineer, MPCA
State Liaison Officer
State of Minnesota
Prairie Island LPM, NRR

NOTICE OF VIOLATION

Northern States Power Company
Prairie Island Nuclear Generating
Plant, Units 1 and 2

Dockets No. 50-282; 50-306
Licenses No. DPR-42, DPR-60
EA 92-096

During an NRC inspection conducted from November 20, 1990, to January 14, 1991, and a subsequent NRC investigation, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1990), the particular violations are set forth below:

- A. 10 CFR 26.27(a) requires, in part, that prior to the initial granting of unescorted access to a protected area, the licensee shall complete a suitable inquiry on a best-efforts basis to determine if that person was, in the past, subject to a plan for treating substance abuse. If such a record is established, the granting of unescorted access must be based upon a management and medical determination of fitness for duty and the establishment of an appropriate follow-up testing program.

Contrary to the above, from June 28, 1990 to October 24, 1990, the licensee granted unescorted access to the protected area to an individual who, in the past, had been subject to a plan for treating substance abuse and the licensee did not make a management and medical determination regarding the individual's fitness for duty and did not establish an appropriate follow-up testing program.

- B. Section 2.c(3)a of Amendment 85 to License No. DPR-42 and Section 2.c(3)a of Amendment No. 78 to License No. DPR-60 require the licensee to fully implement and maintain in effect all provisions of the Security Plan, including amendments and changes made pursuant to the authority of 10 CFR 50.54(p).

Section 1.2.1.3. "Armed Personnel Requirements - Addiction", in Revision 8 of the approved Northern States Power "Security Force Training & Qualification Plan," dated April 12, 1988, requires in part, that armed personnel must have no established medical history or medical diagnosis of habitual alcoholism or, where such a condition has existed, the individual must provide certified documentation of having completed a rehabilitation program which would give a reasonable degree of confidence that the individual would be capable of performing assigned security duties.

Contrary to the above, from September 6, 1990 to October 24, 1990, the licensee permitted an individual to act as an armed guard notwithstanding the fact that the individual had a medical history of habitual alcoholism and had failed rehabilitation, resulting in his not being able to provide certified documentation of having completed a rehabilitation program.

Notice of Violation

- 2 -

This is a Severity Level III problem (Supplements VII and III).

Pursuant to the provisions of 10 CFR 2.201, Northern States Power Company (Licensee) is hereby required to submit a written statement of explanation to the U.S. Nuclear Regulatory Commission, with a copy to the Regional Administrator, Region III, and a copy to the NRC Resident Inspector at Prairie Island Nuclear Generating Plant within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Glen Ellyn, Illinois
this 25th day of June 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

APR 18 1993

Docket No. 50-344
License No. NPF-1
EA 92-223

Portland General Electric Company
ATTN: Mr. James E. Cross
Chief Nuclear Officer/Vice President
Nuclear Division
121 S. W. Salmon Street, TB-17
Portland, Oregon 97204

SUBJECT: NOTICE OF VIOLATION (NRC INVESTIGATION REPORT NO.
5-91-008)
(NRC ENFORCEMENT CONFERENCE MEETING REPORT
50-344/93-01)

This refers to an investigation conducted by the NRC Office of Investigations (OI) from June 20, 1991 through September 23, 1992, at the Trojan Nuclear Plant. A synopsis of the OI report was sent to you in a Region V letter dated December 23, 1992. As noted in that letter, the investigation identified apparent violations of NRC requirements prohibiting employment discrimination. Specifically, licensee security management actions had the effect of discouraging Trojan security officers from raising concerns to management and the NRC. This matter was discussed with you during an enforcement conference held in the Region V Office on February 2, 1993. Our discussion during the enforcement conference was summarized in Report No. 50-344/93-01, transmitted to you on February 12, 1993.

As stated in the enclosed Notice of Violation (Notice), licensee security management violated 10 CFR 50.7, which prohibits discrimination and agreements that would discourage employees from raising safety concerns. Certain security management instructions to security force members between November 1989 and August 1991 indicated that the security officers should let their presence be known when checking on security posts and firewatches, creating the impression among security staff that they were not to find or report sleeping/inattentive individuals. In addition, there were attempts on the part of security management to determine, through questioning of security officers, the identity of the author(s) of an anonymous letter to the NRC, creating the impression that management would retaliate against the author(s). These actions violate 10 CFR 50.7 in that they demonstrate a condition of employment that security officers should not raise safety concerns under penalty of adverse action.

Many security personnel interpreted these management directions and actions to mean that they were not to report sleeping/inattentive individuals or other security concerns to management or to the NRC. Such an interpretation created an atmosphere at the Trojan Nuclear Plant site that discouraged security force members from maintaining open and honest communications with the NRC and PGE management.

As noted in the report on the Enforcement Conference, you concluded, based on your own investigation, that your former security managers had not discriminated against or intimidated the security force, basing this conclusion in part on your July 1991 determination that 65% of your uniformed officers had expressed no hesitation to report incidents to PGE management and/or the NRC. However, the NRC does not, and PGE should not, take comfort in the knowledge that up to 35% of the security force may refuse to come forward with reports of safety issues.

The actions by licensee security managers created a chilling effect that discouraged employees from raising concerns. Such an environment cannot be tolerated if licensees are to fulfill their responsibility to protect public health and safety. It is imperative that managers and supervisors of licensees and their contractors avoid actions that suggest discrimination against individuals who raise or who wish to raise safety concerns. Instead, the actions of licensees and their contractors must create an environment conducive to the reporting of safety issues. Your failure to ensure appropriate actions by your managers between November 1989 and August 1991, including the then-Acting Security Manager, two of your Security Watch Supervisors, and a Smith Security manager, is cause for significant regulatory concern. Therefore, this violation has been categorized at Severity Level III.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III violation. The mitigation and escalation factors in the Enforcement Policy were considered in deciding whether to issue a civil penalty in this case and, normally, a civil penalty would have been proposed. However, in this case, pursuant to Section VII.B.6 of the Enforcement Policy, the staff has concluded a civil penalty is not warranted. This decision was due to several factors, including: steadily improving performance both during and after the violation, culminating in a rise from SALP 3 to SALP 1 in security; reorganization of the security force, including replacement of the manager responsible for creating the atmosphere discussed above, and evidence that the new managers have made progress in this area; and a decline in the number of allegations, evidencing a clearly improved atmosphere for raising safety matters.

The staff is aware of the recent decision to immediately and permanently shutdown Trojan. The operating status of the plant did not affect this enforcement decision because, although the plant is currently shutdown, the activities are still licensed and must be performed in compliance with the regulatory requirements and an atmosphere for raising safety concerns must be maintained. Future similar violations may result in additional enforcement action, including civil penalties where appropriate.

In addition to the two examples of discrimination discussed above, evidence was found of management actions that might have intimidated employees and discouraged them from reporting safety concerns. Specifically, these examples included licensee security managers: (a) directing security force members to change reports concerning sleeping officers, (b) telling officers they had overreacted when reporting sleeping/inattentive officers, and (c) making statements to an officer relating his firing, after the fact, to his contacts with the NRC. Although these cases are not included in the Notice of Violation, you should take appropriate action to ensure that employees are not chilled by these and similar incidents.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice of Violation (Notice) when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Regional Administrator

Enclosure: Notice of Violation

NOTICE OF VIOLATION

Portland General Electric Company Docket No. 50-344
Trojan Nuclear Plant License No. NPF-1
EA 92-223

During an NRC investigation conducted from June 20, 1991 through September 23, 1992, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violation is listed below:

10 CFR 50.7(a) provides in part that discrimination by a Commission licensee against an employee for engaging in certain protected activities is prohibited. Discrimination includes discharge and other actions that relate to compensation, terms, conditions and privileges of employment. The activities protected are established in section 210 (now section 211) of the Energy Reorganization Act of 1974, as amended, and include, but are not limited to, preparing to provide to the NRC, the licensee, or a contractor of the licensee, information about possible violations of NRC requirements.

10 CFR 50.7(f) provides that "No agreement ... may contain any provision which would prohibit, restrict, or otherwise discourage, an employee from participating in protected activity ... including, but not limited to, providing information to the NRC on potential violations or other matters within NRC's regulatory responsibilities."

Contrary to the above, and as described below, licensee management actions and directions discouraged the Trojan security force from providing information to licensee management or to the NRC concerning potential violations and other matters within NRC's regulatory responsibilities. Specifically, between November 1989 and August 1991, licensee managers took certain actions which many officers interpreted to mean that they were not to report sleeping/inattentive individuals or other security concerns to management or to the NRC. These actions included:

1. Security managers giving instructions and taking actions indicating that security officers should let their presence be known when checking on security posts and firewatches. As a result, several security officers stated that they felt intimidated with regard to reporting sleeping officers.
2. Security managers attempting to determine, through questioning of security force members, the identity of the author(s) of an anonymous June 11, 1991, letter to the NRC that had complained about Trojan security management, creating the impression that management would retaliate against the author(s). As a result, several security officers stated that they were intimidated with regard to raising safety concerns to the NRC.

Notice of Violation

- 2 -

This is a Severity Level III violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, Portland General Electric Company (Licensee) is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region V, and a copy to the NRC Resident Inspector at Trojan, within 30 days of the date of this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) the reason for the violation or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Commission may issue an order or a demand for information as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Walnut Creek, California
this 16th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

JUN 21 1993

Docket Nos. 50-338, 50-339
License Nos. NPF-4, NPF-7
EA 93-094

Virginia Electric and Power Company
ATTN: Mr. W. L. Stewart
Senior Vice President - Nuclear
5000 Dominion Boulevard
Glen Allen, Virginia 23060

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 50-338/93-17 AND 50-339/93-17)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. M. Lesser on April 16 - 23, 1993, at the North Anna Power Station. The inspection included a review of the facts and circumstances related to actions taken by operators following the Unit 2 reactor trip on April 16, 1993, in which the automatic start function of the auxiliary feedwater (AFW) pumps was defeated for at least 18 minutes while a valid start signal was present. The report documenting the NRC inspection was sent to you by letter dated May 10, 1993. An enforcement conference was conducted in the NRC Region II office on May 20, 1993, to discuss a number of potential violations, their causes, and your corrective actions to preclude recurrence. This enforcement conference was open for public observation in accordance with the Commission's trial program for conducting open enforcement conferences as discussed in the Federal Register, 57 FR 30762, July 10, 1992. A summary of the enforcement conference was sent to you by letter dated May 28, 1993.

Violation A described in the enclosed Notice of Violation (Notice) involved defeating the automatic actuation function of the AFW pumps. After an automatic reactor trip due to a main generator voltage regulator circuitry problem, all safety systems responded as designed. Approximately nine minutes into the event, a reactor operator defeated the automatic actuation function of the AFW system by placing the motor driven AFW pump switches in pull-to-lock and isolating steam to the turbine driven AFW pump in order to arrest the primary plant cooldown. At the time the pump switches were placed in pull-to-lock, a valid AFW pump start signal from a low-low steam generator level was still present. Approximately 18 minutes later, the condition was identified by another operator as an incorrect alignment and the AFW system was immediately returned to automatic standby.

At the time of the reactor trip, the crew initiated Emergency Procedure 2-E-0, Reactor Trip and Safety Injection, to stabilize plant conditions, and after approximately three minutes transitioned to Procedure 2-ES-0.1, Reactor Trip Response. The AFW pumps had automatically started and total AFW flow reached 1425 gpm with all throttle valves fully open as a result of a valid initiation

JUN 21 1993

signal due to steam generator level decrease. This high AFW flow rate to the steam generators caused the reactor coolant system (RCS) temperature to decrease below the no-load value of 547°F, which was noted by the primary plant reactor operator who alerted the Unit 2 supervisor of the condition.

The Unit 2 supervisor, intent on arresting primary plant cooldown, recognized that AFW flow had to be reduced. The Unit 1 supervisor, acting as the procedure reader, requested to read aloud the procedural steps designed to accomplish that task. Rather than allowing the steps to be read, the Unit 2 supervisor commenced shifting steam generator feeding from AFW to main feedwater by giving the balance-of-plant (BOP) operator permission to secure the AFW system at nine minutes into the event. The Unit 2 supervisor's interpretation of the word "secure" was to close the AFW valves to stop flow. However, the BOP operator had a different interpretation and secured the AFW system by placing both motor driven AFW pumps in pull-to-lock and closing the steam supply trip valves to the turbine driven AFW pump. The BOP operator then commenced to feed two of the three steam generators through main feedwater bypass valves and after approximately 18 minutes the primary temperature and pressure stabilized at acceptable values.

The actions taken above did not conform with those specified in the applicable procedure. The NRC is concerned that two licensed operators on the same crew would fail to consult their procedures and, notwithstanding the communications problem in securing AFW, failed to recognize the existence of a bypassed safety system upon receipt of the annunciator alarm when the turbine driven AFW pump was defeated. This is of particular concern considering your recent development and distribution of the policy statement on defeating automatic safety system actuations. The NRC is also concerned with the poor communication between the Unit 2 supervisor and the BOP operator. This lack of effective communication directly contributed to the defeating of the automatic safety function of the AFW system.

Approximately 27 minutes after initiation of the event, the Unit 1 supervisor observed that the AFW pump switches were in the pull-to-lock position and notified the shift supervisor, who directed that the switches be immediately placed in the automatic start position. Based on the fact that the automatic actuation function of the AFW system was defeated when the pump switches were placed in the pull-to-lock position and the supply trip valves were closed, the auxiliary feedwater system was inoperable and incapable of automatic actuation as required by Technical Specifications for approximately 18 minutes.

The NRC understands that the actual safety consequence of this event was minor because the steam generators were adequately fed and an adequate heat sink was quickly achieved and maintained. However, as stated above the NRC considers the failures of the operating crew to be a significant regulatory concern. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation has been categorized at Severity Level III.

JUN 21 1993

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III violation. The base civil penalty for a Severity Level III violation is \$50,000. However, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations and Research, I have decided that a civil penalty will not be proposed for this case. The escalation and mitigation factors in the Enforcement Policy were considered. Escalation was warranted based on the factor of prior opportunity to identify because your training and guidance in response to NRC Information Notice 92-47 and the two earlier events at Surry (EA 91-141 and 92-093) were not effectively communicated to all licensed personnel. However, that escalation was more than offset by the mitigation warranted based on the factors of identification, corrective action, and licensee performance.

The enclosed Notice also contains Violation B, cited at Severity Level IV, for the operator's failure to follow the established procedures. The NRC considered combining this violation with Violation A as a Severity Level III problem. However, in order to emphasize the particular significance with which the NRC views the operation of a safety system without its automatic actuation function, the violations have been cited separately.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation

Virginia Electric and
Power Company

- 4 -

JUN 21 1993

cc w/encl:

M. L. Bowling, Jr., Manager
Nuclear Licensing
Virginia Electric & Power Company
5000 Dominion Boulevard
Glen Allen, VA 23060

G. E. Kane, Station Manager
North Anna Power Station
P. O. Box 402
Mineral, VA 23117

Executive Vice President
Old Dominion Electric Cooperative
4201 Dominion Boulevard
Glen Allen, VA 23060

Dr. W. T. Lough
Virginia Corporation Commission
Division of Energy Regulation
P. O. Box 1197
Richmond, VA 23209

William C. Porter, Jr.
County Administrator
Louisa County
P. O. Box 160
Louisa, VA 23093

Michael W. Maupin, Esq.
Hunton and Williams
Riverfront Plaza, East Tower
951 E. Byrd Street
Richmond, VA 23219

Attorney General
Supreme Court Building
101 North 8th Street
Richmond, VA 23219

Robert B. Strobe, M.D., M.P.H.
State Health Commissioner
Office of the Commissioner
Virginia Department of Health
P. O. Box 2448
Richmond, VA 23218

NOTICE OF VIOLATION

Virginia Electric and
and Power Company
North Anna Power Station Unit 2

Docket No. 50-339
License No. NPF-7
EA 93-094

During an NRC inspection conducted on April 16 - 23, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. Technical Specification (TS) 3.7.1.2 requires that at least three independent steam generator auxiliary feedwater pumps and associated flow paths be operable with two motor driven auxiliary feedwater pumps and one steam turbine driven auxiliary feedwater pump operable in Modes 1, 2, or 3. With three inoperable feedwater pumps, immediately initiate corrective action to restore at least one auxiliary feedwater pump to operable status as soon as possible.

Contrary to the above, on April 16, 1993, with Unit 2 in Mode 3, both motor driven auxiliary feedwater (AFW) pump control switches were placed in the pull-to-lock position and the steam supply trip valves were shut on the turbine driven AFW pump resulting in all three AFW pumps being inoperable, in that, the automatic start feature was defeated for a period of 18 minutes while a valid AFW pump start signal from a low-low steam generator level was present.

This is a Severity Level III violation (Supplement 1).

- B. TS 6.8.1 requires that written procedures be established, implemented and maintained covering the activities recommended in Appendix A of Regulatory Guide 1.33, Revision 2, February 1978. This appendix includes recovery from reactor trip.

Procedure 2-ES-0.1, Reactor Trip Response, Step 1, checks reactor coolant system temperature stable at or trending to 547°F. The Response Not Obtained (RNO) column states that if a cooldown continues then adjust total AFW flow to 400 gpm until at least one steam generator (SG) narrow range level is greater than 11 percent.

Procedure 2-ES-0.1, Step 6, checks SG levels greater than 11 percent. The RNO column states that if all levels are not greater than 11 percent, maintain total AFW flow greater than 400 gpm until narrow range level is greater than 11 percent in at least one SG. Procedure 2-ES-0.1, Step 12, requires that when all SG narrow range levels are verified greater than 20 percent, reset Anticipated Transient Without Scram (ATWS) Mitigation System Actuation Circuitry (AMSAC), and stop AFW pumps by placing the switches to auto.

Notice of Violation

- 2 -

Contrary to the above, on April 16, 1993, operators failed to follow the requirements of Procedure 2-ES-0.1 in that AFW flow was neither adjusted nor maintained as required, AMSAC was reset, and AFW pumps were stopped prior to SG narrow range levels returning to greater than 20 percent level.

This is a Severity Level IV violation (Supplement I).

Pursuant to the provisions of 10 CFR 2.201, Virginia Electric and Power Company (Licensee) is hereby required to submit a written statement of explanation to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region II, and a copy to the NRC Resident Inspector at North Anna Power Station within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Atlanta, Georgia
this 21st day of June 1993

II.A. MATERIALS LICENSEES, CIVIL PENALTIES AND ORDERS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

SEP 21 1982

Docket No. 040-08977
License No. STB-1526
EA 92-171

Aircraft Components, Inc.
ATTN: Mr. Michael V. Bruno
President
174 Cedar Street
Branford, Connecticut 06405

Dear Mr. Bruno:

Subject: ORDER MODIFYING LICENSE (EFFECTIVE IMMEDIATELY) AND
DEMAND FOR INFORMATION

The enclosed Order and Demand are being issued because of a willful violation of your license possession limits. The terms of the Order, as set forth in Section V, require you to survey your facility and develop a decommissioning plan with appropriate financial assurance. The procedures for consenting to or contesting this Order are described therein. The Demand for Information, set forth in Section VII, seeks information as to why the NRC should not order that your facility be decommissioned and your license revoked. Issuance of this action does not preclude further enforcement action for the underlying violations.

Questions concerning this Order and Demand should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at (301) 504-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosures:

1. Order and Demand for Information
2. Manual for Conducting Radiological Surveys
3. Guidelines for Decontamination of Facilities and Equipment
4. Disposal or Onsite Storage of Thorium or Uranium Wastes

cc w/encl:
Nuclear Safety Information Center (NSIC)
State of Connecticut

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 040-08977
AIRCRAFT COMPONENTS, INC.	)	License No. STB-1526
Bradford, Connecticut	)	EA 92-171

ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)
AND
DEMAND FOR INFORMATION

I

Aircraft Components, Inc. (ACI) or (Licensee) is the holder of Source Material License No. STB-1526 (License) issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The License authorizes the Licensee to possess, store, and precision-machine magnesium-thorium castings for aircraft components. The License also limits the Licensee's possession of radioactive material of natural thorium to 45 kilograms in the form of thorium oxide not exceeding 4% alloyed with magnesium. The License was originally issued on December 21, 1988, and is due to expire on January 31, 1994.

II

On August 26, 1992, an inspector from the NRC Region I office conducted an inspection at the Licensee's facility in Branford, Connecticut. The inspection was conducted to review the Licensee's activities to determine compliance with NRC requirements and to assure safe performance of those activities. At the outset of the inspection, the inspector questioned Mr. Michael V. Bruno, President and Radiation Safety Officer for

the facility, concerning the amount of thorium possessed by the Licensee on that date. Mr. Bruno estimated that the Licensee possessed approximately 71 kilograms of thorium. Since this amount was in excess of the limit authorized by the License, the inspector reviewed the Licensee's inventory records for the period between May 30, 1990, and the date of the inspection. Based upon that review, as well as information subsequently provided to the NRC by the Licensee, the NRC determined that the Licensee had, in fact, exceeded its possession limits for thorium throughout the period between June 30, 1989 and August 26, 1992. The largest amount of thorium possessed during that period was 306.5 kilograms on April 25, 1991. During that period, on at least one occasion (i.e., May 9, 1991) the Licensee possessed more than 200 kilograms of thorium in a dispersible form (i.e., a form that can be easily distributed creating widespread contamination).

The inspector questioned Mr. Bruno concerning his knowledge of whether the Licensee's possession limit was exceeded, and if so, the length of time it had been exceeded. Mr. Bruno indicated that he was aware that the limit had been exceeded for several months. The inspector then questioned Mr. Bruno as to why he did not seek and obtain a license amendment from the NRC to authorize possession of larger amounts of natural thorium. Mr. Bruno indicated that he did not seek a license amendment because he knew that to obtain such an amendment, the Licensee would first

be required to provide financial assurance for decommissioning (which assures that the Licensee has adequate funds available for decommissioning of the facility). On September 11, 1992, Region I management, as well as representatives from the NRC's Office of the General Counsel, contacted Mr. Bruno by phone to verify the statements made to the inspector. Mr. Bruno confirmed his prior conversations with the inspector concerning why the violation occurred, and also indicated that he was aware, since June 1989, that the Licensee had exceeded the possession limit.

III

Condition B of License No. STB-1526 limits the Licensee's possession of thorium to 45 kilograms. Contrary to this requirement, from June 30, 1989 to August 26, 1992, the Licensee, at various times, possessed more than 45 kilograms of thorium. As set forth in Section II of this Order, the Licensee's President and Radiation Safety Officer was aware of the possession limit in License Condition 8, and was aware that the amount of thorium in the Licensee's possession exceeded that limit.

In addition, as required by 10 CFR 40.36, any licensee authorized to possess greater than 10 millicuries of source material (which equates to 45.5 kilograms of natural thorium) in a readily dispersible form shall submit, on or before July 27, 1990, a

certification of financial assurance for decommissioning, or a decommissioning funding plan, in accordance with the criteria set forth therein. These requirements were developed to assure that licensees who possessed substantial quantities of readily dispersible material would have in place a financial mechanism that would assure protection of public health and safety by providing adequate funding for the ultimate decontamination and decommissioning of the facility. In its initial license application, dated October 21, 1988, ACI requested a possession limit of 500 kilograms of natural thorium. Since ACI had not provided the necessary financial assurance required by 10 CFR 40.36 in its license application, the NRC sent a letter to ACI on November 25, 1988, stating that the Licensee must submit a certification that financial assurance has been provided before the NRC could authorize possession of greater than 45 kilograms of thorium. ACI responded to the NRC, in a letter dated December 1, 1988, by changing its requested possession limit to 45 kilograms. In that December 1, 1988 letter, the requested authorization limit was changed "[d]ue to the fact that we [ACI] were not aware of the recent regulatory requirements to submit financial assurance in the amount of \$150,000... ."

IV

Based on the above, I conclude that Mr. Bruno, the Licensee's President and Radiation Safety Officer, intentionally violated

NRC requirements in that he knew possession of natural thorium in amounts greater than 45 kilograms of natural thorium was contrary to the conditions of its License. Further, Mr. Bruno also intentionally failed to seek an amendment to the License authorizing possession of greater amounts because he wanted to avoid the cost of providing the required financial assurance for decommissioning to the NRC. Although the Licensee, subsequent to the inspection, reduced its inventory of natural thorium to an amount less than its licensed limit, the willful actions by the most senior person in the Licensee's organization raise serious questions concerning the willingness of the Licensee to comply with NRC regulatory requirements. Consequently, further action and information as described in Sections V and VII is necessary in order to determine (1) whether NRC should have the requisite reasonable assurance that the Licensee's current operations can be conducted under License No. STB-1526 in compliance with the Commission's requirements, (2) whether, because of the Licensee's possession and use of material exceeding license limits, the site has been contaminated such that remedial measures are needed, and (3) whether the health and safety of the public, including the Licensee's employees, will be protected. Therefore, the public health, safety, and interest require that pending receipt and evaluation of that information the Licensee take the actions described below to determine the extent of contamination at the facility and the cost of its decommissioning. In light of the past possession of significantly more than 45 kilograms of

natural thorium in dispersible form, it is necessary to provide evidence of financial assurance to complete decommissioning activities. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the willful conduct described above is such that the public health, safety, and interest require that this Order be immediately effective.

V

Accordingly, pursuant to Sections 161b, 161c, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Part 40, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Within 30 days of the date of this Order, the Licensee shall:

1. Conduct a radiation survey of the premises in accordance with the guidance in the "Manual for Conducting Radiological Surveys in Support of License Termination", NUREG/CR 5849 (June 1992), where licensed activities were carried out or licensed materials were stored and submit a written report of the results of that survey as set forth in 10 CFR 40.42(c)(1)(v), to the NRC Regional Administrator, Region I. The survey is to be performed by an independent qualified health physicist.

2. Prepare and submit to the NRC Regional Administrator, Region I, a plan and schedule for NRC approval for decommissioning the facility for unrestricted use, together with a detailed cost estimate for completing the plan according to the schedule for releasing the facility for unrestricted use. The plan shall meet "Guidelines for Decontamination of Facilities and Equipment Prior to Release for Unrestricted Use or Termination of License for Byproduct Source, or Special Nuclear Material" July 1982, and Options 1 or 2 of "Disposal or Onsite Storage of Thorium or Uranium Wastes from Past Operations", 46 FR 52061 (October 23, 1981).

3. Submit to the NRC Regional Administrator, Region I, a certification that financial assurance for completing the decommissioning activities described in the plan submitted pursuant to Paragraph 2 has been provided in the amount estimated pursuant to Paragraph 2. The certification shall use one of the methods described in 10 CFR 40.36(e). See Regulatory Guide 3.66 "Standard Format and Content of Financial Assurance Mechanisms for Decommissioning under 10 CFR Parts 30, 40, 70, and 72" (July 1990). A copy of the executed financial instrument obtained to meet this certification

requirement must also be sent to the NRC Regional Administrator, Region I.

The Regional Administrator, Region I, may, in writing, relax or rescind this order upon demonstration by the Licensee of good cause.

VI

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons as to why this Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of

Prussia, Pennsylvania 19406, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which that person's interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), 57 FR 20194 (May 12, 1992), the Licensee, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section V above shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR

A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

VII

In addition to issuance of this Order Modifying License No. STB-1526, the Commission requires further information from the Licensee in order to determine whether the Commission can have reasonable assurance that in the future the Licensee will conduct its activities in accordance with the Commission's requirements and will not willfully violate those requirements.

Accordingly, pursuant to Sections 161c, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 40.31(b), in order for the Commission to determine whether the License should be further modified, suspended, or revoked or other enforcement action taken, the Licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 within 30 days of the date of this Demand for Information, in writing and under oath or affirmation, a statement of why, in light of the willful violation of the requirements by the President and Radiation Safety Officer described above, (1) NRC should conclude that the Licensee and its employees will in the future comply with Commission requirements, (2) the Licensee should not be required to promptly

decommission the facility for unrestricted use, and (3) License No. STB-1526 should not be revoked.

Copies should also be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and to the NRC Regional Administrator, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

After reviewing your response, the NRC will determine whether decommissioning and revocation will be required or other enforcement action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 21st day of September, 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137

October 7, 1992

General Licensee
10 CFR 150.20
EA 92-102

American Testing and Inspection, Inc.
ATTN: Mr. Ronald Preston
President
1904 Cherry Hill Road
Joliet, Illinois 60433

Dear Mr. Preston:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$15,000
(NRC INSPECTION REPORT NO. 15000012/92001(DRSS))

This refers to the inspection, conducted on February 12 through March 27, 1992, of activities that were conducted in the States of Indiana and Michigan. The report documenting this inspection was sent to you by letter dated May 19, 1992. A transcribed Enforcement Conference was held on May 21, 1992, at the NRC Region III Office. The report summarizing the conference was sent to you by letter dated June 2, 1992.

As a result of the inspection the NRC has determined that a number of violations of NRC requirements occurred under the general license granted to American Testing & Inspection, Inc. (ATI). The violations which are described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) include: (1) failure to file Form NRC-241 on 174 days in 1991 when performing radiography in non-Agreement States in accordance with 10 CFR 150.20(b)(1); (2) performing radiography in non-Agreement States on more than 180 days within calendar year 1991 in violation of 10 CFR 150.20(b)(3); and (3) failure of your qualified independent organization to observe licensee radiographers or conduct an audit of the radiation safety program in violation of Section IV.C of the Order Modifying License dated November 30, 1989 (EA 88-290).

The failure to file Form NRC-241 is a repeat violation. During a previous inspection on January 5, 1989, the NRC identified that on 55 occasions from January 13 to December 20, 1988, ATI failed to notify the NRC prior to conducting licensed activities in non-Agreement States, in accordance with 10 CFR 150.20(b)(1). This was

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

October 7, 1992

discussed in the Order to Show Cause Why License Should Not Be Revoked and Order Suspending License dated February 27, 1989, (EA 88-290) which was issued for that violation and other willful violations, and which suspended your general license. That Order was superseded by the Order Modifying License issued November 30, 1989 and revised January 29, 1990 (EA 88-290), which allowed you to resume operations upon completion of certain conditions set forth in Sections IV and V of the Order. Section IV.B of the Order provided that, at least 7 days prior to engaging in licensed activities at locations under NRC jurisdiction, you would give notice to the NRC by filing 4 copies of NRC Form 241.

The NRC can only perform inspections of your activities in non-Agreement States when you comply with the requirement to file NRC Form 241. By not properly filing NRC Form 241, you essentially removed the NRC's ability to perform its function of verifying that you were performing activities under NRC jurisdiction in a safe manner. Furthermore, Section IV.C of the Order Modifying License issued on November 30, 1989, required that you engage the services of a qualified independent consultant or organization capable of auditing and evaluating your radiography program that would, at intervals not to exceed 3 months, observe all of your radiographers and conduct an audit of your radiation safety program for work performed in non-Agreement States to ensure compliance with NRC regulations. Failure of your qualified independent organization to observe radiographers and conduct audits of your radiation safety program is another example of your violation of the conditions for resumption of your licensed activities as set forth in the Order Modifying License dated November 30, 1989.

Since the violations resulted from your careless disregard of NRC requirements, the violations are considered to be particularly significant. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations have been categorized as a Severity Level III problem.

The NRC entrusts you with the responsibility for radiation safety at ATI. Incumbent upon you is the responsibility to protect the public health and safety, including the health and safety of your employees, by assuring that all NRC requirements are met and any potential violations are identified and promptly corrected. Further, you certified to NRC in your letter dated March 9, 1990, that you understood the requirements of the Order and would ensure that your employees met the requirements. To emphasize the need for your effective oversight of NRC-licensed activities, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$15,000 for the Severity Level III problem.

October 7, 1992

The base value of a civil penalty for a Severity Level III problem is \$5,000. The civil penalty adjustment factors in the Enforcement Policy were considered. Full 50 percent escalation of the base civil penalty was warranted for the identification factor in that the NRC identified all of the violations. Full 50 percent escalation was warranted for the corrective action factor in that your corrective actions presented at the Enforcement Conference were only minimally acceptable. You did not satisfactorily outline your plans for assuring that the violations would not recur. The only corrective actions you proposed were your intent to maintain better communication with your consultant and Radiation Safety Officer, and an improved attitude on your part. It was unclear how you would ensure that NRC requirements are fully complied with in the future. Full 100 percent escalation was warranted for your poor past performance based on the previous Orders that were issued to you (EA 88-290). The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 200 percent.

Section II of the enclosed Notice describes three violations involving: (1) failure to limit the whole body dose of an individual in a restricted area to one and one quarter rems per calendar quarter; (2) failure to make a report to the Commission of an exposure which exceeded the limits specified in 10 CFR 20.101(a); and (3) failure to properly mark an overpack used for transporting a radiography source. These violations were not assessed a civil penalty.

In addition to the enclosed Notice, you are reminded that the Order Modifying License issued to ATI on November 30, 1989, and revised on January 29, 1990, remains in effect until NRC rescinds the Order or ATI is no longer a business entity.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, you are requested to respond to the following: (1) state whether ATI will remain in business; (2) if not, please provide copies of the instruments terminating ATI as a corporation; (3) if ATI remains in business, please describe the activities ATI will undertake in the future and whether it will continue as a licensee of an Agreement State; and (4) if Mr. Preston intends to continue to be involved in licensed activities, please explain what licensed activities he will be involved with and under whose license.

October 7, 1992

After reviewing your response to this Notice, including your proposed corrective actions, and your response to the above questions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of
Civil Penalty

cc w/enclosures:
DCD/DCB (RIDS)
State of Michigan
State of Illinois
State of Indiana

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

American Testing and
Inspection, Inc.
Joliet, Illinois

General Licensee
10 CFR 150.20
EA 92-102

During an NRC inspection conducted on February 12 through March 27, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 150.20(b)(1) requires that, when engaging in activities in non-Agreement States under the general license granted by 10 CFR 150.20(a), the licensee file four copies of Form NRC-241 (revised) and four copies of the Agreement State specific license with the Regional Administrator of the NRC Regional Office for the region in which the Agreement State that issued the license is located at least three days prior to engaging in such activity.

Section IV.B of the Order Modifying License (revised), dated January 29, 1990, requires that, at least 7 days prior to engaging in licensed activities at locations that are under NRC jurisdiction, the licensee will give notice to the NRC by filing 4 copies of NRC Form 241. If the licensee receives less than 7 calendar days notice of opportunity to engage in licensed activities at locations that are under NRC jurisdiction, the licensee will document the date and time the customer approves commencement of work and notify the NRC by filing NRC Form-241 by facsimile as soon as possible after customer approval to begin work, but always before commencing work.

Contrary to the above, on 174 days during the period from January 28, 1991, through December 1, 1991, the licensee performed radiography in Indiana and Michigan (non-Agreement States) without filing the required forms.

- B. 10 CFR 150.20(b)(3) prohibits any person engaging in activities in non-Agreement States under the general license granted under 10 CFR 150.20(a) from possessing or using radioactive materials, or engaging in the activities authorized in 10 CFR 150.20, for more than 180 days in any calendar year.

Contrary to the above, the licensee performed radiography, an activity authorized by 10 CFR 150.20(a), in Indiana and Michigan (non-Agreement States) on 205 days during calendar year 1991.

- C. Item IV.C of the Order Modifying License, dated November 30, 1989, requires that the licensee's qualified independent organization, at intervals not to exceed 3 months, beginning with the date of resumption of activities in non-Agreement States, to observe all licensee radiographers and conduct an audit of the licensee's radiation safety program for work performed in non-Agreement States to ensure compliance with NRC regulatory requirements.

Contrary to the above, the licensee's qualified independent organization failed to observe any licensee radiographers or conduct an audit of the licensee's radiation safety program from the time the licensee resumed activities in non-Agreement States on June 22, 1990, through March 27, 1992.

This is a Severity Level III problem (Supplement VI).
Cumulative Civil Penalty - \$15,000 (assessed equally among the 3 violations).

II. Violations Not Assessed a Civil Penalty

- A. 10 CFR 20.101(a) requires that the licensee limit the whole body radiation dose of an individual in a restricted area to one and one quarter rems per calendar quarter, except as provided by 10 CFR 20.101(b). 10 CFR 20.101(b) allows a licensee to permit an individual in a restricted area to receive a whole body radiation dose of three rems per calendar quarter provided specified conditions are met.

Contrary to the above, the licensee did not limit the whole body radiation dose of an individual working in a restricted area to one and one quarter rems per calendar quarter and the conditions of 10 CFR 20.101(b) were not met. Specifically, the individual received a whole body dose of 1.80 rems during the second calendar quarter of 1991.

This is a Severity Level IV violation (Supplement IV).

- B. 10 CFR 20.405(a) requires, in part, that within 30 days, each licensee make a written report to the Commission concerning each exposure to radiation in excess of any applicable limit in Part 20 or in the NRC license.

Contrary to the above, as of February 12, 1992, the licensee had not made a report to the Commission of an exposure which exceeded the limits specified in 10 CFR 20.101(a) (1.250 rems) during the second calendar quarter of 1991.

This is a Severity Level IV violation (Supplement IV).

- C. 10 CFR 71.5(a) requires that licensees who transport licensed material outside the confines of their plants or deliver license material to a carrier for transport comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

49 173.25(a)(2) and (4) require the licensee to mark each overpack used for transportation of packages containing hazardous material with the proper shipping name and identification number, and label as required. Each overpack must be marked with a statement that the inner package complies with prescribed specifications, unless specification markings on the inside packages are visible.

Contrary to the above, on February 25, 1992, the NRC inspector observed that an overpack which had been used for transporting a 39 curie Iridium-192 source to a jobsite in Clinton, Indiana, was not marked with the proper shipping name and identification number (Radioactive Material, Special Form, NOS UN 2974), and the Radioactive Yellow II labels affixed to the overpack were not legible. Additionally, the overpack was not marked with a statement that the inner package complies with the prescribed specifications, and there were no visible specification markings on the inside packages.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, American Testing and Inspection, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to

why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

Notice of Violatin

- 5 -

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, IL 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 7 day of October 1992

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555-0001

FEB 23 1993

General Licensee
10 CFR 150.20
EA 92-102

American Testing and Inspection, Inc.
ATTN: Mr. Ronald Preston
President
1904 Cherry Hill Road
Joliet, Illinois 60433

Dear Mr. Preston:

SUBJECT: STATUS ON NOTICE OF VIOLATION AND PROPOSED
IMPOSITION OF CIVIL PENALTY - \$15,000

This refers to the telephone conversation on January 26, 1993, between you and Ms. Patricia A. Santiago, of my office, regarding your letter dated November 30, 1992 in reply to our Notice of Violation and Proposed Imposition of Civil Penalty-\$15,000 dated October 7, 1992. In your November 30, 1992 reply, you admitted the violations in the Notice, but requested that the proposed imposition of civil penalty be vacated due to the fact that you have gone into Chapter 7 bankruptcy and that American Testing & Inspection, Inc. ceased industrial radiography operations on September 6, 1992.

As Ms. Santiago explained, the civil penalty is still outstanding. However, under the circumstances of this case, we have decided to offer you two alternatives. First, you may choose to pay the civil penalty over time with interest. Alternatively, we will withdraw the proposed civil penalty if you agree to a Confirmatory Order (Order) whereby you will not be involved in licensed activities in NRC jurisdiction for a period of three years.

If you desire to avail yourself of the alternative of payment over time, in order that a schedule may be developed for payment and to support your position, you will need to submit documentation of your Chapter 7 bankruptcy petition. That documentation must be submitted within 30 days of the date of this letter to me at the address indicated in the following paragraph. I will then provide you with a note for payment over three years at an interest rate of 4 percent.

If you prefer the second alternative, you must sign the enclosed Order in duplicate, under oath or affirmation, and submit it within 30 days of the date of this letter to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. Following receipt, I will return a copy of the

signed Order to you. If you decide to enter into this Confirmatory Order, the NRC will not impose the civil penalty and the matter will be considered settled without payment of the previously proposed civil penalty. However, should you violate any of the terms of Section IV of the Order, then the civil penalty of \$15,000 would be due in full.

If I do not receive your acceptance of either of the above options, NRC will proceed to issue you an Order imposing the civil penalty of \$15,000. If you have any questions, please contact me at 301-504-2741.

Sincerely,

James Lieberman, Director
Office of Enforcement

Encl: Confirmatory Order

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	General License
American Testing & Inspection, Inc.	)	10 CFR 150.20
Joliet, Illinois 60433	)	EA 92-102

ISSUANCE OF CONFIRMATORY ORDER

The Nuclear Regulatory Commission is publishing the attached Confirmatory Order that restricts American Testing & Inspection, Inc. and Mr. Ronald Preston, the former President of American Testing & Inspection, Inc., from the performance of licensed activities. The purpose of this action is to provide public notice of a significant enforcement action.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 4th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	General License
American Testing & Inspection, Inc.	)	10 CFR 150.20
Joliet, Illinois 60433	)	EA 92-102

CONFIRMATORY ORDER

I

American Testing and Inspection, Inc. (ATI), was formerly holder of State of Illinois Byproduct Material License No. 01085-01 (License) issued on January 8, 1988. The License authorized the possession and use of sealed sources of iridium-192 in industrial radiographic exposure devices to perform licensed activities within the State of Illinois. Pursuant to 10 CFR 150.20 and its License, ATI was authorized to possess and use licensed byproduct materials to perform industrial radiography in non-Agreement States. ATI's License expired on August 31, 1992. The License was transferred to McNDT Leasing, Inc. and amended in its entirety in accordance with letters dated August 31, 1992 and September 3, 1992.

II

An inspection by the Nuclear Regulatory Commission (NRC) was conducted on February 12 through March 27, 1992, of ATI's activities that were conducted in the States of Indiana and Michigan (non-Agreement States). Six violations were identified, including (1) the failure to file NRC Form 241 on 174 days in 1991 when performing radiography in non-Agreement States in accordance with 10 CFR 150.20(b)(1); (2) performing

radiography in non-Agreement States on more than 180 days within calendar year 1991 in violation of 10 CFR 150.20(b)(3); and (3) the failure of ATI to have a qualified independent organization observe ATI's radiographers or conduct an audit of ATI's radiation safety program in violation of Section IV.C. of an Order Modifying License that was issued by the NRC to ATI on November 30, 1989.

The NRC issued Enforcement Action (EA) 92-102 against ATI consisting of a Notice of Violation and Proposed Imposition of Civil Penalty-\$15,000 (Notice) dated October 7, 1992. Mr. Ronald Preston, formerly President, ATI, responded on November 30, 1992, to the Notice admitting the violations, but requesting that the proposed civil penalty be vacated since ATI had gone into Chapter 7 bankruptcy and ceased industrial radiography operations. However, there is nothing in that Notice that precludes Mr. Preston from performing radiography under another licensee's Agreement State license and, pursuant to 10 CFR 150.20, from engaging in licensed activities in NRC jurisdiction.

III

The Notice proposed a civil penalty which is still outstanding. As the parties desire to resolve all matters pending between them, Mr. Preston agrees, for a period of three years from the date he signs this Confirmatory Order, that he, ATI, or a

successor entity wherein Mr. Preston is an authorized user, radiographer, radiographer's assistant, Radiation Safety Officer, an Assistant Radiation Safety Officer, an officer, or a controlling stockholder, shall not apply to the NRC for a new license, nor shall Mr. Preston, ATI, or a successor entity, as described above, engage in licensed activities within the jurisdiction of the NRC for that same period of time.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 186, and 234 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 2.205, and 10 CFR Parts 30, 34, and 150, IT IS HEREBY ORDERED, STIPULATED AND AGREED between the NRC and Mr. Preston as follows:

1. The NRC withdraws the civil penalty of \$15,000 as proposed in the Notice dated October 7, 1992 (EA 92-102);
2. For a period of three years from the date Mr. Preston signs this Confirmatory Order, Mr. Preston, ATI, or any successor entity, wherein Mr. Preston is an authorized user, radiographer, radiographer's assistant, Radiation Safety Officer, an Assistant Radiation Safety Officer, an officer, or a controlling stockholder, will not apply to the NRC for a new license, nor shall Mr. Preston, ATI, or a successor entity, as described above, engage in licensed activities within the jurisdiction of the NRC for that same period of time.

3. This Confirmatory Order constitutes settlement without payment of a civil penalty proposed in the Notice dated October 7, 1992 (EA 92-102). However, if Mr. Preston, ATI, or a successor entity violates paragraph 2 of this section, then the civil penalty of \$15,000 will be reinstated by an Order Imposing Civil Penalty and the civil penalty of \$15,000 will be due in full within 30 days of the date of that Order Imposing Civil Penalty.

4. Mr. Preston, ATI, or any successor entity waive the right to contest this Order in any manner, including requesting a hearing on this Order or the Order Imposing Civil Penalty, should one be issued as provided in paragraph 3 of this section.

FOR AMERICAN TESTING AND INSPECTION, INC.

Dated: 3-19-93

BY: Ronald W. Preston
Ronald Preston

Notary: Donna Baumgardner

FOR THE NUCLEAR REGULATORY COMMISSION

Dated: 3-24-93

BY: James Lebrun

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

May 24, 1993

Docket No. 030-03207
License No. 37-13919-01
EA No. 93-086

Mr. Mark S. McCandless, Vice President
Professional Services
Chestnut Hill Hospital
8835 Germantown Avenue
Philadelphia, Pennsylvania 19118

Dear Mr. McCandless:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$6,250
(NRC Inspection No. 030-03207/93-001)

This letter refers to the NRC inspection conducted on March 9, 10, 16, and 17, 1993, at the Chestnut Hill Hospital located in Philadelphia, Pennsylvania, of activities authorized by NRC License No. 37-13919-01. The inspection was continued in the Region I office until April 2, 1993, to review information subsequently received from your staff. The inspection report was sent to you on April 28, 1993. During the inspection, several violations of NRC requirements were identified. On May 5, 1993, an enforcement conference was conducted with you and other members of the management and staff at Chestnut Hill Hospital to discuss the apparent violations, their causes and your corrective actions. A copy of the enforcement conference report was sent to you on May 13, 1993.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) (Enclosure 1). The violations include, but are not limited to: (1) four examples of failure by the Radiation Safety Officer (RSO), to ensure that radiation safety activities are performed in accordance with approved procedures and regulatory requirements; (2) failure of the Radiation Safety Committee to review annually the radiation safety program, as required; (3) failure to provide certain required training to workers; (4) use of radioactive materials by individuals who were not authorized by the license; (5) failure either to perform, or perform adequately, certain required checks of the facility's dose calibrator; (6) failure to

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MAY 24 1993

Chestnut Hill Hospital

2

perform required surveys of areas where material was used, as well as survey of incoming packages of radioactive material; (7) failure to provide required personnel dosimetry to temporary technologists; and (8) failure to maintain certain required records of licensed activities.

The large number of the violations, as well as the diversity of those violations across most areas of the radiation safety program at the facility, collectively demonstrate that a significant breakdown in the control of licensed activities existed at your facility. Particularly disturbing was the apparent lack of knowledge of this condition by your RSO, who admitted during the inspection that he lacked involvement in the program, and relied on the consultant physicist to oversee the program. Furthermore, the Radiation Safety Committee (RSC) at your facility did not identify the violations, notwithstanding the number and nature of these violations and the fact that some of them were longstanding.

The NRC license issued to Chestnut Hill Hospital entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility of management in general, and the RSC and RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and expeditiously corrected. Given this lack of management attention towards licensed responsibilities, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem, and are set forth in the enclosed Notice.

In response to these violations, the NRC issued a Confirmatory Action Letter (No. 1-93-003) to you on March 22, 1993, which confirmed your commitment to (1) hire an independent consultant (who had not had previous involvement with the licensed activities at your facility) and submit the consultant's credentials and contractual arrangements to the NRC by March 26, 1993; (2) provide training to temporary and permanent personnel as required by 10 CFR Part 19.12; (3) complete an audit of the entire radiation safety program, including the quality management program, by April 23, 1993; and (4) submit the results of the audit and any corrective actions taken as the result of the audit to the NRC by April 30, 1993.

MAY 24 1993

The NRC also recognizes that actions were taken or planned to correct the violations and effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, included (1) the review of the entire program by your consultant; (2) plans for monthly audits of the program by your consultant for at least six months, and then quarterly thereafter; (3) training of the RSO regarding the applicable NRC regulations (10 CFR Parts 19, 20, 30, 35 and 71) and conditions of your license, with plans to complete all training by October 1, 1993; and (4) an increase in the RSO's involvement in the program via review of consultant audits and weekly surveys. These actions, although acceptable, were not considered prompt and comprehensive because the RSO apparently has not yet received significant additional training.

To emphasize (1) the importance of aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected, and (2) the need for ensuring that your corrective actions are long-lasting, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$6,250 for the violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation or problem is \$2,500. The base civil penalty amount has been increased by 50% because the violations were identified by the NRC, and by 100% because you had prior opportunity to identify the violations had appropriate management control been exercised. With respect to the prior opportunity to identify the violations, information was previously communicated to you regarding some of the individual violations, and also the importance of management control of the radiation safety programs. For example, the NRC has issued several Information Notices (INs), reports and bulletins relevant to these issues, such as "Effective Use of Radiation Safety Committees to Exercise Control Over Medical Use Programs," (IN 90-71, November 6, 1990, "Dose Calibrator Quality Control," (IN 93-10, February 2, 1993), and "Training and Supervising Individuals Supervised by an Authorized User," (IN 91-71, November 12, 1991). Accordingly, on balance, the civil penalty for this Severity Level III problem is escalated by 150% to \$6,250. The other escalation/mitigation factors were considered and no further adjustment is warranted.

In addition to the violations described in the enclosed notice, the NRC also identified other potential violations during review of your report, dated April 28, 1993, in response to the CAL. Those potential violations involve an iodine-131 therapy misadministration, the failure to report that misadministration to the NRC, and the failure to maintain accurate records of the misadministration. Your staff confirmed during a telephone conversation on May 6, 1993, between Dr. Woodruff and Mr. Thompson of our staff, that a misadministration occurred in this case. These apparent violations are still being reviewed and evaluated by the NRC and will be handled as a separate issue at a later date.

MAY 24 1993

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In this regard, please address how you plan to enhance management oversight to ensure compliance with the requirements. In your response, you may also reference, as appropriate, information previously provided to the NRC, including your presentation at the enforcement conference. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure Notice of Violation and Proposed Imposition
 of Civil Penalty

cc w/encl:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Commonwealth of Pennsylvania

ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Chestnut Hill Hospital
Philadelphia, Pennsylvania 19118

Docket No. 030-03207
License No. 37-13919-01
EA No. 93-086

During an NRC inspection conducted between March 9 and April 2, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer (RSO), ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's procedures are described in the licensee's Policy and Procedure Manual which was approved and signed by the RSO on August 28, 1992, and in the license application, dated April 28, 1986.
1. Page 905 of the licensee's Policy and Procedures Manual indicates that wipe tests for removable contamination are to be counted for one minute by placing the wipe into the collimator of the ADC Model 300 spectrometer.
 2. Item 10 of the licensee's application, dated April 28, 1986, indicates that the dose calibrator calibration procedures will be performed in accordance with Appendix D of Regulatory Guide 10.8, Revision 1, October 1980. Part G of Appendix D describes the annual accuracy test, and specifies, in Step 2, that an average of three measurements be taken for each reference standard.
 3. Item 11 of the licensee's application, dated April 28, 1986, describes the facilities and equipment, and states, in part, in Paragraph 10, that the radioisotope suite will be maintained at negative pressure to assure that the air entering the room is vented through the separate exhaust system, and this will be verified at least annually.

4. Item 17 of the licensee's application, dated April 28, 1986, indicates that the licensee will follow Appendix I of Regulatory Guide 10.8, Revision 1, October 1980, for area survey procedures. Paragraph I of Appendix I states that all elution, preparation, and injection areas will be surveyed daily with an appropriate low range survey meter and decontaminated if necessary.

Contrary to the above, the licensee through the RSO did not ensure that radiation safety activities were performed in accordance with the above approved procedures, as evidenced by the following examples:

1. on March 9, 16 and 17, 1993, each technologist performing wipe tests did not include counting the wipe in the collimator for one minute.
 2. accuracy tests performed on March 22, 1991 and March 25, 1992, involved only one measurement of each of the three reference standards.
 3. inflow measurements of the air supply to the Nuclear Medicine Laboratory (radioisotope suite) were not performed in 1991 and 1992.
 4. between March 1991 and March 1993, the licensee did not perform daily surveys in the hallway where patients had been routinely injected.
- B. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, from March 1991 to March 1993, the licensee did not survey the hallway for removable contamination, an area where radiopharmaceuticals were routinely administered.

- C. 10 CFR 35.13(b) requires that a licensee apply for and must receive a license amendment before it permits anyone, except a visiting authorized user described in 10 CFR 35.27, to work as an authorized user under the license.

Contrary to the above, from July 1989 to March 1993, the licensee permitted a physician to work as an authorized user under the license; however, that individual was not a visiting authorized user as described in 10 CFR 35.27, and as of those dates, the licensee had not received a license amendment specifically naming that physician as an authorized user.

- D. 10 CFR 35.14 requires that a licensee notify the NRC by letter within thirty days when an authorized user, Radiation Safety Officer, or Teletherapy Physicist permanently discontinues performance of duties under the license or has a name change, or when the licensee's mailing address changes.

Contrary to the above, in July 1989, the licensee's authorized user for iodine-131 therapy permanently discontinued performance of duties under the license and the licensee did not notify the NRC until March 1993, a period in excess of 30 days.

- E. 10 CFR 35.22(b)(6) requires that, to oversee the use of licensed material, the Radiation Safety Committee must review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Contrary to the above, from March 1991, until March 17, 1993, the licensee's Radiation Safety Committee did not review, with the assistance of the Radiation Safety Officer, the licensee's radiation safety program.

- F. Condition No. 17 of License No. 37-13919-01, Amendment No. 12 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in the licensee's application dated April 28, 1986.

The Application dated April 28, 1986, Item 12, "Personnel Training Program", paragraph 2, states that the licensee will provide refresher training to nuclear medicine technologists at least annually and will provide additional training whenever there is a significant change in duties, regulations or the terms of the license. The training would cover the terms of the license pertinent to radiation safety; areas where radioactive material may be used and stored; potential hazards associated with radioactive materials; radiation safety procedures appropriate for the radioisotope used; pertinent NRC regulations; in-house rules and regulations; obligations to report unsafe conditions to the Radiation Safety Officer; appropriate response to emergencies or unsafe conditions; the right to be informed of their radiation exposure and bioassay results; and the location where the licensee posts or makes available certain documents as required in 10 CFR Part 19.

Contrary to the above, as of March 17, 1993, annual refresher training in the subjects stated in the licensee's application dated April 28, 1986, had not been provided to the nuclear medicine technologists in 1991 and 1992.

- G. 10 CFR 35.50(b)(1) requires, in part, that a licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use and that the check be done on a frequently used setting.

Contrary to the above, on December 12, 1992, and February 28, 1993, the licensee did not check the dose calibrator for constancy, and the dose calibrator was used to measure patient doses of radiopharmaceuticals on those days.

- H. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, the licensee's dose calibrator linearity tests performed on September 21, 1992, and December 28, 1992, covered only the range between 100 millicuries and 300 microcuries, rather than a range from 100 millicuries to 10 microcuries.

- I. 10 CFR 35.50(e) and 35.50(e)(1) require, in part, that a licensee retain records of daily constancy checks of the dose calibrator for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check.

Contrary to the above, as of March 9, 1993, the licensee's records of daily constancy checks of its dose calibrator performed between March 1991 and March 1993, did not include the identity of the radionuclide contained in the check source.

- J. 10 CFR 35.50(e) and 35.50(e)(2) require, in part, that a licensee retain records of annual accuracy tests of the dose calibrator for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the signature of the Radiation Safety Officer.

Contrary to the above, as of March 9, 1993, the licensee's record of the annual accuracy test of its dose calibrator performed on March 22, 1991 and March 25, 1992, did not include the signature of the Radiation Safety Officer.

- K. 10 CFR 35.50(e) and 35.50(e)(3) require, in part, that a licensee retain records of quarterly dose calibrator linearity tests for three years unless directed otherwise, and that the records include the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the signature of the Radiation Safety Officer.

Contrary to the above, as of March 9, 1993, the licensee's records of the quarterly linearity tests of its dose calibrator performed on September 21, 1992 and December 28, 1992, did not include the signature of the Radiation Safety Officer.

- L. 10 CFR 35.51(a)(3) requires that a licensee conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration, and the date of calibration on any survey instrument used to show compliance with 10 CFR Part 35.

Contrary to the above, as of March 9, 1993, the licensee did not have the apparent exposure rate from a dedicated check source as determined at the time of calibration conspicuously noted on its Victoreen 470A ionization survey instrument and the licensee used this survey instrument to show compliance with 10 CFR Part 35.

- M. 10 CFR 35.53(c) requires that a licensee retain records of the measurement of radiopharmaceutical dosages for three years, and that the record contain the following:

- (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide;
- (2) Patient's name, and identification number if one has been assigned;
- (3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 10 microcuries;
- (4) Date and time of the measurement; and
- (5) Initials of the individual who made the record.

Contrary to the above, the licensee's records of the measurement of radiopharmaceutical dosages for March 5, 6, and 9, 1993, did not contain all of the required information, such as either the activity of the dosage at the time of measurement, the date and the time of the measurement, the patient's name, or the initials of the individual who made the record.

- N. 10 CFR 35.70(d) requires, in part, that a licensee establish radiation dose trigger levels for daily and weekly surveys of areas where radiopharmaceuticals are routinely prepared for use or administered and areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, as of March 9, 1993, the licensee did not establish radiation dose trigger levels for its daily and weekly surveys of any of the areas where radiopharmaceuticals were prepared, administered, stored, or held as waste.

- O. 10 CFR 35.70(g) requires, in part, that a licensee establish removable contamination trigger levels for weekly surveys of all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, as of March 9, 1993, the licensee did not establish removable contamination trigger levels for its weekly surveys of any of the areas where radiopharmaceuticals are prepared, administered, or stored.

- P. 10 CFR 35.205(c) requires, in part, that before receiving, using, or storing a radioactive gas, the licensee calculate the amount of time needed after a spill to reduce the concentration in the room to the occupational limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, from March 1991 to March 1993, the licensee used radioactive xenon-133 gas in the scanning room and the licensee did not calculate the amount of time needed after a spill to reduce the concentration therein to the occupational limit listed in 10 CFR Part 20, Appendix B.

- Q. 10 CFR 35.205(d) requires, in part, that a licensee post the safety measures to be instituted in case of a spill of a radioactive gas at the area of use and the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 20, Appendix B.

Contrary to the above, from March 1991 to March 1993, the licensee used radioactive xenon-133 gas in the scanning room and the licensee did not post the calculated time needed after a spill to reduce the concentration to the occupational limit listed in 10 CFR Part 20, Appendix B.

- R. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

Contrary to the above, from March 1991 to March 1993, the licensee used a reusable collection system for radioactive xenon-133 gas and did not check the operation of the collection system.

- S. 10 CFR 20.205(d) requires that each licensee establish and maintain procedures for safely opening packages in which licensed material is received, and assure that such procedures are followed, and due consideration be given to special instructions for the type of package being opened.

The Licensee's application, dated November 27, 1991, states in Item 10.7 that the licensee will establish and implement the model procedure for opening packages (containing radioactive materials) that was published in Appendix L to the Regulatory Guide 10.8, Revision 2.

Item 2(c) of the model procedure described in Appendix L of Regulatory Guide 10.8, Revision 2, requires that each package be surveyed prior to opening the package.

Contrary to the above:

- a. On March 6, 1993, the licensee failed to survey an incoming package containing radioactive materials prior to opening the package.
 - b. On March 10, 1993, the licensee failed to follow the survey opening procedure for each of the two packages containing radioactive materials that the licensee received on March 10, 1993. Specifically, both the packages were wipe tested for contamination with one wipe test and the radiation levels at one meter and at the surface were measured by placing both the packages together.
- T. Condition No. 17 of License No. 37-13919-01, Amendment No. 12 requires that licensed material be possessed and used in accordance with the statements, representations and procedures contained in the licensee's application dated April 28, 1986.

Item 24 of the licensee's application dated April 28, 1986, requires that the licensee will provide personnel monitoring devices to its workers.

Contrary to the above, the licensee failed to provide personnel dosimetry (whole body and ring badges) to the temporary technologists from March 12 to March 17, 1993.

- U. 10 CFR 35.22(a)(5) requires in part, that the Radiation Safety Committee (RSC) promptly provide each member with a copy of the meeting minutes.

Contrary to the above, as of March 23, 1993, meeting minutes were not available for the December 23, 1992, committee meeting, an interval of three months.

These violations collectively represent a Severity Level III problem (Supplements IV and VI).

Civil Penalty - \$6,250

Pursuant to the provisions of 10 CFR 2.201, Chestnut Hill Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pa 19406.

Dated at King of Prussia, Pa
this 24th day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

MAR 2 9 1993

Docket No. 030-14577
License No. 34-00466-03
EA 92-110

Cleveland Clinic Foundation
ATTN: Floyd Loop, M.D.
Chief Executive Officer
9500 Euclid Avenue
Cleveland, Ohio 44195-5199

Dear Dr. Loop:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$1,250, AND DEMAND FOR INFORMATION
(INSPECTION REPORT 030-14577/90001)
(INVESTIGATION REPORT 3-90-011)

This refers to the special safety inspection conducted from March 7 to April 5, 1990, and a subsequent investigation by the NRC Office of Investigations concerning the repair of a teletherapy unit by an individual who was not authorized to perform such repairs. The report documenting the inspection was mailed to you by letter, dated April 27, 1990, and a copy of the investigation report was furnished to you prior to the enforcement conference. A significant violation of NRC requirements was identified during the inspection and investigation, and on November 30, 1992, an enforcement conference was held in the Region III office. Attending the enforcement conference were Mr. Thomas Keys, Director of the Office of Quality Management, Cleveland Clinic Foundation; Dr. Carl J. Paperiello, Deputy Regional Administrator, NRC Region III; and other members of our respective staffs. A copy of the enforcement conference report was mailed to you on December 24, 1992.

The inspection and subsequent investigation determined that a medical physicist/nuclear engineer, employed by the Cleveland Clinic Foundation, rewired the control console of the teletherapy unit during October - November 1989. Prior to commencing the repairs, he was aware of the NRC requirement that such repairs must be performed by an individual specifically authorized by the NRC or an Agreement State. The medical physicist's/nuclear engineer's supervisor, the chief medical physicist, was also aware of the NRC requirement and he knew that the medical physicist/nuclear engineer would be making the repairs. The medical physicist/nuclear engineer was not authorized by the NRC

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

or an Agreement State to make such repairs, and the medical physicist/nuclear engineer and chief medical physicist knew this.

The violation, described in the enclosed Notice of Violation, concerns the repair of the control console (a mechanism that exposes the source in a teletherapy unit) by an individual who was not authorized to do so by the NRC or an Agreement State. Based on the medical physicist's/nuclear engineer's education, training and experience, he would have been qualified to make the repair, although he was never authorized to perform such activities. Therefore, the violation is considered to be of less safety significance than if the individual were not qualified, and, absent willfulness, would have been categorized at Severity Level IV in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C (1989). The violation is categorized at Severity Level III because both the medical physicist/nuclear engineer and the chief medical physicist were aware, prior to starting the repair, that only a person authorized by the NRC or an Agreement State could make the repair. The deliberate actions of the medical physicist/nuclear engineer caused a willful violation of NRC regulations and the actions of the chief medical physicist contributed to a willful violation of NRC requirements and are of significant regulatory concern.

The root causes of the violation and the subsequent corrective action were discussed during the November 30, 1992, enforcement conference. The major factors contributing to the violations appeared to be: (1) ineffective communications between the Radiation Therapy and Radiation Safety Departments; (2) an error in judgement on the part of the chief medical physicist; and (3) the inability to locate an authorized repairman. The NRC recognizes that your RSO identified this violation. In addition, you took immediate corrective action to prevent the teletherapy unit from being used following the unauthorized repairs by removal of fuses which renders the unit inoperable and that the unit was not subsequently used. We acknowledge that License No. 34-00466-03 was terminated on February 19, 1991, and that you recently hired a new Radiation Safety Officer. However, while you counseled the individuals, you did not take any formal measures to address the willful nature of the violation, such as a letter of reprimand to an individual not complying with NRC requirements or license conditions.

Nevertheless, when the NRC issues a license, it is expected and required that the licensee, as well as its employees and contractors, follow the NRC regulations and the specific

conditions of the NRC license. In this case, at least two employees of the Cleveland Clinic Foundation, one of whom was a supervisor, contributed to the willful violation of NRC requirements by permitting or performing maintenance and repair of the teletherapy unit by an unauthorized individual. A willful violation of regulations and license requirements is of significant regulatory concern to the NRC. A licensee cannot choose which requirements to follow. Therefore, to emphasize that willful violations of NRC requirements cannot be tolerated, I have been authorized, after consultation with the Commission, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1,250 for the Severity Level III violation. The base penalty for a Severity Level III violation by a medical institution is \$2,500. The penalty was mitigated 50 percent based on licensee identification of the violation.

While, as noted above, License No. 34-00466-03 has been terminated, the medical physicist/nuclear engineer and the chief medical physicist remain in your employ involved with licensed activities. Two other NRC licenses (No. 34-00466-01 and No. SNM-1972) are held by the Cleveland Clinic Foundation. Therefore, in order to determine whether your licenses should be modified or other further enforcement action taken, you are hereby required, pursuant to sections 161c, 161o, 182, and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204 and 10 CFR 30.32(b), to provide the following information within 30 days of the date of this letter, in writing and under oath or affirmation:

- (1) a written description of the duties and activities currently performed by the chief medical physicist and the medical physicist/nuclear engineer;
- (2) the basis for your concluding that the chief medical physicist and the medical physicist/nuclear engineer fully understand their responsibilities under the NRC license and their obligation to fulfill NRC regulations and license requirements; and
- (3) a statement describing the procedures that you have established to ensure that employees comply with Commission regulations and the conditions of your NRC licenses.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, your written assurance that certain employees understand their obligations and responsibilities, and the results of future inspections, the NRC

will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your responses will be placed in the NRC Public Document Room.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Cleveland Clinic Foundation
Cleveland, Ohio

Docket No. 030-14577
License No. 34-00466-03
EA 92-110

During an NRC inspection conducted from March 7 to April 5, 1990, and a subsequent investigation, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1989), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.209. The particular violation and associated civil penalty are set forth below:

10 CFR 15.605 and Condition 21 of NRC Byproduct Material License 34-00466-03 require, in part, that only a person specifically licensed by the Commission or an Agreement State shall perform teletherapy unit maintenance and repair of the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source.

Contrary to the above, during October and November 1989, the licensee permitted an employee to repair the control console, a mechanism of a teletherapy unit that could expose the source, and the employee was not specifically licensed by the Commission or an Agreement State to perform such teletherapy unit maintenance and repair.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$1,250.

Pursuant to the provisions of 10 CFR 2.201, Cleveland Clinic Foundation (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this

response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1989), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional

Administrator, U.S. Nuclear Regulatory Commission, Region III,
799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A handwritten signature in cursive script, appearing to read "A Bert Davis".

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 29 day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 10, 1993

Docket No. 030-14950
License No. 29-18376-01
EA 92-230

Rhoda H. Cobin, M.D.
44 Godwin Avenue
Midland Park, New Jersey 07432

Dear Dr. Cobin:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTIES - \$3,800
(NRC Inspection Report No. 92-001 and OI Investigation Report 1-92-009)

This letter refers to the NRC inspection conducted on February 7, 1992, as well as a subsequent investigation by the NRC Office of Investigations (OI), at your facility in Midland Park, New Jersey, of activities authorized by NRC License No. 29-18376-01. The inspection report, as well as the synopsis of the OI investigation, were sent to you on December 11, 1992. During the inspection, apparent violations of NRC requirements were identified. In response to these violations, the NRC issued a Confirmatory Action Letter to you on February 12, 1992, which confirmed commitments made by you to the NRC to terminate patient treatments at the facility and correct the identified deficiencies. On December 17, 1992, an enforcement conference was conducted with you to discuss the apparent violations, their causes and your corrective actions. The enforcement conference report was sent to you on January 20, 1993.

The violations that are being cited are described in the enclosed Notice. Three of the violations are of particular concern to the NRC because of their willful nature. Those violations involve: (1) the failure to have, on certain occasions, the necessary and required survey instruments at the facility prior to the use of byproduct material; (2) the failure to repair or replace the dose calibrator when the results of daily constancy tests showed, on a number of occasions, that the constancy error exceeded 10 percent; and (3) the use of therapy level doses of iodine-131 in patients on a number of occasions when the dose calibrator reading indicated that the patient dose differed from the prescribed dose by more than 10 percent.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Although you indicated, at the enforcement conference, that you did not willfully violate any of the requirements, the NRC nonetheless maintains that the three violations were willful because you clearly knew the requirement in each case, but chose to disregard it. With respect to Violation I, you admitted to the NRC investigators, in a signed and sworn statement dated June 16, 1992, that there have been occasions when you administered iodine-131 treatments to patients without the second survey instrument being physically present in the office as needed, and you also stated that you knew that you were supposed to have both instruments on the premises and did not do so at all times. With respect to Violation II.A, you admitted to the NRC investigator, during a telephone interview in July 1992, that you were aware of the requirement to repair or replace the dose calibrator when the accuracy or constancy error exceeds 10%; however, you continued to use this instrument to assay patient doses even though the results of your accuracy and constancy tests indicated that the instrument should be repaired or replaced. With respect to Violation II.B, you stated during the transcribed enforcement conference that you were aware of the requirement to assay each patient dose in the dose calibrator and to not use the dose if it varies from the prescribed dose by more than 10 percent. It appears from your statements at the conference that you disregarded the requirement on the assumption that (1) the dose calibration performed by your supplier was correct, (2) the health status of your patients necessitated timely treatment, and (3) you did not believe that the difference between the prescribed activity and the activity indicated by the dose calibrator reading was biologically significant.

Although you indicated that the latter violation occurred in part because the health status of your patients necessitated timely treatment, Violation II.B covers at least eight patient doses administered between May 5, 1988, and March 12, 1991; and during that time, you did not seek assistance or relief by notifying NRC that the violation was occurring, you did not have the machine repaired or replaced, and you did not make backup arrangements to assure that you could perform an independent calibration of the patient dose elsewhere, or treat the patient elsewhere, at a facility equipped with properly functioning instrumentation.

You also maintained during the enforcement conference that you believed that the dose calibrator was malfunctioning and therefore felt justified in administering the patient doses even though the dose calibrator reading indicated that the activity of the doses exceeded the prescribed activity by more than 10 percent. As you were aware, your NRC license requires that you assay each patient dose in the dose calibrator. Even setting aside the question of the true activity of the patient doses, you clearly did not fulfill the requirement if you assayed the doses in a dose calibrator that you believed to be malfunctioning and then disregarded the dose calibrator reading and administered the doses. This violation is even more disturbing given the fact that the importance of proper measurement of doses in the dose calibrator prior to administration was emphasized to you during an inspection in 1988, and in a prior inspection and telephone enforcement conference in 1983.

A license to use radioactive material is a privilege that confers upon the licensee the special trust and confidence of the public. When the NRC issues a license, it is expected and required that the licensee, as well as its officials and employees, will strictly adhere to the requirements and conditions of the license and will not engage in any willful violation of those requirements. Given the willful nature of Violation I, it has been classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C (1992). Given the isotope involved and the therapeutic activity range of the patient doses, in addition to the willful nature of the violations, Violations II.A and B are classified in the aggregate at Severity Level II.

The NRC recognizes that corrective actions, as described at the enforcement conference, have been taken or planned to correct the violations and preclude recurrence. These actions, which were described in the Confirmatory Action Letter and at the enforcement conference, included: (1) termination of all patient treatments with NRC regulated material since February 1992 until the NRC approves resumption of patient treatment; (2) leasing a new dose calibrator and survey instruments; and (3) ensuring that a substitute survey instrument in the required range is available at your facility if your instrument is sent out for calibration. Notwithstanding the corrective actions that have been taken or planned and the fact that you have not performed licensed activities since the Confirmatory Action Letter was issued in February 1992, in order to emphasize: (1) the importance of strict adherence to the terms and conditions of your license, to ensure that such activities are conducted safely and in accordance with those requirements; and (2) the seriousness with which the NRC views willful violations, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties in the cumulative amount of \$3,800 for the violations set forth in the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is \$500. The base civil penalty amount for a Severity Level II violation is \$800. The escalation and mitigation factors set forth in the enforcement policy were considered and the NRC has decided that the civil penalty for Violation I should be increased by 100% to \$1,000, and the civil penalty for Violations II.A and B should be increased by 250% to \$2,800.

With respect to Violation I: (1) the violation was identified by the NRC, and therefore, 50% escalation of the base civil penalty amount on this factor is warranted; (2) your corrective actions, as described herein, were considered prompt and comprehensive, and therefore, 50% mitigation on this factor is warranted; and (3) the violations occurred on more than one occasion, and therefore, 100% escalation on the multiple example factor is warranted. The other escalation and mitigation factors were considered and no further adjustment on these factors is warranted.

With respect to Violations II.A and B: (1) the violations were identified by the NRC, and therefore, 50% escalation of the base civil penalty amount on this factor is warranted; (2) in the case of Violation II.A you had prior notice, via the NRC letter dated April 2, 1988, that iodine-131 was not to be administered to patients in the absence of a properly functioning dose calibrator, and in the case of Violation II.B your past performance included a violation in 1983 involving the failure to assay doses in the dose calibrator prior to treatment, and therefore, 100% escalation based on the combination of these two factors is warranted; and (3) the violations occurred on more than one occasion, and therefore, 100% escalation on the multiple example factor is warranted.

Your corrective actions for Violations II.A and B appear to adequately address the problem with the dose calibrator. In addition, you have agreed to have compliance audits performed by an outside consultant at quarterly intervals. However, during the enforcement conference, you maintained that you were justified in ignoring the underlying regulatory requirements because, among other reasons, the health status of your patients required timely treatment. The NRC requires that you maintain your program in compliance with NRC regulations. You are not at will to pick and choose which regulatory requirements you will follow. Your corrective action did not address how you will resolve conflicts between the need for timely patient care and the need for compliance with NRC regulations. Therefore, mitigation based on the corrective action factor is not considered appropriate. The other escalation and mitigation factors were considered, and no further adjustment on these factors is warranted with respect to Violations II.A and B.

Finally, the NRC recognizes that you did maintain for NRC inspection accurate records of the results of the dose calibrator accuracy and constancy tests, and the activities of the patient doses as indicated by the dose calibrator. Further, following the February 1992 inspection, you voluntarily agreed to suspend licensed activities until the program weaknesses and apparent violations identified during the inspection were corrected, and to seek approval from the NRC Region I Office before resuming licensed activities. But for these facts, given the regulatory significance that NRC ascribes to willful violations, the NRC staff would have considered more serious enforcement action.

The other violations identified during the inspection and investigation involve: (1) the failure to perform all required constancy, linearity, and geometry tests, and the failure to conduct accuracy tests of the dose calibrator in the manner required by regulations; (2) the failure to maintain records of tests of the dose calibrator for constancy; and (3) the failure to survey the area where patients are administered doses for removable contamination. These violations are classified at Severity Level IV and V and are described in the enclosed Notice.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. With respect to Violations II.A and B, you should specifically address corrective action to eliminate, wherever possible, the possibility of conflict between NRC regulatory requirements and potential patient needs. Such action could, for example, include arrangements for the use of backup equipment or privileges at a backup facility in the event of instrumentation failures. Your corrective action should also include plans to contact NRC and seek emergency relief from a regulatory requirement (to the extent that it is feasible to do so) in the event that an unforeseen patient emergency requires that you act in violation of an NRC regulatory requirement, and, if this is not feasible, to notify NRC as soon as possible thereafter. After reviewing your response to this letter and Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosure: Notice of Violation and Proposed Imposition
of Civil Penalties

ENCLOSURE

**NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES**

Rhoda H. Cobin, M.D.
Midland Park, New Jersey

Docket No. 030-14950
License No. 29-18376-01
EA 92-230

During an NRC inspection conducted on February 7, 1992, and a subsequent investigation by the NRC Office of Investigations, violations of NRC regulatory requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (1992), the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

VIOLATIONS ASSESSED CIVIL PENALTIES

- I. 10 CFR 35.320 requires that a licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, on a number of days between 1987 and February 1992, the licensee administered iodine-131 to patients and did not have on hand, on the date of the use of the licensed material, a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$1,000

- II. A. 10 CFR 35.50(d) requires, in part, that a licensee repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

Contrary to the above:

1. On a number of days between February 12, 1990 and February 7, 1992, the results of the licensee's dose calibrator constancy tests indicated that the constancy error exceeded 10 percent; however, the licensee did not repair or replace the dose calibrator and continued to use it to assay patient doses of iodine-131. For example, the licensee's constancy check result differed from the calculated value by 137 percent on February 12, 1990; 14 percent on June 2, 1990; 27 percent on August 3, 1990; and 49 percent on February 8, 1991.
2. On September 20, 1989, the result of an accuracy test performed on the licensee's dose calibrator differed from the calculated value by 10.7 percent; however, the licensee did not repair or replace the dose calibrator and continued to use it to assay patient doses of iodine-131.

- II. B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's Procedures for Safe Use of Radiopharmaceuticals are described in Item 10.4 of the license application dated July 3, 1989, and were approved by License Condition No. 13, Amendment No. 4, dated September 13, 1990.

Item 10.4 of the license application dated July 3, 1989 states that the licensee will follow the model procedures listed in Appendix I of NRC Regulatory Guide 10.8, Rev. 2, August 1987.

Model Rule 14 of Appendix I requires that each patient dose be assayed in the dose calibrator before it is administered and that the dose not be used if it is more than 10 percent off from the prescribed dose.

Contrary to the above, on numerous occasions between May 6, 1988 and February 7, 1992, the licensee administered doses of iodine-131 to patients even though the dose as determined by the reading on the licensee's dose calibrator exceeded the prescribed dose by more than 10 percent. For example, the following doses of iodine-131 were administered to patients:

<u>Date</u>	<u>Prescribed Dose</u>	<u>Dose Calibrator Reading</u>
05/06/88	30 millicuries	40.92 - 42.80 millicuries
08/17/88	20 millicuries	27.96 - 28.11 millicuries
09/29/88	20 millicuries	23.96 - 27.71 millicuries
01/13/89	20 millicuries	26.04 - 26.52 millicuries
08/03/90	05 millicuries	06.12 - 06.23 millicuries
02/08/91	10 millicuries	11.17 - 11.35 millicuries
03/12/91	30 millicuries	34.25 - 41.63 millicuries

Violations II.A and B constitute a Severity Level II problem (Supplement VI).
Civil Penalty - \$2,800

III. VIOLATIONS NOT ASSESSED A CIVIL PENALTY

- A. 10 CFR 35.50(b)(2) requires, in part, that the licensee test each dose calibrator for accuracy by assaying at least two sealed sources containing different radionuclides.

10 CFR 35.50(b)(3) requires, in part, that the licensee test each dose calibrator for linearity upon installation and at least quarterly thereafter.

Contrary to the above, as of February 7, 1992, the licensee had not checked the dose calibrator for linearity and the annual accuracy tests were performed with only one sealed source (Ba-133).

This is a Severity Level IV violation (Supplement VI).

- B. CFR 35.50(b)(1) requires, in part, that a licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. 10 CFR 35.50(e) requires, in part, that a licensee retain records of constancy checks of the dose calibrator for three years unless directed otherwise.

Contrary to the above, on March 15, 1989, April 19, 1989, August 23, 1989, January 10, 1990, July 27, 1990, and August 3, 1990, the dose calibrator was used to measure patient doses of radiopharmaceutical, and as of February 1992, the licensee did not retain a record of the daily constancy checks of its dose calibrator performed on those dates, and the licensee was not directed to have some other retention period.

This is a Severity Level V violation (Supplement VI).

- C. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered or stored.

Contrary to the above, as of February 7, 1992, the licensee had not surveyed for removable contamination certain areas where radiopharmaceuticals are routinely prepared for use, administered or stored, namely, the hot lab, where radiopharmaceuticals are prepared for use and stored, as well as the scanning room, where radiopharmaceuticals are administered to the patient.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Rhoda H. Cobin, M.D. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed above, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282(c).

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 10th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON D C 20545-0001

JUN 04 1993

Docket No. 030-14950
License No. 29-18376-01
EA 92-230

Rhoda H. Cobin, M.D.
44 Godwin Avenue
Midland Park, New Jersey 07432

Dear Dr. Cobin:

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTIES - \$3,800
(Inspection Report 92-001 and OI Investigation
Report 1-92-009)

This letter refers to your two letters, dated March 11 and 16, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalties (Notice) sent to you by our letter dated March 10, 1993. Our letter and Notice described six violations of NRC requirements, three of which the NRC found to be willful. To emphasize (1) the importance of strict adherence to the terms and conditions of your license, to ensure that such activities are conducted safely and in accordance with those requirements; and (2) the seriousness with which the NRC views willful violations, a Notice of Violation and Proposed Imposition of Civil Penalties in the cumulative amount of \$3,800 was proposed for the three willful violations.

In your responses, you did not deny the violations. However, you requested mitigation of the civil penalties, for the reasons set forth in your responses, as summarized in the Appendix attached to the enclosed Order. After consideration of your responses, we have concluded, for the reasons given in the Appendix to the enclosed Order Imposing Civil Monetary Penalties, that an adequate basis was not provided for mitigation of the penalties. Accordingly, we hereby serve the enclosed Order on you imposing civil monetary penalties in the amount of \$3,800.

In your March 11, 1993 response, you raised a question regarding the acceptability of proposed alternative procedures as "back-up arrangements" in the event that the dose calibrator fails. To the extent that any alternative procedure does not meet an NRC regulatory requirement, you should contact NRC Region I to request an exemption from the requirement via the license amendment process.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Rhoda H. Cobin, M.D.

- 2 -

We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

James Lieberman, Director
Office of Enforcement

Enclosures:
As Stated

cc w/encs:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
State of New Jersey

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-14950
Rhoda H. Cobin, M.D	)	License No. 29-18376-01
44 Goodwin Avenue	)	EA 92-230
Midland Park, New Jersey 07432	)	

ORDER IMPOSING CIVIL MONETARY PENALTIES

I

Rhoda H. Cobin, M.D. (Licensee) is the holder of License No. 29-18376-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on March 26, 1979. The license authorizes the Licensee to use iodine-131 as sodium iodide for thyroid uptake and imaging studies, treatment of hyperthyroidism, cardiac dysfunction, and thyroid carcinoma in accordance with the conditions specified therein.

II

An inspection of the Licensee's activities was conducted on February 7, 1992. In addition, an investigation was conducted by the NRC Office of Investigations (OI). The results of the inspection and investigation indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was served upon the Licensee by letter dated March 10, 1993. The Notice states the nature of the violations, the provisions of the NRC's

requirements that the Licensee had violated, and the amount of the civil penalties proposed for the violations.

The Licensee responded to the Notice on March 11, 1993 and March 16, 1993. In its responses, the Licensee did not deny any of the violations, but requested mitigation of the civil penalties.

III

After consideration of the Licensee's responses and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated and that the penalties proposed for the violations designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay civil penalties in the amount of \$3,800 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the

- 3 -

Treasurer of the United States and mailed to the Director,
Office of Enforcement, U.S. Nuclear Regulatory Commission,
ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issues to be considered at such hearing shall be:

- (a) whether the Licensee was in violation of the Commission's requirements as set forth in the Notice referenced in Section II above, and
- (b) whether, on the basis of such violations, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

James Lieberman, Director
Office of Enforcement

Dated at Rockville, Maryland
this 4th day of June 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On March 10, 1993, a Notice of Violation and Proposed Imposition of Civil Penalties (Notice) was issued for three violations identified during an NRC inspection on February 7, 1992, and a subsequent investigation conducted by the NRC Office of Investigations (OI). The licensee responded to the Notice on March 11 and 16, 1993. In its response, the licensee did not deny the violations, but requested mitigation of the civil penalties. The NRC's evaluations and conclusions regarding the licensee's requests are as follows:

1. Restatement of Violations Assessed Civil Penalties

- I. 10 CFR 35.320 requires that a licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

Contrary to the above, on a number of days between 1987 and February 1992, the licensee administered iodine-131 to patients and did not have on hand, on the date of the use of the licensed material, a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

This is a Severity Level III violation (Supplement VI).

Civil Penalty - \$1,000

- II.A. 10 CFR 35.50(d) requires, in part, that a licensee repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

Contrary to the above:

1. On a number of days between February 12, 1990 and February 7, 1992, the results of the licensee's dose calibrator constancy tests indicated that the constancy error exceeded 10 percent; however, the licensee did not repair or replace the dose calibrator and continued to use it to assay patient doses of iodine-131. For example, the licensee's constancy check result differed from the calculated value by 137 percent on February 12, 1990; 14 percent on June 2, 1990; 27

percent on August 3, 1990; and 49 percent on February 8, 1991.

2. On September 20, 1989, the result of an accuracy test performed on the licensee's dose calibrator differed from the calculated value by 10.7 percent; however, the licensee did not repair or replace the dose calibrator and continued to use it to assay patient doses of iodine-131.

II.B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's Procedures for Safe Use of Radio-pharmaceuticals are described in Item 10.4 of the license application dated July 3, 1989, and were approved by License Condition No. 13, Amendment No. 4, dated September 13, 1990.

Item 10.4 of the license application dated July 3, 1989, states that the licensee will follow the model procedures listed in Appendix I of NRC Regulatory Guide 10.8, Rev. 2, August 1987.

Model Rule 14 of Appendix I requires that each patient dose be assayed in the dose calibrator before it is administered and that the dose not be used if it is more than 10 percent off from the prescribed dose.

Contrary to the above, on numerous occasions between May 6, 1988 and February 7, 1992, the licensee administered doses of iodine-131 to patients even though the dose as determined by the reading on the licensee's dose calibrator exceeded the prescribed dose by more than 10 percent. For example, the following doses of iodine-131 were administered to patients:

<u>Date</u>	<u>Prescribed Dose</u>	<u>Dose Calibrator Reading</u>
05/06/88	30 millicuries	40.92 - 42.80 millicuries
08/17/88	20 millicuries	27.96 - 28.11 millicuries
09/29/88	20 millicuries	23.96 - 27.71 millicuries
01/13/89	20 millicuries	26.04 - 26.52 millicuries
08/03/90	05 millicuries	06.12 - 06.23 millicuries
02/08/91	10 millicuries	11.17 - 11.35 millicuries
03/12/91	30 millicuries	34.25 - 41.63 millicuries

Violations II.A and B constitute a Severity Level II problem (Supplement VI).

Civil Penalty - \$2,800

2. SUMMARY OF Licensee Responses

In the written responses, the licensee does not deny any of the three violations. However, the licensee protests characterization of the violations as willful, noting reliance upon the judgement of a consultant physicist.

With respect to Violation I, the licensee concedes that the instrument was not in the office on all occasions; however, the licensee protests the characterization of this violation as being willful and its impact on the assigned penalties.

With respect to Violation II.A, the licensee maintains that the fact that she did keep records and did not try in any way to deny or avoid the fact that the dose calibrator reading was off by more than 10%, should make it quite clear to anyone investigating this matter that it was not the licensee's intent to willfully disregard the regulations or hide any information. The licensee further states that review of the log book reveals that although there was more than one dose administered when the dose calibrator did not seem to be working properly, there were many doses administered in between when the dose calibrator was working very well. The licensee claims that it was because of the intermittent nature of this problem that she was assured by her consultant physicist that the equipment did not need to be sent out for repair.

With respect to Violation II.B, the licensee states again that through the advice of her physicist, she believed that the machine did not need repair. The licensee also states that she intends to fully comply with the regulations and if there is a variance of more than 10% in the future, she will immediately notify the NRC at the moment when the reading is taken and ask for further guidance on whether or not the material can be administered to the patient. The licensee explains that at the time when doses were administered where the variation was more than 10%, she did not intend to willfully violate any regulations, but simply felt that she was administering an appropriate dose to a patient and gave that dose. The licensee contends that since the dose was not off by an order of magnitude, it was safe and a medically indicated dose to be given to her patient.

The licensee also contests the NRC taking into account her previous problems in assessing the severity of the penalties, and believes she should not be labelled as a repeat offender, noting that no violation was identified in 1988 and that the problems in the past were not directly related to this problem.

The licensee also requests mitigation of the penalties on the basis that the "multiple examples" factor should not have been used to escalate the penalties because the

problems were intermittent, and with regard to the "corrective action" factor, she has been honest and cooperative with the NRC and she believes that she is penalized unfairly for pointing out inconsistencies between regulations and the need for prompt, carefully timed, medical treatment. Furthermore, the licensee notes that she has agreed to corrective actions.

The licensee also states that the penalties represent an economic hardship for her and her family, and requests that they be reduced and that any remaining fine be divided into installments for payment over the next one to two years.

1. **NRC Evaluation of Licensee's Responses**

The three violations are appropriately characterized as willful because, in each case, the licensee knew the specific requirement but did not adhere to it. While the licensee indicates that she relied on the judgement of the consulting physicist, it is the licensee who is responsible for fulfilling all NRC requirements associated with licensed activities.

With respect to Violation I, the licensee admitted to the NRC investigators, in a signed and sworn statement dated June 16, 1992, that there have been occasions when she administered iodine-131 treatments to patients without the second survey instrument being physically present in the office as needed, and the licensee also stated that she knew that she was supposed to have both instruments on the premises and did not do so at all times.

With respect to Violation II.A, the licensee also admitted to the NRC investigator, during a telephone interview in July 1992, that she was aware of the requirement to repair or replace the dose calibrator when the accuracy or constancy error exceeds 10%; however, the licensee continued to use this instrument to assay patient doses even though the results of the accuracy and constancy tests indicated that the instrument should be repaired or replaced. While the NRC agrees that the licensee kept records and did not try in any way to deny or avoid the fact that the dose calibrator reading was off by more than 10%, that fact does not diminish the finding that the licensee knew the requirement at the time, yet chose not to adhere to it. Further, although there were many doses administered when the dose calibrator appeared to be working well, the licensee had, on a number of occasions, indications that the dose calibrator was not functioning properly, yet the licensee did not repair or replace the dose calibrator as required. Finally, the licensee claims that it was because of the intermittent nature of this problem that she was assured by the consultant physicist that the equipment did not need to be sent out for repair. However, during the

enforcement conference, which was transcribed, the consultant stated that the licensee should allow the dose calibrator to warm up for a longer period of time. When the licensee tried this proposed solution and the problem continued to recur on intermittent days, the licensee should have repaired or replaced the dose calibrator in accordance with the regulatory requirement.

With respect to Violation II.B, the licensee stated during the enforcement conference that she was aware of the requirement to assay each patient dose in the dose calibrator and to not use the dose if it varies from the prescribed dose by more than 10 percent. Although the patient dose as measured in the dose calibrator differed from the prescribed dose by more than 10% on numerous occasions, the licensee used the dose (i.e., administered the dose to a patient) anyway. Thus the licensee knew the requirement at the time, yet chose not to adhere to it.

At the enforcement conference, the licensee explained that her actions were based on her belief that: (1) the dose calibration performed by the supplier was correct, (2) the health status of the patients necessitated timely treatment, and (3) the difference between the prescribed activity and the activity indicated by the dose calibrator reading was not biologically significant. In her response to the Notice, the licensee simply states that she believes that she was administering an "appropriate" dose to the patients. These explanations do not change the fact that the licensee knew the requirement at the time, yet chose not to adhere to it on at least eight separate occasions.

Additionally, in two of the eight cases, the prescribed dose was 30 millicuries and the dose as measured in the licensee's dose calibrator exceeded the prescribed dose by more than 10%. The NRC license does not allow the licensee to administer more than 30 millicuries of iodine-131 to a patient at the licensee's office on an outpatient basis. Further, the administration of iodine-131 in quantities greater than 30 millicuries requires that the patient be hospitalized in accordance with 10 CFR 35.75. Therefore, from a regulatory standpoint, it is clear that a dose in excess of 30 millicuries would not be an "appropriate" dose. The licensee indicated at the enforcement conference that she was well aware that outpatients were limited to a dose of 30 millicuries or less.

With respect to the licensee's contention that her past record is not relevant to this matter because she believes the issues were not similar in 1983, and no violations were identified in 1988, the licensee is referring to the escalation of the base civil penalty for Violations II.A and B based on: (1) prior opportunity to identify and (2) licensee performance. The application of these factors is

discussed below.

The NRC Enforcement Policy provides, in Section VI.B.2(d), that the base civil penalty may be escalated by as much as 100% for cases where the licensee should have identified the violation sooner, such as through specific NRC notification. The licensee received specific notice, by NRC letter dated April 2, 1988, that the licensee should not administer iodine-131 in the absence of a properly functioning dose calibrator. With respect to Violation II.A, the base civil penalty was escalated by 50% because the licensee administered iodine-131 on numerous occasions when the licensee did not have a properly functioning dose calibrator.

The Policy also provides, in Section VI.B.2(c), that the base civil penalty may be escalated by as much as 100% if the current violation is reflective of the licensee's poor performance over the last two inspections, with consideration given to the effectiveness of previous corrective action for similar problems, including escalated and non-escalated enforcement actions. The licensee was cited on August 18, 1983 for failure to assay patient doses in the dose calibrator prior to administration (a non-escalated enforcement action). With respect to Violation II.B, the base civil penalty was escalated by 50% because the licensee violated the same requirement. (i.e., Since the licensee believed that the dose calibrator was malfunctioning, disregarded the dose calibrator readings, and administered the doses to patients anyway, she did not fulfill the requirement to assay patient doses in the dose calibrator prior to administration.)

The licensee further contends that the "multiple examples" factor should not have been used to escalate the penalties because the problems were intermittent. The NRC Enforcement Policy, Section VI.B.2(e), provides that the base civil penalty may be escalated by as much as 100% where multiple examples of a particular problem are identified during the inspection period. The Policy grants no special relief for intermittent problems. As noted above, the problem continued to recur on intermittent days and the licensee was well aware of each occurrence; therefore, the licensee should have repaired or replaced the dose calibrator as required.

The licensee believes that she is being penalized unfairly for pointing out inconsistencies between regulations and the need for prompt, carefully timed, medical treatment. As noted in the Commission's Policy Statement on Medical Uses (44 FR 8242, Feb. 9, 1979), the NRC seeks to minimize intrusion into medical judgments affecting patients. However, the NRC must ensure that its requirements are adhered to and that activities involving licensed material

are conducted safely. The licensee's desire to provide prompt medical treatment does not provide an excuse for repeated violations of the requirements that the licensee has agreed to adhere to as a condition of the NRC license. Violation II.B involved at least eight patient doses administered between May 5, 1988, and March 12, 1991, and during that time, the licensee did not seek assistance or relief by notifying NRC that the violation was occurring, did not have the machine repaired or replaced, and did not make backup arrangements to assure the performance of an independent calibration of the patient dose elsewhere, or to treat the patient elsewhere, at a facility equipped with properly functioning instrumentation. Clearly, considering the recurring nature of the violation and the licensee's knowledge of the requirement, arrangements should have been made to assure compliance, even in the face of the need for prompt, carefully timed medical treatment. Moreover, if the licensee believed such arrangements could not be made, she should have sought an exemption from the requirement through the license amendment process.

The licensee also notes that she has taken corrective actions. Full 50% mitigation of the base civil penalty was allowed for the licensee's corrective action in response to Violation I. Mitigation based on corrective action was not allowed with respect to Violations II.A and B because, at the time of the March 10, 1993 Notice, the licensee's corrective actions did not address how the licensee will resolve future conflicts between the need for timely patient care and the need for compliance with NRC regulations.

With respect to the licensee's claim that the penalties created an economic hardship for her and her family, the licensee was contacted by NRC Region I personnel on April 2, 1993 and was told that she must submit income tax returns to justify her contention and to establish a payment schedule. The licensee stated that she would like the NRC to consider the information provided thus far and submit a "counterproposal" before she gathers the additional information to support her claim of financial hardship. Since the licensee has not provided any specific financial information to demonstrate that the payment of the civil penalties would create a financial hardship, the licensee's claim of financial hardship has not been considered.

¹ In addition, since the claim was not supported, the NRC staff has not sought the licensee's basis for concluding that she has sufficient resources to safely conduct licensed activities and pay required licensing and inspection fees. See, 10 CFR Part 2, Appendix C, Section VI.B.1.

4. NRC Conclusion

The NRC concludes that the licensee has not provided an adequate basis for mitigating the civil penalties. Accordingly, the NRC has determined that proposed civil penalties in the amount of \$3,800 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1416

APR 05 1993

Docket No. 030-30180
License No. 29-28088-01
EA No. 93-049

Mr. Jesse R. Wingerter, President
Jersey Technology Laboratories, Incorporated
154 Wright Street
Newark, New Jersey 07114

Dear Mr. Wingerter:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$250
(NRC Inspection Report No. 030-30180/93-002)

This letter refers to the NRC inspection conducted on February 9, 1993, at your facility in Newark, New Jersey, of activities authorized by NRC License No. 29-28088-01, and continued in the Region I office until February 23, 1993, to review additional information provided by you related to the inspection findings. The inspection report was sent to you on March 12, 1993. During the inspection, seven apparent violations of NRC requirements were identified. On March 19, 1993, an enforcement conference was conducted with you and Mr. A. N. T. Mohan, your acting Radiation Safety Officer (RSO), to discuss the apparent violations, their causes and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

The most significant violation identified during the inspection involved two instances during which proper security and control over licensed radioactive material were not maintained. First, on January 8, 1993, at a temporary job site in Summit, New Jersey, the gauge operator left a Troxler moisture/density gauge (which contained eight millicuries of cesium-137 and 40 millicuries of americium-241) unattended in an unrestricted area. The unattended gauge was damaged by a dump truck backing into it. In addition, on the day of the inspection at your Newark, New Jersey facility, the NRC inspector observed that both doors to the storage area (also an unrestricted area) containing the gauges were unlocked and open, and the shipping containers and the handles to the gauges were without locks, thereby creating the potential for unauthorized entry to the room and removal of the licensed material.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

APR 05 1993

**Jersey Technology Laboratories,
Incorporated**

2

With respect to the first instance, the NRC recognizes that the gauge user contacted the acting RSO who determined, after contacting the gauge manufacturer, that the damage was not significant. Notwithstanding the actual extent of the damage in this instance, your failure on this occasion to maintain adequate control over licensed radioactive material could have resulted in the loss or theft of the radioactive material and unnecessary exposure of individuals to radiation. With respect to the second instance, the gauge not only could have been lost or stolen, but the sealed source could have been exposed or removed resulting in unnecessary exposure of individuals to radiation. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C, and as described in Section I of the enclosed Notice, this violation is categorized at Severity Level III.

The other six violations consisted of: (1) failure of the RSO to perform the duties of the position; (2) failure to perform leak tests of sealed sources within the required time interval; (3) unauthorized cleaning procedures for the source rod; (4) failure to maintain records for inventories of sealed sources; (5) failure to maintain a utilization log for gauge check-out; and (6) failure to make required postings. A failure to understand and implement all aspects of the radiation safety program during the RSO transition seems to be a common element in these violations. The violations are described in Section II of the enclosed Notice and are classified at either Severity Level IV or V. However, one of these violations, involving the failure to leak test sources, was identified during a previous inspection in 1989, and therefore, is of particular concern to the NRC. Any similar recurrence of this violation in the future may result in an escalated enforcement action.

The NRC recognizes that subsequent to the inspection, prompt and comprehensive actions were initiated to correct the violation and prevent recurrence. These actions, which were described at the enforcement conference, included: (1) contacting the gauge manufacturer immediately following the damage to the gauge, which resulted in an assessment that the sealed sources and gauge operability were not affected; (2) counselling the technician as to the requirement for securing the gauges at temporary job sites; (3) allocating a locked storage space for the gauges with the access key to be controlled by only the RSO; (4) using a toll free number for the technicians to call the RSO in case difficulty is encountered at the field; (5) assembling a shipment documentation kit for each gauge, and informing all the authorized users about the use of the documentation and that the kit must accompany the gauge at all times; (6) preparing a procedure for gauge cleaning, and training the technicians concerning the procedure; (7) enhanced and more frequent monitoring of gauge use in the field by the RSO; (8) posting of NRC Form 3 and other documents that are required to be posted; and (9) the RSO personally ensuring that periodic leak tests are done as required, and appropriate leak test reports, inventory record and the gauge utilization log are maintained. Additionally, you agreed that the RSO will inform the authorized users about pertinent information issued by the NRC, including Information Notice 93-18, "Portable Moisture-Density Gauge User Responsibilities During Field Operations", dated March 10, 1993, provided to you at the meeting, by using "read and sign" transmittals.

APR 05 1993

**Jersey Technology Laboratories,
Incorporated**

3

Notwithstanding this action, to emphasize the need to maintain adequate control over licensed material at all times, and to assure that your corrective actions are long lasting, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$250 for the Severity Level III violation. The base amount of a civil penalty for a Severity Level III violation is \$500.

The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was escalated by 50% due to NRC's identification of the violation, mitigated 50% in view of your prompt and comprehensive corrective actions, and mitigated an additional 50% based on your past good enforcement history. Therefore, on balance, 50% mitigation of the civil penalty was warranted. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, P. L. No. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement Conference Report

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Jersey Technology Laboratories, Incorporated
Newark, New Jersey 07114

Docket No. 030-30180
License No. 29-28088-01
EA 93-049

During an NRC inspection conducted at the licensee's facility on February 9, 1993, and continued in the NRC Region I Office until February 23, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above,

- a. on January 8, 1993, licensed material consisting of eight millicuries of cesium-137 and 40 millicuries of americium-241 located at a temporary job site at 556 Morris Avenue, Summit, New Jersey, an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee; and
- b. on February 9, 1993, licensed material (consisting of gauges containing eight millicuries of cesium-137 and 40 millicuries of americium-241) stored in an unrestricted area at the licensee's Newark, New Jersey facility, was not secured against unauthorized removal from place of storage. Specifically, both doors to the storage area were unlocked and open and shipping containers and handles to the gauges were without locks.

This is a Severity Level III violation (Supplements IV and VI).
Civil Penalty - \$250

II. Violations Not Assessed a Civil Penalty

- A. Condition 16 of License No. 29-28088-01 requires that the licensee conduct its program in accordance with the statements, representations, and procedures contained in an application dated August 14, 1987.

1. Item 10 of the application dated August 14, 1987, states that Dr. Madhu Salanki has been designated as the company Radiation Safety Officer and will assume certain duties and responsibilities.

Contrary to the above, from December 1992 through February 9, 1993, Dr. Salanki did not work for the licensee and therefore did not assume the duties and responsibilities as the Radiation Safety Officer.

This is a Severity Level IV violation (Supplement VI).

2. Item 10 of the application dated August 14, 1987, requires that no maintenance will be performed in which the radioactive source is removed from the gauge and that only Troxler Electronics will conduct source removal procedures.

Contrary to the above, as of February 9, 1993, the licensee had routinely performed cleaning maintenance of Troxler gauges where the source rod was lowered, and the source was removed by the licensee in order to clean the source rod, rather than by Troxler Electronics.

This is a Severity Level IV violation (Supplement VI).

3. Item 10 of the application dated August 14, 1987, states that a utilization log book will be used to control the gauge's whereabouts at all times - signing it out and back in when returning from the field.

Contrary to the above, as of February 9, 1993, the utilization log book had not been used to control the whereabouts of the Troxler gauges during 1992 in that there were no entries in the log book indicating that the gauge had been signed in or out.

This is a Severity Level V violation (Supplement VI).

- B. Condition 13.A of License No. 29-28088-01 requires that sealed sources or detector cells be tested for leakage and/or contamination at intervals not to exceed six months.**

Contrary to the above, as of February 9, 1993, sealed sources containing eight millicuries of cesium-137 and 40 millicuries of americium-241 had not been tested for contamination or leakage during the period for November 21, 1991 to February 10, 1993, a period greater than six months.

This is a repetitive Severity Level IV violation (Supplement VT).

- C. Condition 15 of License No. 29-28088-01 requires that the licensee conduct a physical inventory every six months to account for all sources and/or devices received and possessed under the license. Records of inventories shall be maintained for two years from the date of the inventory.**

Contrary to the above, as of February 9, 1993, no records were maintained of physical inventories for the past two years of sealed sources containing eight millicuries of cesium-137 and 40 millicuries of americium-241.

This is a Severity Level V violation (Supplement VT).

- D. 10 CFR 19.11(a) and (b) require, in part, that the licensee post current copies of Part 19, Part 20, the license, license conditions, documents incorporated into the license, license amendments and operating procedures; or that the licensee post a notice describing these documents and where they may be examined. 10 CFR 19.11(c) requires that a licensee post Form NRC-3, "Notice to Employees."**

Contrary to the above, as of February 9, 1993, the licensee did not post any of the required documents, or notices describing the documents and where they may be examined.

This is a Severity Level V violation (Supplement VT).

Pursuant to the provisions of 10 CFR 2.201, Jersey Technology Laboratories, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received with the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedures for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 5th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8084

MAR 22 1993

Docket: 030-03496
License: 49-01380-01
EA 93-011

Memorial Hospital of Laramie County
ATTN: Jon M. Gates
Administrator
Department of Radiology
300 East 23rd Street
Cheyenne, Wyoming 82001

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$1,250 (NRC INSPECTION REPORT NO. 030-03496/92-02)

This is in reference to the special inspection conducted on November 19-20, 1992, of Memorial Hospital of Laramie County (MHLC) in Cheyenne, Wyoming in response to your November 2, 1992, report to the NRC of a therapeutic misadministration. A report describing the results of this inspection was issued on February 2, 1993. This inspection disclosed two violations of NRC requirements.

As a result of this inspection, a telephonic enforcement conference was conducted on February 17, 1993, with you and members of your staff. The purpose of the enforcement conference was to ensure that NRC had all the information relevant to these violations to assist it in making an enforcement decision. A list of the enforcement conference participants is enclosed (Enclosure 1).

The violations in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involve: (1) the failure to perform an appropriate verification of source strengths of brachytherapy sources prior to implantation; and (2) the failure of MHLC to conduct training of the radiation physicists on the elements of the Quality Management Program (QMP). The first violation, which resulted from a failure to follow the requirements of the QMP, was a direct cause of the therapeutic misadministration.

The MHLC's report dated November 2, 1992, stated that the misadministration occurred on August 19, 1992, and it was not discovered until October 21, 1992, when the dosimetrist was preparing to order sources for another implant. Prior to this misadministration, MHLC had primarily used one specific vendor for the supply of implant sources and had developed a practice of referring to the previous order for the quantity and activity of the sources to be ordered.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In this case, the sources were ordered from a different vendor utilizing the same ordering procedure. After the shipment was received, the dosimetrist checked and verified the prescription order against the receipt, a practice that was used in the past for verification prior to implant, and noted that the numerals preceding the activity and the quantity of sources matched. However, the dosimetrist failed to note that the activity of the sources was stated in milligrams radium equivalent (mgRaeq) rather than millicuries (mCi). The information was entered in the dose calculation computer in mCi instead of mgRaeq, which resulted in a total treatment dose which exceeded by more than 20 percent the prescribed dose for the patient treated on August 19, 1992. The prescribed dose was 3258 centigray (cGy) and the patient received 5669 cGy.

As detailed in the inspection report, similar circumstances caused a second event involving a different patient on August 4, 1992. As indicated in the attached Notice, both events involved violations of NRC regulatory requirements. The issue of whether or not the August 4 event also constitutes a misadministration (within the definition of 10 CFR 35.2) is currently under NRC review. You will be notified in a separate communication when a determination is made. If the August 4 event is determined to be a misadministration, at that time you will be required to fulfill the notification, reporting, and recordkeeping requirements of 10 CFR 35.33.

At the time that these events took place, the MHLC QMP procedures required "a verification of brachytherapy source strengths. . . using an appropriate verification method such as the use of a dose calibrator [used to measure source strength], using color-coded sealed sources, or using the clearly marked storage locations inside the mold room safe." The NRC staff believes that both events resulted from the failure to perform an appropriate verification of the source strengths as called for in your QMP procedures. The dosimetrist relied on the information in the shipping invoice to verify the source strength. This method of verification did not catch the error because it focused on the shipping document instead of a physical attribute of the sources (such as measured source activity). Moreover, this method of verification would be useless in any situation where the shipping paper bears the correct information but is accompanied by the wrong sources.

At the enforcement conference, a licensee representative raised the defense that the verification method used by the dosimetrist did meet the letter of your QMP procedure as written. Given the discussion in the preceding paragraph, if NRC were to grant this argument, then the QMP procedure itself clearly did not meet the requirement in 10 CFR 35.32(a) to provide high confidence that byproduct material will be administered as directed by an authorized user. Thus the question is not whether a violation occurred but rather how to characterize the violation. The NRC staff believes that the violation is most accurately characterized as a failure to follow the licensee's QMP procedure rather than a failure of the QMP procedure itself.

The second violation in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty involves the failure of MHLC to conduct training of two consultant radiation physicists on the content of the MHLC QMP. MHLC relied on these physicists, since the departure of the MHLC physicist, to determine whether the prescribed therapy treatment plans were accomplished.

NRC acknowledges that you took immediate corrective actions following the identification of the misadministration on October 21, 1992. These included: (1) the cessation of implant activities until all personnel involved with implantation therapy were briefed and thoroughly understood the QMP; (2) providing a copy of the QMP to the consulting physicists who reviewed the QMP with the Radiation Safety Officer (RSO); (3) the development of forms and revision of receipt procedures to ensure appropriate verification of radioactive material by requiring that checklists be initialed by the dosimetrist, physicist or RSO; and (4) conducting inservice training on the current QMP for the oncology nursing staff. Additionally, MHLC stated during the enforcement conference that it is planning to revise the QMP.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the failure to first verify the source strengths with an appropriate verification method prior to implantation and failure to instruct two radiation physicists in the elements of the QMP are classified collectively as a Severity Level III problem.

To emphasize the significance that NRC places on: (1) proper instruction and training in QMP procedures for individuals with responsibilities for administering or verifying radiation therapy treatment, and (2) strict compliance with the elements of the QMP, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1,250 for the Severity Level III problem.

The base value of a civil penalty for a Severity Level III problem is \$2,500. The civil penalty adjustment factors in Section VI.B.2 of the Enforcement Policy were considered and resulted in a decrease of \$1,250. Although the NRC identified the failure to instruct the radiation physicists and the failure to verify the source strengths by an appropriate method prior to implantation, MHLC identified and reported the misadministration, determined the contributing causes, and took immediate corrective action prior to the NRC inspection, thus warranting a decrease of 50% of the base value. The remaining adjustment factors were considered, but no further adjustment of the civil penalty was considered appropriate.

The violation in Section II of the Notice was discussed during the enforcement conference but had not been identified prior to that time. The violation was identified as a result of a discussion of the definition of "written directive" as it relates to QMP procedures. Although not assessed a civil penalty, the violation is considered to be further evidence of the need for concentrated management attention to NRC requirements for the brachytherapy program and the QMP procedures.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence.

After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosures:
List of Participants at Enforcement Conference
Notice of Violation and Proposed Imposition
of Civil Penalty

cc:
Wyoming Radiation Control Program Director

Enclosure 1

List of participants in the February 17, 1993, telephonic enforcement conference between NRC and Memorial Hospital of Laramie County.

Memorial Hospital of Laramie County

Jon M. Gates, Administrator
Dan J. Hommel, M.D., Radiation Safety Officer
Linda Gill, Director, Radiology/Radiation Oncology
David Taylor, Radiation Physicist

Nuclear Regulatory Commission, Region IV

John M. Montgomery, Deputy Regional Administrator
William L. Brown, Regional Counsel
L. Joseph Callan, Director, Division of Radiation Safety and Safeguards
Dwight D. Chamberlain, Deputy Director, Division of Radiation Safety and Safeguards
Charles L. Cain, Chief, Nuclear Materials Inspection Section
Mark Shaffer, Radiation Specialist
Gary F. Sanborn, Enforcement Officer
Russell Wise, Enforcement Specialist

Nuclear Regulatory Commission, HQ

Ed Kline, Nuclear Materials Safety and Safeguards
Joe DeMedico, Enforcement Specialist, Office of Enforcement

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Memorial Hospital of Laramie County
Cheyenne, Wyoming

Docket No. 030-03496
License No. 49-01380-01
EA 93-011

During an NRC inspection conducted on November 19-20, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

10 CFR 35.32(a)(4) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objective that each administration is in accordance with the written directive.

Section No. 3.2.5 of the licensee's quality management program dated January 23, 1992, states, in part, that a verification of brachytherapy source strengths will be performed using an appropriate verification method such as the use of a dose calibrator, using color-coded sealed sources, or using the clearly marked storage locations inside the mold room safe.

10 CFR 35.25(a) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b) shall: (1) instruct the supervised individual in the licensee's written quality management program; (2) require the supervised individual to follow the instructions of the supervising authorized user and to follow the written radiation safety and quality management procedures established by the licensee; and (3) periodically review the supervised individual's use of byproduct material.

- A. Contrary to the above, on August 4, 1992, and August 19, 1992, the licensee used brachytherapy sources for patient treatments and did not first verify the source strengths to be used by an appropriate verification method. Specifically, the only verification method used was the visual inspection of shipping documents accompanying the sources.

- B. Contrary to the above, as of November 20, 1992, the licensee had not instructed two radiation physicists, who were under the supervision of an authorized user, in the licensee's written quality management program.

These violations represent a Severity Level III problem (Supplement VI).
Civil Penalty - \$1,250.

II. Violation Not Assessed a Civil Penalty

10 CFR 35.32(a)(1)(iii) requires that a licensee's quality management program include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose. In accordance with 10 CFR 35.2, a written directive is defined for brachytherapy as an order in writing for a specific patient, dated and signed by an authorized user prior to implantation, containing the radioisotope, number of sources, and source strengths.

Contrary to the above, for patients administered brachytherapy sources on August 4, 1992, and August 19, 1992, the written directives prepared, dated, and signed by the licensee's authorized user did not include, prior to implantation, the number of sources nor the source strengths.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Memorial Hospital of Laramie County (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to

the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV.

Dated at Arlington, Texas
this 22nd day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

APR 20 1993

Docket No. 030-08702
License No. 37-00993-05
EA No. 93-052

Ms. Lauren Pilhauskas, Vice President
for Patient Services
Mercy Catholic Medical Center
Fitzgerald-Mercy Division
Lansdowne Avenue and Bailey Road
Darby, Pennsylvania 19023

Dear Ms. Pilhauskas:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTIES - \$12,500
(NRC Inspection Report No. 030-08702/93-001)

This letter refers to the NRC inspection conducted on February 23 and 24, 1993, at the Mercy Catholic Medical Center facilities located in Philadelphia and Darby, Pennsylvania, of activities authorized by NRC License No. 37-00993-05. The inspection report was sent to you on March 19, 1993. During the inspection, 17 apparent violations of NRC requirements were identified. On March 30, 1993, an open enforcement conference was conducted with you and other members of the management and staff at Mercy Catholic Medical Center to discuss the apparent violations, their causes and your corrective actions. A copy of the enforcement conference report is enclosed (Enclosure 2).

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) (Enclosure 1), and included a violation of the Quality Management (QM) program requirements in that written directives were not prepared, as required, prior to the performance of an iodine-131 whole body scan and a cesium-137 implant. In addition, several other written directives for brachytherapy implants did not contain all of the required information. Although this violation did not result in any misadministration of materials, this violation is of particular concern because the failure to prepare a written directive creates the potential for a misadministration.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

APR 20 1993

Mercy Catholic Medical Center

2

The sixteen other violations identified during the inspection include, but are not limited to: (1) failure to limit radiation levels in unrestricted areas to 2 millirem per hour or less; (2) failure to measure the dose rates in contiguous unrestricted areas promptly after administering iodine-131 doses, or after implanting brachytherapy sources; (3) failure to measure the thyroid burden of individuals preparing or administering iodine-131 doses; (5) failure to perform adequate surveys; (6) failure to perform quarterly reviews of external radiation doses of contractor nuclear medicine technologists; (7) failure to supply personnel dosimeters to nurses caring for patients receiving radiopharmaceutical therapy; (8) failure to test the dose calibrator quarterly for linearity; (9) failure to calibrate survey instruments appropriately; (10) failure to test sealed sources for leakage at intervals not to exceed six months; and (11) not maintaining certain required records. The large number of the violations and their diversity across most areas of the radiation safety program at the facility, collectively represent a breakdown in the control of licensed activities.

An apparent shortage in Radiation Safety staff, as well as the inability of the interim Radiation Safety Officer (RSO) to devote sufficient time to her radiation safety program activities, appear to have contributed to these violations, which represent a significant lack of management attention to, and oversight of, licensed activities at the facility. In addition, the NRC is also concerned that the reviews performed by the Radiation Safety Committee (RSC) at your facility failed to identify the violations, notwithstanding the number and nature of these violations and the fact that some of them were long standing.

The NRC license issued to Mercy Catholic Medical Center entrusts responsibility for radiation safety to the management of the hospital; therefore, the NRC expects effective oversight of its licensed programs. Incumbent upon each NRC licensee is the responsibility of management in general, and the RSC and RSO in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and any potential violations of NRC requirements are identified and expeditiously corrected. The violation of QM program requirements is of significant regulatory concern to the NRC since each of the specific program requirements provide a safety barrier which, if not adhered to, could result in a misadministration. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation is classified at Severity Level III and is set forth in Section I of the enclosed Notice. The sixteen other violations that collectively represent a breakdown in the control of licensed activities, are also categorized in the aggregate as a Severity Level III problem, and are set forth in Section II of the enclosed Notice.

The NRC recognizes that prior to the recent inspection, the management of Mercy Catholic Medical Center recognized the staffing shortage at the facility and took actions to correct it by hiring an additional physicist in January, 1993, and a new permanent RSO who will join the staff shortly. In addition, you procured the services of a consulting firm to review and improve the radiation safety program, and the consultant was in the process of performing a program audit at the time of the NRC inspection and identifying some of the program weaknesses that were identified by the NRC.

APR 20 1993

The NRC also recognizes that actions were taken or planned to correct the violations and effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, included: (1) providing written reminders to all authorized users (of iodine-131 and brachytherapy sources) regarding the requirement to prepare and sign written directives prior to administrations; (2) use of a Quality Management checklist for each patient receiving more than 30 microcuries of iodine-131 to ensure that all necessary requirements of the QM program are completed; (3) instructing the personnel involved in patient room assignment about the requirement of limiting the dose rate in unrestricted areas to 2 millirems per hour and that adjacent rooms be left vacant if the limit is exceeded; (4) an improved survey program and techniques to address the deficiencies identified in the NRC inspection; (5) reminding all physicians about the requirement of completing a thyroid burden measurement after iodine-131 use, and restricting access of individuals who do not comply with the requirement; (6) providing all nurses with radiation monitors during iodine-131 therapy procedures; (7) developing procedures and providing necessary training for periodic leak testing of sealed sources, radioactive gas collection system checks, and dose calibrator tests; (8) completing calibration of all survey instruments; and (9) an improved method of record keeping, and periodic monitoring by quarterly and annual audits. At the time of the enforcement conference, most of these corrective actions were in place or planned to be completed within a short time frame.

Notwithstanding those actions, to emphasize (1) the importance of aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected, and (2) the need for ensuring that your corrective actions are long-lasting, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of \$12,500 for the seventeen violations set forth in the enclosed Notice.

With respect to the violation of the QM program requirement, the base civil penalty amount for this Severity Level III violation is \$2,500. A basis exists for a 50% escalation of the penalty because the violation was identified by the NRC, as well as 100% escalation of the penalty because the violation involves multiple examples. Therefore, on balance, 150% escalation of the base civil penalty is warranted. The other escalation/mitigation factors were considered and no further adjustment is considered appropriate.

APR 20 1993

Mercy Catholic Medical Center

4

With respect to the remaining violations that were classified in the aggregate at Severity Level III, the base civil penalty amount of \$2,500 has been increased by 50% because the violations were identified by the NRC. In addition, since your internal reviews and audits should have identified these violations (some of which were long standing), but failed to do so, you had prior opportunity to identify these violations, and therefore, an additional 100% escalation on this factor is considered appropriate. Accordingly, on balance, the civil penalty for this Severity Level III problem is escalated by 150% to \$6,250. The other escalation/mitigation factors were considered and no further adjustment is warranted.

In both cases, although your corrective actions were considered prompt and comprehensive to address the individual violations, no credit for this factor is warranted because you have not yet comprehensively addressed the underlying root cause, namely, the failure of management to provide oversight of the radiation safety program.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In this regard, please address how you plan to enhance management oversight to ensure compliance with the requirements. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition
of Civil Penalties
2. Enforcement Conference Report

APR 20 1993

Mercy Catholic Medical Center

5

cc w/encs:

Public Document Room (PDR)

Nuclear Safety Information Center (NSIC)

Commonwealth of Pennsylvania

Sister Mary Jo McGinley, Vice President for

Patient Services, Misericordia Division

Ms. Virginia Pelligrino, Vice President

Professional and Administrative Services,

Fitzgerald-Mercy Division

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Mercy Catholic Medical Center
Darby, Pennsylvania 19023

Docket No. 030-08702
License No. 37-00993-05
EA No. 93-052

During an NRC inspection conducted on February 23 and 24, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violation of OM Program Requirements

10 CFR 35.32(a) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose and any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

10 CFR 35.2 defines a written directive for an administration of quantities greater than 30 microcuries of either sodium iodide iodine-125 or iodine-131 as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical and which contains the dosage. For a brachytherapy procedure the written directive for a specific patient, dated and signed by an authorized user must contain, in part, prior to implantation: the radioisotope, number of sources, and the source strengths.

The licensee's written quality management program (dated January 27, 1992), written to comply with 10 CFR 35.32(a), requires, in part, that the authorized user date and sign a written directive (prescription) prior to administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131 and prior to performing a brachytherapy procedure.

Contrary to the above, a written directive signed and dated by the authorized user was not prepared prior to the administration of 5 millicuries of iodine-131 to a patient on September 14, 1992, nor prior to implanting cesium-137 sources in a patient on November 24, 1992. In addition, adequate written directives were not prepared prior to implanting sources for seven brachytherapy procedures performed during the period February 1, 1992 to February 23, 1993, in that the written directives that were prepared did not contain the number of sources and source strengths, as required, and two of the written directives only indicated the intent to perform brachytherapy.

This is a Severity Level III violation (Supplement VI).

Civil Penalty - \$6,250.

II. Other Violations of NRC Requirements

- A. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee shall allow the creation of radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in the individual receiving a dose in excess of 2 millirems in any one hour.

Contrary to the above, the licensee allowed the creation of radiation levels in unrestricted areas such that if an individual were continuously present in the area, he could receive a dose in excess of 2 millirems in any one hour. Specifically, on four occasions from January 17, 1992 to February 24, 1993, the licensee allowed radiation levels in unrestricted areas, namely, the patient rooms or hallways, that ranged from 2.6 millirems per hour to 4.5 millirems per hour.

- B. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, that the measurements be performed within three days after the administration of the dosage, and that a record of each thyroid burden measurement be maintained for the period required by 10 CFR 20.401(c)(1).

Contrary to the above:

1. On December 15 and 29, 1992, the licensee administered 127 and 125.6 millicuries of iodine-131, respectively, dosages of iodine-131 in amounts that required the patients to be hospitalized for compliance with 10 CFR 35.75, and the licensee did not measure the thyroid burden of the physicist who prepared the dosages and the physician who administered the dosages within three days after the administration of the dosages.

2. The licensee did not maintain records of measurements of the thyroid burden of the physicist who prepared dosages and/or the physician who administered dosages of iodine-131 ranging from 104 millicuries to 200 millicuries on four occasions from June 19, 1992 to October 13, 1992.

- C. 10 CFR 35.315(a)(4) requires, in part, that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee, promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

Contrary to the above, on May 12, 1992, the licensee administered to a patient a dosage of 104 millicuries of iodine-131 for radiopharmaceutical therapy, a dosage which requires hospitalization for compliance with 10 CFR 35.75, and the licensee did not measure the dose rates in contiguous unrestricted areas. Specifically, the dose rates in a room adjacent to the room occupied by the patient receiving radiopharmaceutical therapy were not measured with a radiation measurement survey instrument to demonstrate compliance with 10 CFR Part 20.

- D. 10 CFR 35.415(a)(4) requires, in part, that a licensee, promptly after implanting brachytherapy sources, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10 CFR Part 20.

Contrary to the above, from January 1, 1992 to February 23, 1993, the licensee implanted cesium-137 and iridium-192 brachytherapy sources during numerous implant procedures, and did not survey the dose rates in unrestricted areas contiguous to the room of the implanted patient, to demonstrate compliance with the requirements of 10 CFR Part 20.

- E. 10 CFR 35.315(a)(7) requires that for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, on numerous occasions, as of February 24, 1993, for patients receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, the licensee did not perform appropriate surveys of the patient's rooms and private sanitary facilities for removable contamination with a radiation detection survey instrument before assigning another patient to the room. Specifically, surveys for removable contamination were performed by using a Geiger-Müller survey instrument over areas of the room and sanitary facility, a method inappropriate for evaluating a removable contamination level of 200 disintegrations per 100 square centimeters since the required sensitivity could not be achieved.

- F. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer (RSO), ensure that radiation safety activities are being performed in accordance with approved procedures.

The licensee's procedures for maintaining occupational radiation exposure as low as reasonably achievable (ALARA) and for radiation safety during radiopharmaceutical therapy are identified in the licensee's application dated February 16, 1989 as those provided in Appendices G and P, Regulatory Guide 10.8, Revision 2 and were approved by License Condition 14.

1. Item 3 of Appendix G requires, in part, that the RSO review at least quarterly the external radiation doses of workers to determine that their doses are ALARA in accordance with Section 6 of Appendix G.

Contrary to the above, as of February 24, 1993, the licensee through the RSO, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, the RSO did not review at least quarterly the external radiation doses of contractor nuclear medicine technologists who used byproduct material on weekend days at the Fitzgerald-Mercy Division.

2. Item 4 of Appendix P requires that nurses caring for patients receiving iodine therapy be supplied film badges, thermoluminescent (TLDs), or pocket dosimeters.

Contrary to the above, as of February 24, 1993, the licensee through the RSO, failed to ensure that radiation safety activities were being performed in accordance with the above procedures. Specifically, nurses caring for patients receiving iodine therapy were not supplied with film badges, TLDs, or ionization chambers.

- G. 10 CFR 35.70(e) and (f) require that a licensee conduct a weekly survey for removable contamination of all areas where radiopharmaceuticals are routinely prepared for use, administered or stored, so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.

Contrary to the above, the licensee did not conduct weekly surveys for removable contamination of all areas where radiopharmaceuticals were prepared for use or stored in such a manner so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute. Specifically, as of February 24, 1993, wipe samples at the Fitzgerald-Mercy Division were assayed with a Geiger-Müller detector with a side window probe (window in closed position), a method insufficient to detect 2000 disintegrations per minute. In addition, as of February 11, 1993, removable contamination surveys were performed at the Misericordia Division by passing a Geiger-Müller survey instrument over areas and recording the observed dose rates, a method also unsuitable for detecting removable contamination.

- H. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, as of February 24, 1993, the licensee did not survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals were routinely prepared for use or administered. Specifically, surveys were not performed on numerous weekend days at the Fitzgerald-Mercy Division and at the Misericordia Division when patient studies were performed. In addition, surveys performed on weekdays at the Fitzgerald-Mercy Division were performed in the morning, not at the end of each day, as required.

- I. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, as of February 24, 1993, the licensee did not survey with a radiation detection survey instrument once each week the remote waste storage room at the Fitzgerald-Mercy Division where waste contaminated with iodine-131 was stored.

- J. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity at least quarterly.

Contrary to the above, the licensee did not test the dose calibrator in use at the Fitzgerald-Mercy Division for linearity during the fourth calendar quarter of 1992.

- K. 10 CFR 35.51(a) requires, in part, that a licensee calibrate survey instruments used to show compliance with 10 CFR Part 35 before first use, annually, and following repair, and conspicuously note the apparent exposure rate from a dedicated check source, as determined at the time of calibration on each survey instrument.

Contrary to the above, as of February 24, 1993, the licensee was using a Keithley survey instrument at the Fitzgerald-Mercy Division to show compliance with 10 CFR Part 35, and this survey instrument had not been calibrated from December 5, 1991 to February 23, 1993. In addition, as of February 24, 1993, the licensee did not have the apparent exposure rate from a dedicated check source, as determined at the time of calibration, conspicuously noted on survey instruments used by the licensee at the Fitzgerald-Mercy Division and Misericordia Division, and the licensee was using these survey instruments to show compliance with 10 CFR 35.

- L. 10 CFR 35.59(b)(2) requires, in part, that a licensee in possession of a sealed source test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State.

Contrary to the above, the licensee, in possession of a 50 millicurie strontium-90 sealed source, did not test the source for leakage from January 1, 1991 to February 24, 1993, an interval in excess of six months, and no other interval was approved by the Commission or an Agreement State.

- M. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source or brachytherapy source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a quarterly physical inventory of its sealed sources. Specifically, inventories of sealed sources in the Nuclear Medicine Departments at the Fitzgerald-Mercy Division and Misericordia Division were conducted semiannually from March 1990 to February 1993, not quarterly as required.

- N. 10 CFR 35.205(e) requires, in part, that a licensee check each month the operation of reusable collection systems for radioactive gases.

Contrary to the above, the licensee routinely used a reusable collection system for radioactive xenon-133 gas at the Fitzgerald-Mercy and the Misericordia Divisions, and did not check the operation of the collection systems from July 1992 through February 1993, a period in excess of one month.

- O. 10 CFR 35.404(b) requires, in part, that a licensee retain records of surveys of patients made immediately after removing temporary implant sources for three years.

Contrary to the above, on numerous occasions from January 1, 1992 to February 23, 1993, the licensee did not retain records of surveys of patients made immediately after removing temporary implant sources.

These violations collectively represent a Severity Level III problem (Supplements IV and VI).

Civil penalty - \$6,250

Pursuant to the provisions of 10 CFR 2.201, Mercy Catholic Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalties proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalties due which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region 1, 475 Allendale Road, King of Prussia, Pa 19406.

Dated at King of Prussia, Pa
this ~~20th~~ day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

MAY 12 1993

Docket No. 030-12684
License No. 45-17395-01
EA 93-076

Metropolitan Hospital, Inc.
ATTN: Mr. Art Doloresco
Chief Executive Officer
701 West Grace Street
Richmond, Virginia 23220

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$5000 (NRC INSPECTION REPORT NO. 45-17395-01/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. W. Loo on March 15-16, 1993, at the Metropolitan Hospital, Richmond, Virginia. The inspection included an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. The report documenting this inspection was sent to you by letter dated April 19, 1993. During the inspection, numerous violations of NRC requirements were identified. An enforcement conference was held on April 28, 1993, in the Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A list of enforcement conference attendees and a corrected copy of your handout, which was provided to us on May 5, 1993, are enclosed.

The violation in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to secure licensed material from unauthorized removal and to maintain constant surveillance and control over licensed material. The violation, identified by the inspector during the inspection, resulted when licensed material consisting of approximately 158 millicuries of cesium-137, 36 millicuries of technetium-99m, and millicurie quantities of radiopharmaceutical waste, located in the nuclear medicine hot laboratory, were neither secured nor under constant surveillance to prevent unauthorized removal from their place of storage. The hot laboratory was unsecured and unattended for approximately 15 minutes while a technician completed a nuclear medicine procedure in another part of the hospital. This is a significant violation in that unrestricted access was possible during this 15 minute period of time which could have resulted in licensed material being taken or handled by persons not authorized to do so and possibly could have resulted in an unnecessary radiation exposure. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," this violation has been categorized at Severity Level III to reflect the significant regulatory concern associated with the violation.

MAY 12 1993

The staff recognizes that once the violation was identified, immediate corrective action was taken to secure licensed material and arrangements were made for the installation of an automatic door closure device on the door to the hot laboratory. Furthermore, at the enforcement conference, you indicated that you would become involved personally in the Radiation Safety Program and ensure that appropriate corrective actions are developed and implemented.

The seven violations in Part II of the enclosed Notice involve the failure to: 1) instruct supervised individuals in the written quality management program as it pertains to the administration of therapeutic quantities of iodine-131 in amounts greater than 30 microcuries, 2) prevent the creation of radiation levels in unrestricted areas which, if an individual were continuously present in the area, could result in a radiation dose in excess of two millirems in any one hour or 100 millirems in any seven consecutive days, 3) perform required quarterly physical inventories of all sealed sources, 4) conduct a review of the quality management program at intervals not to exceed 12 months, 5) survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered to patients, 6) check a survey instrument for proper operation each day of use with the dedicated check source used at the time the instrument was calibrated, and 7) possess an operable portable radiation measurement survey instrument capable of detecting dose rates over the range of one millirem per hour to 1000 millirem per hour.

Although these violations were categorized at Severity Level IV, they nevertheless collectively represent a significant weakness in the Radiation Safety Program and require management attention. The NRC is concerned that the overall root cause of all the violations appears to be ineffective management oversight of NRC licensed activities at Metropolitan Hospital. In addition, previous NRC inspections in 1988 and 1991 identified violations that appeared to be the result of ineffective oversight. Based on the discussion at the enforcement conference, some of the factors that may have contributed to this situation include the Radiation Safety Officer not being able to devote sufficient time and attention to adequately managing the Radiation Safety Program, difficulties in retaining experienced staff in the program, lack of continuity in the program, and the lack of involvement, control and oversight of the program by senior management to ensure compliance with regulations.

Of further concern is the fact that Violation C in Part II (item 3 above), pertaining to the requirement to perform quarterly physical inventories of all sealed sources, was a repeat violation that had been identified in previous inspections. The NRC expects licensees to correct problems and ensure that corrective actions preclude recurrence of violations. Furthermore, the NRC Enforcement Policy provides for the issuance of civil penalties for repetitive violations categorized at Severity Level IV or Severity Level V. In this case, however, because there was no immediate safety issue associated with the violation and because leak tests accounted for the sources at least every six months, no civil penalty is being proposed.

MAY 12 1993

In addition to the above violations, two non-cited violations related to NRC record keeping requirements were identified during the inspection and involved the failure to include the signature of the Radiation Safety Officer on sealed source leak test records and the failure to maintain records of weekly removable contamination survey in disintegrations per minutes per 100 square centimeters.

To emphasize the importance of maintaining effective control over the radiation safety program and complying with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$5,000 for the Severity Level III violation set forth in Part I of the enclosed Notice. The base civil penalty for a Severity Level III violation is \$2,500. The escalation and mitigation factors in the Policy were considered as discussed below.

Escalation of 50 percent was applied for the factor of identification because the violation in Part I of the Notice was identified by the NRC. Neither escalation nor mitigation was warranted for corrective action. Immediate corrective action to secure the hot laboratory and install an automatic door closure device was offset by the fact that long term corrective action to address the broader implications of security for licensed material and compliance with requirements as measures to prevent recurrence had not been developed at the time of the enforcement conference. Escalation of 50 percent was applied for the factor of licensee performance based on the results of two previous inspections conducted by the NRC. On November 2, 1988, an inspection identified three Severity Level IV violations related to inventories, surveys and equipment testing, and four Severity Level V violations related to record keeping requirements. On April 16, 1991, an inspection identified four Severity Level IV violations related to inventories, surveys and the proper use of protective clothing, and three Severity Level V violations related to record keeping requirements. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 100 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. Your response should also indicate how you will exercise continual oversight to ensure compliance with regulatory requirements including the checks and balances (e.g., audits) to ensure the Radiation Safety Officer and Radiation Safety Committee adequately perform their oversight duties even during periods of staff turnover. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

MAY 12 1993

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebnetter
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed
Imposition of Civil Penalty
2. List of Enforcement Conference
Attendees
3. Enforcement Conference Handout

cc w/encs:

Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Metropolitan Hospital, Inc.
701 West Grace Street
Richmond, Virginia 23220

Docket No. 030-12684
License No. 45-17395-01
EA 93-076

During an NRC inspection conducted on March 15-16, 1993, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on March 16, 1993, licensed material consisting of approximately 158 millicuries of cesium-137, 36 millicuries of technetium-99m labeled radiopharmaceuticals, and millicurie quantities of technetium-99m labeled radiopharmaceutical waste located in the nuclear medicine hot laboratory, an unrestricted area at the time of the observation, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$5000

II. Violations Not Assessed a Civil Penalty

- A. 10 CFR 35.25 (a)(1) requires, in part, that the licensee instruct supervised individuals in the licensee's written quality management program.

Contrary to the above, between January 27, 1992, and March 16, 1993, the licensee did not instruct seven supervised individuals in the licensee's quality management program.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 20.105(b) requires that, except as authorized by the Commission in 10 CFR 20.105(a), no licensee allow the creation of radiation levels in unrestricted areas which, if an individual

were continuously present in the area, could result in his receiving a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days.

Contrary to the above, on March 16, 1993, the licensee allowed the creation of radiation levels in a hallway adjacent to the nuclear medicine hot laboratory, an unrestricted area, from millicurie quantities of technetium-99m labeled radiopharmaceutical waste, such that if an individual were continuously present in the area, he could have received a dose in excess of 2 millirems in any one hour or 100 millirems in any seven consecutive days. Specifically, an individual continuously present in the area could have received 5.0 millirem in any one hour.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 35.59(g) requires, in part, that a licensee in possession of a sealed source conduct a quarterly physical inventory of all such sources in its possession.

Contrary to the above, the licensee did not conduct a physical inventory of its sealed sources from May 19, 1992, to November 15, 1992, a period in excess of a calendar quarter.

This is a second repeat Severity Level IV violation (Supplement VI).

- D. 10 CFR 35.32 (b)(1) requires, in part, that the licensee conduct a review of the quality management program at intervals no greater than 12 months.

Contrary to the above, between January 27, 1992, and March 16, 1993, the licensee did not conduct a review of the quality management program, a period in excess of 12 months.

This is a Severity Level IV violation (Supplement VI).

- E. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, between October 5, 1992 and March 16, 1993, the licensee routinely did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely prepared for use or administered. Specifically, the licensee surveyed all areas where radiopharmaceuticals were routinely prepared for use or administered at the beginning of each day of use rather than at the end of each day of use.

This is a Severity Level IV violation (Supplement VI).

- G. 10 CFR 35.51(c) requires, in part, that a licensee check each survey instrument for proper operation with the dedicated check source each day of use.

Contrary to the above, as of March 16, 1993, the licensee did not routinely check its survey meter with a dedicated check source on days when the instrument was used. Specifically, the licensee did not check its survey meter with the dedicated check source used at the time the meter was calibrated.

This is a Severity Level IV violation (Supplement VI).

- F. 10 CFR 35.320 requires, in part, that a licensee authorized to use byproduct material for radiopharmaceutical therapy have in its possession a portable radiation measurement survey instrument capable of detecting dose rates over the range 1 millirem per hour (mR/hr) to 1000 mR/hr.

Contrary to the above, as of March 16, 1993, the licensee did not have in its possession a portable radiation measurement survey instrument capable of measuring dose ranges over the range 1 mR/hr to 1000 mR/hr. Specifically, the licensee possessed an inoperable portable radiation measurement survey instrument, in that, the instrument could not be zeroed according to manufacturer's instructions.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Metropolitan Hospital, Inc., (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to

the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia.

Dated at Atlanta, Georgia
this 12th day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
799 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

May 3, 1993

Docket No. 030-00806
License No. 21-00021-29
EA 93-062

Michigan State University
ATTN: Gordon Guyer, Ph.D., President
Michigan State University
Hannah Administration Building
East Lansing, MI 48824

Dear Dr. Guyer:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$3,750
(NRC INSPECTION REPORT NO. 030-00806/93001(DRSS))

This refers to the inspection conducted on March 10 through 23, 1993, at Michigan State University. The inspection included a review of the circumstances surrounding an incident beginning on February 26, 1993, in which carbon-14 contamination was spread throughout the National Superconducting Cyclotron Laboratory (NSCL) and to several off campus locations including a private residence and a rental car. The report documenting this inspection was sent to you by letter dated April 8, 1993. During this inspection violations of NRC requirements were identified.

An enforcement conference was held on April 15, 1993, to discuss the violations, their causes, and your corrective actions. You reported the event to the NRC Operations Center on March 12, 1993. Subsequently, you submitted a written report dated March 31, 1993.

On February 26, 1993, a visiting researcher at NSCL obtained keys to locked cabinets assigned to a principal investigator in order to search for equipment needed for a future experiment. The keys were obtained from a post graduate student working with the principal investigator. During the researcher's search through the cabinets, he handled a carbon-14 target, contaminating himself and the immediate area. Neither the container holding the target nor the cabinet were labeled as containing radioactive materials.

The visiting researcher continued with his schedule of work at NSCL without knowledge of his contamination, never surveyed

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

himself, and departed Lansing on March 3, 1993. On March 9, 1993, a health physicist detected low energy beta contamination during a routine survey of the NSCL vault area. Contaminated areas at NSCL and off campus were identified and decontaminated as necessary.

Two violations are described in Section I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violations involve the failure to keep licensed material under constant surveillance and immediate control, and failure to label radioactive material. The root cause of the contamination event appears to be inadequate management oversight of licensed activities at NSCL along with inadequate control and accountability of licensed materials. A contributing cause appears to be inadequate training of the principal investigator who was responsible for the carbon-14 material. The safety consequences of the event were potentially significant in that the carbon-14 contamination was widespread, especially in the public domain.

The violations described above represent a significant failure to control licensed material. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, these violations are classified in the aggregate as a Severity Level III problem.

Your short-term corrective actions included, but were not limited to, prompt involvement by the Radiation Safety Officer, restriction of access to NSCL, attempts to identify the source of contamination, and extensive on-site and off-site surveys. Your long-term corrective actions included, but were not limited to, ensuring that all NSCL licensed materials were located, labeled, inventoried, included in the master database, and stored in the hot laboratory; recommending the revocation of the principal investigator's authorization to receive and use licensed materials; and reviewing all inactive investigators' approvals.

Notwithstanding, we are concerned that the NRC had to focus your staff on the potential off-site contamination, obtaining the itinerary of the visiting researcher, and in the long-term, reviewing the active users' control and accountability of licensed materials in addition to the inactive users. Besides identifying the source of contamination, you should have, in parallel, placed equal priority on responding to the off-site contamination. Once isolated, restoration of the NSCL should have been secondary.

As holder of an academic broad scope license, you have been granted the authority to name and train your own users of licensed material. The NRC entrusts the responsibility of radiation safety to the management of the university. Incumbent upon you is the responsibility to protect the public health and safety by assuring that all NRC requirements are met and any

May 3, 1993

potential violations are identified and promptly corrected.

To emphasize the importance the NRC places on adequate oversight of the authorized users, and adequate labeling, control and accountability of licensed material, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$3,750 for the Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is \$2,500.

The civil penalty adjustment factors in the Enforcement Policy were considered. The base civil penalty was mitigated 50 percent for identification in that your health physicist identified the contamination during a routine survey. The base civil penalty was not mitigated for corrective actions because we had several concerns in this area as discussed above. The base civil penalty was escalated 100 percent for duration in that the carbon-14 target was stored unlabeled in the cabinet for an extensive period of time. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

Section II of the Notice contains seven violations which were not assessed a civil penalty. These involve the (1) failure to report an unplanned contamination event within 24 hours; (2) failure to review approvals for new users at quarterly Radiation Safety Committee meetings; (3) failure to perform 10 CFR 19.12 training; (4) possession of special nuclear material not authorized by the license; and ((5)-(7)) transportation of portable moisture density gauges without shipping papers, proper blocking and bracing, and availability of emergency response information.

Additionally, four concerns were identified during the inspection involving (1) a lack of managerial authority exercised by your Office of Radiation, Chemical, and Biological Safety (ORCBS) with regard to radiation safety activities at NSCL; (2) inadequate site specific radiation safety training at NSCL; (3) failure to perform audits for inactive users who may begin to use radioactive material already on hand without notifying ORCBS; and (4) inaccurate inventory of radioactive materials. Please ensure you address these concerns in your response.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

Michigan State University

4

May 3, 1993

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc/enclosure:
John D. Palmer, Director, ORCBS
James Camburn, Michigan Department
of Health

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Michigan State University
East Lansing, Michigan

Docket No. 030-00806
License No. 21-00021-29
EA 93-062

During an NRC inspection conducted on March 10-23, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. 10 CFR 20.207(b) requires that materials not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, as of February 26, 1993, licensed material consisting of 10 millicuries carbon-14 (unsealed, unlabeled target material) located in a storage cabinet at the National Superconducting Cyclotron Laboratory (NSCL), an unrestricted area, was not secured against unauthorized removal, and was not under constant surveillance and immediate control of the licensee.

- B. 10 CFR 20.203(f) requires that, except as provided by 10 CFR 20.203(f)(3), each container of specified amounts of licensed material bear a durable, clearly visible label identifying the radioactive contents.

Contrary to the above, as of February 26, 1993, a container containing 10 millicuries of carbon-14 did not bear any label identifying the radioactive contents and the container was not excepted from such labeling.

This is a Severity Level III problem (Supplement IV).
Civil Penalty - \$3,750.

II. Violations Not Assessed a Civil Penalty

- A. 10 CFR 30.50(b) requires, in part, that each licensee notify the NRC within 24 hours after the discovery of an unplanned contamination event that requires access to the contaminated area, by workers or the public, to be restricted for more than 24 hours by imposing additional radiological controls or by prohibiting entry into the area; involves a quantity of material greater than five times the lowest annual limit on intake specified in appendix B of paragraph §§20.1001-20.2401 of 10 CFR part 20 for the material; and has access to the area restricted for a reason other than to allow isotopes with a half-life of less than 24 hours to decay prior to decontamination. 10 CFR 30.50(c)(1) states that licensees shall make reports required by this section by telephone to the NRC Operations Center.

Contrary to the above, the licensee failed to report within 24 hours an unplanned contamination event that was discovered on March 9, 1993, and that met the above criteria. Specifically, the event was reported to the NRC Operations Center on March 12, 1993, a period in excess of 24 hours.

This is a Severity Level IV violation (Supplement VI).

- B. Condition 26 of License No. 21-00021-29 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in the application dated August 30, 1990, and a letter dated October 29, 1991 (excluding Appendices 1, 2, 3, and 4).

Item I.G. of letter dated October 29, 1991, titled "NRC Renewal Letter Response Michigan State University License No. 21-00021-29," requires that reviews of approvals by the committee will be conducted at the quarterly meetings for new users, high activity uses, or uses which present unusual safety concerns. Interim approval for radioisotope applications may be given by the Radiation Safety Officer, with the final approval given at the next meeting of the Radiation Safety Committee.

Contrary to the above, since December 18, 1991 (date of license renewal), review of approvals for new users were independently conducted by each committee member, instead of during the quarterly Radiation Safety Committee meetings.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 19.12 requires, in part, that all individuals working in a restricted area be instructed in the precautions and procedures to minimize exposure to radioactive materials, in the purpose and functions of protective devices employed, and in the applicable provisions of the Commission's regulations and licenses.

Contrary to the above, as of March 18, 1993, individuals who were working in restricted areas of the National Superconducting Cyclotron Laboratory had not been instructed in the applicable provisions of the regulations and the conditions of the license. Specifically, principal investigators, visiting scientists and laboratory workers who are not radiation workers, but who frequent restricted areas, have not completed the Office of Radiation, Chemical, and Biological Safety training session or an examination covering the basic topics required in 10 CFR 19.12.

This is a Severity Level IV violation (Supplement VI).

- D. Conditions 6, 7, and 8, of License No. 21-00021-29 limit the type, chemical form and amount of licensed material that may be possessed at any one time to the amount specified by the conditions.

Contrary to the above, since December 18, 1991 (date of license renewal), the licensee has possessed Special Nuclear Material uranium-235 (99.89% enriched) consisting of 300 milligrams uranium oxide which is not authorized by the license.

This is a Severity Level IV violation (Supplement VI).

- E. 10 CFR 71.5(a) requires that a licensee, who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.
 - 1. 49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200-203. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, since December 18, 1991 (date of license renewal), the licensee transported hazardous material consisting of Americium-241 and Cesium-137 in portable moisture density gauges outside the confines of its plant without shipping papers.

This is a Severity Level IV violation (Supplement V).

2. 49 CFR 177.842 requires, in part, that packages of radioactive materials be so blocked and braced that they cannot change position during conditions normally incident to transportation.

Contrary to the above, since December 18, 1991 (date of license renewal), the licensee has transported hazardous material consisting of Americium-241 and Cesium-137 in portable moisture density gauges outside the confines of its plant, and the packages were not blocked and braced such that the packages could not change position during conditions normally incident to transportation. Specifically, no blocking and bracing has been used by users of the gauges during transportation.

This is a Severity Level IV violation (Supplement V).

3. 49 CFR 172.600(c) requires that no person may offer for transportation a hazardous material unless emergency response information is immediately available for use at all times the hazardous material is present. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, since December 18, 1991 (date of license renewal), hazardous material consisting of Americium-241 and Cesium-137 in moisture/density gauges, has been transported without the immediate availability of emergency response information with the hazardous material. Specifically, no emergency response information accompanied the hazardous material during transportation.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Michigan State University (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement,

U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance is achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney

Notice of Violation

-6-

General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY
COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 3rd day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

MAY 7 1993

Docket No. 030-19809
License No. 45-21121-01
EA 93-061

Northern Virginia Endocrinologists
ATTN: Peter S. Ross, M.D.
3299 Woodburn Road, Suite 450
Annandale, Virginia 22003

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$500
(NRC INSPECTION REPORT NO. 45-21121-01/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. M. Fuller of this office on February 11, 1993, at your Annandale, Virginia facility. The inspection included a review of the activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. The report documenting this inspection was sent to you by letter dated March 11, 1993. As a result of this inspection, violations of NRC requirements were identified.

The violations in Part I of the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to: 1) provide a written directive and to verify the patient's identity by more than one method for medical administrations of iodine-131 in quantities between 30 microcuries and approximately 100 microcuries, and 2) instruct individuals using licensed materials under the supervision of an authorized user in the licensee's written quality management program (QMP).

These violations are of particular concern to the NRC because failure to provide a written directive and to verify the patient's identity by more than one means for medical administrations of iodine-131 greater than 30 microcuries could have resulted in the administration of byproduct material to a patient which was not directed by the authorized user. A medical misadministration could have occurred and possibly resulted in unnecessary radiation exposure to an individual. In addition, had you instructed all supervised individuals in your QMP they would have been aware that your policies and procedures for the QMP were applicable to all administrations of iodine-131 greater than 30 microcuries and would have noted that the procedures were not being followed. Therefore, the violations have been classified in the aggregate as a Severity Level III problem.

The staff recognizes that immediate corrective action was taken when the violations were identified such as implementing the QMP policies and procedures for therapeutic administrations of iodine-131 for diagnostic

MAY 7 1993

studies and providing prompt training on the new policy to the staff responsible for administering iodine-131 for diagnostic purposes.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, Severity Level III violations generally are considered for escalated enforcement action. Prior to taking escalated enforcement action, the NRC normally holds an enforcement conference to discuss the violations, their causes and safety significance, and the corrective actions to preclude recurrence. On March 29, 1993, the Enforcement Policy relative to enforcement conferences was discussed with you by telephone. Our letter dated March 30, 1993, documented the issues discussed during the phone call. During the March 29 phone call, and in your letter dated April 9, 1993, you agreed that the NRC had all the relevant information concerning the violation and that an NRC enforcement conference was not needed in this case.

To emphasize the importance of full implementation of your QMP, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$500 for the Severity Level III problem set forth in Part I of the Notice. The base value of a civil penalty for a Severity Level III problem is \$500.

The escalation and mitigation factors in the Enforcement Policy were considered. The base civil penalty was escalated 50 percent because the violations were identified by the NRC and mitigation of 50 percent was warranted because of your prior good performance. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, no adjustment to the base civil penalty has been deemed appropriate.

The violation cited in Part II of the Notice involved the disposal of licensed material in ordinary trash without holding the material for decay to a minimum of ten half-lives before disposal. Although the violation was categorized at Severity Level IV, it is a concern because of the implication associated with releasing radioactive material to unrestricted areas.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

MAY 7 1992

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebnetter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Northern Virginia Endocrinologists
Annandale, Virginia

Docket No. 030-19809.
License No. 45-21121-01
EA 93-061

During an NRC inspection conducted on February 11, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Assessed a Civil Penalty

- A. 10 CFR 35.32(a) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. 10 CFR 35.32(a) further requires that prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, and that the patient's identity is verified by more than one method as the individual named in the written directive.

As defined in 10 CFR 35.2, a written directive means an order in writing for a specific patient, dated, and signed by an authorized user prior to the administration of a radiopharmaceutical which includes the dosage and route of administration.

Contrary to the above, as of February 11, 1993, the licensee administered greater than 30 microcuries of sodium iodide I-131 for diagnostic studies to a patient, and prior to administration failed to prepare a written directive for the administration of the dose and to identify the patient by more than one method.

- B. 10 CFR 35.25(a)(1) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b) shall instruct the supervised individual in the licensee's written quality management program.

Contrary to the above, as of February 11, 1993, individuals under the supervision of the licensee's authorized user had not been instructed in the written quality management program as it pertains to the use of quantities of sodium iodide I-131 between 30 microcuries and approximately 100 microcuries.

This is a Severity Level III problem (Supplement VI).
Cumulative Civil Penalty - \$500 (assessed equally between the two violations.)

II. Violation Not Assessed a Civil Penalty

10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash, provided, in part, that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, as of February 11, 1993, the licensee routinely disposed of sodium iodide I-131 in ordinary trash without first holding this material for decay a minimum of ten half-lives.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Northern Virginia Endocrinologists (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia.

Dated at Atlanta, Georgia
this 7th day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

NOV 23 1991

Docket No. 030-31758
License No. 34-26201-01
EA 91-154

Randall C. Orem, D.O.
6900 Meeker Road
Dayton, Ohio 45414

Dear Dr. Orem:

SUBJECT: ORDER REVOKING LICENSE (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued to immediately revoke your license. This action is being taken pursuant to Section 186 of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2236) and 10 CFR 30.61(b) which provides, in part, that any license may be revoked because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission to refuse to grant a license on an original application.

In your application dated May 25, 1990, the description, status of completion, and location of your facility was inaccurate in material respects. It was only through efforts to schedule an inspection, over a year after the license was issued, that the NRC learned that your facility had not been constructed as described in your license application. You have not demonstrated the capability at the location identified in your license to receive and use licensed material. We discussed this matter with you on September 30, 1991. During that discussion you agreed to request termination of your license. We issued a Confirmatory Action Letter (CAL) to you on October 3, 1991, confirming that agreement. You responded to the CAL by letter dated October 20, 1991, but did not request license termination. Instead, you indicated that you intended to use your license as soon as you resolved the issue of office space. We discussed your October 20 letter with you on October 28, 1991, and again you agreed to request termination of your license. On November 4, 1991, however, you submitted a letter indicating that you no longer intend to voluntarily request termination of your license.

Please note that our investigation into this matter is continuing and further action may be taken following completion of that investigation. In that regard, we will not act on an application to amend the Piqua Memorial Hospital license to add you as an authorized user until the investigation is completed. As to your question concerning the fee that you paid on August 5, 1991, the

Randall C. Orem

- 2 -

fee was for the past fiscal year, during which you held an NRC license. If you desire to pursue that matter, contact Diane Dandois, the NRC Controller's office at 301-492-7558. Your FOIA request will be addressed by separate letter.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at (301) 492-0741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards and Operations Support

Enclosure: Order Revoking License
(Effective Immediately)

cc w/enclosure: DCD/DCB (RIDS)
State of Ohio

**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

**In the Matter of
Randall C. Orem, D.O.**

)
) **Docket No. 030-31758**
) **License No. 34-26201-01**
) **EA 91-154**

**ORDER REVOKING LICENSE
(EFFECTIVE IMMEDIATELY)**

I

Randall C. Orem, D.O. (Licensee) is the holder of Byproduct Material License No. 34-26201-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The license authorizes the possession and use of radiopharmaceuticals in nuclear medicine activities described in 10 CFR 35.200. The license, originally issued on August 21, 1990, is due to expire on October 31, 1995.

II

In an application dated May 25, 1990, Randall C. Orem, D.O., requested an NRC license to use any byproduct material identified in 10 CFR 35.200 for cardiovascular procedures. The location of use indicated in the application was 6900 Meeker Road, Dayton, Ohio. The application included a detailed drawing of a nuclear cardiology clinical facility and stated that the facility was being finished at that time. After review of the information provided in the application, including the Licensee's statement that an amendment would be requested prior to use of material if the final facility differed from the drawing in the application,

NRC License No. 34-26201-01 was issued to Randall C. Orem, D.O., on August 21, 1990.

On September 17, 1991, an NRC Region III inspector attempted to contact Dr. Orem by telephone to schedule an initial inspection of the licensee's activities. After unsuccessful efforts to contact Dr. Orem directly, the inspector was able to reach Dr. Orem through his consultant. In a September 17, 1991, telephone conversation with the inspector, Dr. Orem indicated that:

(1) the facility location referenced in his application was his personal residence; (2) the facility described in his application was never constructed; and (3) he had no plans to receive or use material at the residence listed in the license application.

On September 30, 1991, a subsequent telephone conference was conducted between NRC personnel and Dr. Orem. The NRC explained to Dr. Orem that the license had been issued on the basis of representations regarding the facility in which licensed activities would be conducted and must be terminated because the facility described in the license does not exist, and the location of use described in the license is a private residence without any provisions for receipt and use of licensed materials. Dr. Orem indicated that he understood the situation and agreed to submit a letter to the NRC requesting termination of the license within 20 days. On October 3, 1991, the NRC issued a Confirmatory Action Letter to Dr. Orem confirming his commitments

not to receive material at his residence and to request termination of his license within 20 days. In a letter to the NRC dated October 20, 1991 responding to the Confirmatory Action Letter, Dr. Orem did not request termination of his license, but stated that he did not intend to receive radioactive material at his personal residence unless he converted the location to an office, that he might instead acquire office space at another location, and that he intended to use the license as soon as the space issue was resolved. On October 28, 1991, this matter was again discussed with Dr. Orem and he committed to request termination of his license. However, in a letter to the NRC dated November 4, 1991, Dr. Orem stated that he would not voluntarily request termination of his license.

III

The Commission's regulations in 10 CFR 30.33(a)(2) require, in part, that an applicant for a specific license for byproduct material must demonstrate that the applicant's proposed equipment and facilities are adequate to protect health and minimize danger to life or property. Section 186 of the Atomic Energy Act and 10 CFR 30.61(b) provide, in part, that any license may be revoked because of conditions revealed by such application or statement of fact or any report, record or inspection or other means which would warrant the Commission's refusal to grant a license on an original application.

The NRC must be able to rely on the accuracy of information provided by applicants for licenses. The Licensee's inaccurate statements to the NRC in his original application regarding the description and status of completion of its facility, and location of use, are apparent violations of 10 CFR 30.9 of the Commission's regulations, which requires that information submitted by an applicant for a license be complete and accurate in all material respects. The NRC would not have issued a license to Dr. Orem had it known that the proposed place of use was a private residence with no adequate facility for the safe receipt, handling and use of licensed material.

Consequently, I lack the requisite reasonable assurance that licensed activities can be conducted under License No. 34-26201-01 in compliance with the Commission's requirements, and that the health and safety of the public will be protected if licensed activities under this license are permitted. Therefore, the public health, safety, and interest require that License No. 34-26201-01 be revoked. Furthermore, pursuant to 10 CFR 2.202 (56 FR 40664 (August 15, 1991)), I find that the public health, safety, and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 182 and 186 of

the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 34-26201-01 IS REVOKED.

V

In accordance with 10 CFR 2.202, the Licensee must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to the Order and the person so consenting is not required to include in its answer the matters set forth below. Otherwise, the answer shall specifically in writing, under oath or affirmation, admit or deny each allegation or charge made in the Order and set forth the matters of fact and law on which the Licensee or other person adversely affected relies and the reasons why the Order should not have been issued. Any answer filed within 20 days of the date of this Order may include a request for a hearing. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region III, 799

Roosevelt Road, Glen Ellyn, Illinois 60137, and to the Licensee if the answer or hearing request is by a person other than the Licensee. If a person other than the Licensee requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by the Licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for hearing, this Order shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr. Deputy Executive
Director for Nuclear Materials Safety,
Safeguards, and Operations Support

Dated at Rockville, Maryland
this 29 day of November 1991

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

'93 JUN -4 12 22

COMMISSIONERS:

Ivan Selin, Chairman
Kenneth C. Rogers
James R. Curtiss
Forrest J. Remick
E. Gail de Planque

SERVED JUN - 4 1993

In the matter of)

RANDALL C. OREM, D.O.)

(Byproduct Materials License)
No. 34-26201-01))

Docket No. 30-31758-EA

MEMORANDUM AND ORDER

CLI-93-14

I. Introduction

The Commission has under consideration the Atomic Safety and Licensing Board's approval of a settlement agreement between the Nuclear Regulatory Commission (NRC) staff and Dr. Randall C. Orem. See LBP-92-18, 36 NRC 93 (1992). The Commission previously issued an order in which we asked the NRC staff to provide additional information regarding its reasons for entering into a particular term of the agreement. CLI-92-15, 36 NRC 251, 252 (1992). The staff has responded to our order with an affidavit explaining the staff's position. The Commission has also received a "Board Notification" from the staff, docketed on March 29, 1993, that transmits the publicly available portions of

a report of the NRC's Office of Investigations on Dr. Orem and other individuals.¹ Upon consideration of these filings and the remaining record of the proceeding, the Commission has determined that it will not overturn the settlement agreement. The Commission is providing, however, guidance on certain matters of regulatory policy.

II. Background

The proceeding was initiated upon Dr. Orem's request for a hearing on an order to revoke Dr. Orem's byproduct materials license. See 56 Fed. Reg. 63,986 (Dec. 6, 1991). The order was signed by Hugh L. Thompson, Jr., the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, on behalf of the NRC staff. The staff issued the order after discovering about a year after granting the license that the facility described in Dr. Orem's license application as the place of possession and use of radioactive material had not been constructed and that the facility's address was that of his private residence. 56 Fed. Reg. 63,986 (Dec. 6, 1991). Dr. Orem had indicated in the facility drawing attached to his license

¹ Board Notification 93-05, Memorandum from R. M. Bernero, Director, Office of Nuclear Material Safety and Safeguards (NMSS), dated March 17, 1993. Pursuant to the Commission's Statement of Policy: Investigations, Inspections, and Adjudicatory Proceedings, 49 Fed. Reg. 36,032 (Sept. 13, 1984), we directed the staff on April 20, 1993, to provide the non-public portions of the report for our in camera review. Although we have examined this material, we have not relied on it nor would it materially change our decision.

application that the facility was "being finished at this time." The staff revoked the license on the basis that, had the NRC known that the proposed place of use of the byproduct material was a private residence without adequate provisions for the safe receipt, handling and use of licensed material, a license would not have been issued. Id. at 63,987.

Dr. Orem requested a hearing on the order, but he and the staff ultimately submitted a joint motion for approval of a settlement agreement, which the Licensing Board granted in LBP-92-18, 36 NRC 93 (1992). Under the agreement, Dr. Orem admitted no wrongdoing or violation of federal statutes and regulations. 36 NRC at 96. Dr. Orem has not contested the basic facts that the listed facility location was his personal residence and that the facility described in his application did not exist.

According to the settlement agreement, the NRC staff has decided not to take any further action against Dr. Orem. In addition, paragraph 4 of the agreement contains the following stipulation:

The NRC staff agrees that none of the facts associated with this proceeding will be held against him in the event Dr. Orem submits another application for a specific license on his own behalf or a license amendment application is submitted to name Dr. Orem as an authorized user. If such application is in compliance with the Atomic Energy Act and the Commission's regulations, such application shall be granted.

36 NRC at 96. In order to understand the staff's bases for entering the settlement, particularly in view of staff's position

and supporting documentation in the record that Dr. Orem had submitted false statements in his application, we asked the staff in CLI-92-15 to explain the "staff's reasons for agreeing not to pursue any further action against Dr. Orem, including its agreement not to hold the facts associated with this proceeding against Dr. Orem in the event that he submits another application for a license." 36 NRC at 252.

III. Staff's Bases for Settlement

The staff replied to the Commission's inquiry with an affidavit from Robert M. Bernero, the Director of NMSS. Mr. Bernero's affidavit affirms that the staff initially sought revocation of the license because Dr. Orem's application contained false information concerning the status of his facility. The affidavit emphasizes that the "key point on which the Order was based was that the proposed facility did not exist."² Mr. Bernero states that at some unidentified time

² Affidavit at 3. Mr. Bernero quotes a letter dated December 19, 1991, from James Lieberman, Director of the Office of Enforcement, to Dr. Orem that states --

The Order that was issued to revoke your license was not issued on the question of whether you would be using material at a later time or at a residence. The Order was issued because you indicated in the application that the facility described in the application was "being finished at this time" when in fact it was learned through further investigation that the facility was never started and, further, the location that you indicated in the application was a location at which there is no capability to receive and use licensed material.

after the order was issued, the materiality of the erroneous information was questioned. Although NMSS had originally concurred in the order, NMSS later concluded that a license could have been issued to Dr. Orem without the facility being complete. Affidavit at 3-4.

NMSS interprets 10 C.F.R. § 30.33(a)(2), which provides that a license will be issued if the applicant's "proposed equipment and facilities are adequate to protect health and minimize danger to life or property," as not requiring a completed facility before a license is granted as long as the licensee does not receive material prior to having "everything in place as specified in the application." Affidavit at 4. An NMSS policy directive attached to the affidavit states that the staff encourages applicants to delay completion of facilities and acquisition of equipment until after the staff's review is completed. See NMSS Policy and Guidance Directive FC 92-04; Issuance of New Licenses for Material Use Programs (Sept. 14, 1992) (Exhibit 2 to the Bernero Affidavit). The purpose of this interpretation is to prevent premature expenditure of resources by license applicants before NRC's safety review of an application is completed.

Mr. Bernero acknowledges that a residual question regarding Dr. Orem's integrity remained because of his indication that the facility was "being finished at this time," but NMSS could not conclude that "Dr. Orem deliberately made inaccurate statements

in the application to deceive the staff in order to obtain a license he would not otherwise obtain." Affidavit at 4-5. Staff saw no undue risk in allowing Dr. Orem to return to licensed activities, because any future application would be subject to the general guidance memorandum attached to the affidavit. The guidance memorandum provides general instructions to NMSS reviewers in handling applications for which facilities are not complete and prescribes limiting license conditions to prohibit acquisition of material prior to completion of facilities.

IV. Material Information under the Atomic Energy Act

Although we have chosen not to disturb the settlement agreement reached between Dr. Orem and the staff, the Commission is taking this opportunity to underscore the importance that we place on the completeness and accuracy of information submitted by applicants and licensees and to reiterate our longstanding interpretation of the concept of "material" information under the Atomic Energy Act. We cannot overstate the importance of a licensee's or an applicant's duty to provide the Commission with accurate information. As we noted in commenting on the obligation of reactor licensees,

In order to fulfill its regulatory obligations, NRC is dependent upon all of its licensees for accurate and timely information. Since licensees are directly in control of plant design, construction, operation, and maintenance, they are the first line of defense to ensure the safety of the public. NRC's role is one primarily of review and audit of licensee activities, recognizing that limited resources preclude 100 percent inspection.

Petition for Emergency and Remedial Action, CLI-78-6, 7 NRC 400, 418 (1978). These same principles are applicable to the regulation of radioactive materials licensees, perhaps even more so given the thousands of materials licenses for which the NRC is responsible. We expect no lesser standard of honesty from materials users: "Nothing less than candor is sufficient".

Hamlin Testing Laboratories, Inc., 2 AEC 423, 428 (1964), aff'd, 357 F.2d 632 (6th Cir. 1966).

The Commission addressed the concept of materiality of statements and omissions of information in our decision in Virginia Electric & Power Co., CLI-76-22, 4 NRC 480 (1976) ("VEPCO"), aff'd, 571 F.2d 1289 (4th Cir. 1978). In VEPCO, the Commission interpreted the term "material false statement" as used in Section 186a of the Atomic Energy Act, 42 U.S.C. § 2236(a). Although the Commission has since promulgated regulations as a primary means of enforcing the Commission's expectations regarding the accuracy of information submitted by applicants and licensees, these regulations do not diminish the basic concept of materiality established in VEPCO.¹ Under VEPCO, a statement is material if "a reasonable staff member should consider the information in question in doing his job"; i.e., "[m]ateriality depends upon whether information has a natural tendency or capability to influence a reasonable agency

¹ See, e.g., 10 C.F.R. § 30.9 (1992); Completeness and Accuracy of Information, Final Rule and Statement of Policy, 52 Fed. Reg. 49362, 49366 (Dec. 31, 1987).

expert". 4 NRC at 486, 491. This test is a common one for materiality and is comparable to the standard applied under the federal statute, 18 U.S.C. § 1001, that provides criminal sanctions for false statements made to agencies of the United States. See United States v. Lueben, 838 F.2d 751, 754 (5th Cir. 1988); Weinstock v. United States, 231 F.2d 699, 701-02 & n.6 (D.C. Cir. 1956); VEPCO, ALAB-324, 3 NRC 347, 358, aff'd, CLI-76-22, 4 NRC 480, 486 (1976). Moreover, the NRC need not rely on a false statement in order for it to be material. Whether a statement would have in fact induced the agency to grant an application has no bearing on materiality.⁴

Applying the standard to the circumstances before us, we conclude that the nature and status of the applicant's proposed facility are certainly material matters in a decision whether to grant a radioactive byproduct materials license. The physical attributes and capabilities of the facility have an obvious relationship to the NRC's licensing decision. Commission regulations governing issuance of licenses for possession and use

⁴ See, e.g., Lueben, 838 F.2d at 754-55 (whether false statements on loan application and related documents actually affected approval of government loan is not an issue under 18 U.S.C. § 1001); United States v. Lopez, 728 F.2d 1359, 1362 (11th Cir.), cert. denied, 469 U.S. 828 (1984) (although false priority dates on immigration applications would not have led to erroneous granting of applications, submission of falsehoods influenced agency's treatment of applications and was thereby material); United States v. McIntosh, 655 F.2d 80, 82-83 (5th Cir. 1981), cert. denied, 455 U.S. 948 (1982) (reliance on false statements in documents related to federally guaranteed loan unnecessary for statements to be material).

of radioactive byproduct material require a determination that the applicant's proposed facility is "adequate to protect health and minimize danger to life or property" before a license may be issued. 10 C.F.R. § 30.33(a)(2).

The status of the facility is also material. An applicant's statements about the status of a proposed facility may reveal or lead to questions concerning the technical qualifications of the applicant. Such statements may also affect the treatment given to a license application, because neither the Atomic Energy Act nor the Commission's regulations indicate that the NRC must issue a materials license to a person who is unlikely to be able to construct the required facilities or to undertake licensed activities for an extended period of time.

The NMSS guidance attached to Mr. Bernero's affidavit supports this analysis. According to the guidance, the staff reviewer should ascertain the status of the proposed facility and, if the applicant does not intend to complete the facility and begin using material within a year, the reviewer should request that the applicant explain why a license is being sought at that time. NMSS Directive FC 92-04, Enclosure 2, at 1. Even though license issuance is not precluded by the fact that facility construction has not begun, information about the status of the facility certainly has a capability of influencing the agency's review.

V. Commission Decision on the Settlement Agreement

The Commission has determined not to overturn the settlement agreement reached between the staff and Dr. Orem and approved by the Licensing Board. However, we had concerns about some aspects of the agreement. Although the staff had represented to the Licensing Board that a determination of willful misconduct or wrongdoing by Dr. Orem was beyond the scope of the instant proceeding,⁵ the staff stated in the agreement, for reasons not readily apparent, that it would forgo any further action against Dr. Orem and stipulated that the facts associated with the proceeding would not be held against him in any future licensing action. The agreement contains no acknowledgement by Dr. Orem of his obligation to ensure that information he provides to the NRC is accurate and complete.

Despite our reservations, we do not find the agreement on balance to be contrary to the public interest. Inasmuch as the original order sought termination of a license granted to a person who did not have appropriate facilities for the possession and use of radioactive material, this result is achieved under the agreement without further litigation. We note that the false statement appears to have been added gratuitously to the application by Dr. Orem's consultant. Although Dr. Orem's reliance on a consultant does not excuse him from responsibility

⁵ See generally Telephone Conference Transcript at 8-11 (Jan. 29, 1992) (remarks of staff counsel).

for the contents of the application, the circumstances surrounding the submission of the false statement do not appear so severe as to warrant Dr. Orem's disqualification from future licensing and, hence, disapproval of the settlement agreement. Once the license was issued, Dr. Orem apparently conducted himself consistently with the terms of the license and our regulations. He seems to have recognized that he could not procure licensed material without having completed the facility described in his application. Considering all these circumstances, we have decided to accede to the settlement agreement between the NRC staff and Dr. Orem.⁶

We caution Dr. Orem, however, that we expect him, as well as all applicants and licensees, to adhere to the standards of accuracy and completeness of information under our regulations in any future dealings with the Commission. Even if the applicant turns to a consultant to help prepare the license application, as was the case here, the applicant remains responsible for the contents of the application.

In conclusion, we are permitting the settlement agreement approved by the Licensing Board in LBP-92-18, 36 NRC 93 (1992), to take effect. The proceeding is hereby terminated.

⁶ Inasmuch as the agreement is between Dr. Orem and the NRC regulatory staff reporting through the NRC's Executive Director for Operations, the agreement has no effect on actions that may be brought as a result of investigations by the NRC's independent Inspector General under the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801 et seq. See generally 10 C.F.R. Part 13 (1993).

The Chairman and Commissioner Curtiss approve this order in part and disapprove it in part. The Chairman's and Commissioner Curtiss's dissenting views are attached.

It is so ORDERED.

For the Commission

Samuel J. Chilk
Secretary of the Commission

Dated at Rockville, Maryland,
this 4 day of June 1993.

Dissenting Views of Chairman Selin:

I would have disapproved the stipulation in the settlement agreement by which none of the facts associated with the proceeding would be held against Dr. Orem in future licensing actions. Although I do not suggest that further enforcement action should be taken against Dr. Orem or that he should be disqualified from future licensing, I believe the stipulation is an unnecessary and inappropriate concession for the proper resolution of this matter.

Dissenting Views of Commissioner Curtiss:

Based upon the facts of this case, it is clear, in my view, that Dr. Orem willfully submitted material false information in his application for a byproduct materials license. While I agree that Dr. Orem's actions in this regard do not justify disqualifying him from all future licensing, I do not agree that those actions should be wholly ignored if and when he again seeks authorization to engage in some NRC licensed activity. Material false statements are extremely serious matters; they warrant strong action and a clear message that applicants who make them, whether on their own or on the advice of some consultant, should expect to have that false statement taken into account by the agency with regard to any future licensed activity concerning that individual. Accordingly, I would reject Paragraph 4 of the settlement agreement (see LBP-92-18, 36 NRC 93 at 96) -- where the staff agrees to ignore the facts of this case in any future licensing action involving Dr. Orem -- and remand the agreement to the Licensing Board. While I realize that this would reopen the settlement question and possibly result in further litigation, I believe that the NRC must be free to take Dr. Orem's conduct in this case into account in any future licensing action that he may request.

UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

APR 02 1993

Docket Nos. 030-14669; 030-31687
License Nos. 34-18214-01; 34-18214-02G
EA 92-219

Overhoff Technology Corporation
Attn: Mario Overhoff, D.Sc.
President
1160 U.S. Route 50
Milford, OH 45150

Dear Dr. Overhoff:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$1,200 AND DEMAND FOR INFORMATION
(NRC INSPECTION REPORT NOS. 030-14669/92001(DRSS) AND
030-31687/92001(DRSS))

This refers to the routine safety inspection conducted at Overhoff Technology Corporation on October 29 and November 5, 1992. The report documenting the inspection was sent to you by letter dated December 14, 1992, and on January 12, 1993, an enforcement conference was conducted in the NRC Region III office. A copy of the enforcement conference summary report was sent to you on January 23, 1993.

The NRC has determined that 10 violations of NRC requirements occurred under the Byproduct Material License No. 34-18214-01 issued to Overhoff Technology Corporation. The violations, which are described in Section I of the enclosed Notice of Violation, include failure to: (1) maintain the quantity of licensed material possessed within authorized limits, and limit the use of licensed material to the uses authorized by the license; (2) secure licensed material against unauthorized removal; ((3) and (4)) post and use licensed material tracking sheets; (5) conduct weekly radiation level surveys and monthly contamination surveys; (6) notify the Radiation Safety Officer prior to the use of any radioactive material; ((7) and (8)) use remote handling equipment and shielding when working with sealed sources; (9) wear personnel monitoring equipment when using licensed material; and (10) make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the extremities and skin of the whole body.

Based on the results of our inspection and the enforcement conference, we find that, as President and Radiation Safety Officer, you have not provided sufficient management oversight of the radiation safety program to ensure that licensed materials are possessed and used in accordance with your license. You indicated during the inspection and again at the enforcement

conference that your main focus has been on the demonstration of devices and equipment manufactured by Overhoff and attending to other business matters. You also indicated during the enforcement conference that you should have complied with the NRC requirements realizing that the regulations are designed to protect you and your employees. In addition, you stated that many of the requirements are contained in the radiation safety manual that you wrote and to which you should have adhered; however, you also stated that you did not believe that adhering to all of them was warranted. You indicated during the inspection and again at the enforcement conference that the violations occurred, in part, from your lack of understanding concerning the requirements. For example, you were unsure as to when radiation surveys and wipe tests of work stations should be performed. Further, you indicated during the enforcement conference that the key to secure the radioactive material was not properly controlled and you suggested that your laziness was, in part, the reason for your failure to maintain proper control over the key, along with the thought that most employees could properly use the material.

The violations described in Section I of the enclosed Notice, taken collectively, represent a significant breakdown in the control of licensed activities at Overhoff Technology Corporation. As the RSO, you should have made more of an effort to achieve a thorough understanding of how to satisfy the NRC requirements and commitments you made in your license. Furthermore, as RSO and licensee manager, you did not assure that radioactive materials were properly controlled and that the RSO responsibilities were properly implemented under the terms of the NRC license and that sufficient time was devoted to those responsibilities. These facts and those discussed above demonstrate careless disregard for meeting regulatory requirements, which is the root cause of the violations in the enclosed Notice. Violations which demonstrate careless disregard towards compliance with NRC regulations and license requirements are of significant regulatory concern to the NRC. Further, because of your lack of control of radioactive materials, in that the radioactive materials were not properly secured from unauthorized use, an unauthorized employee used a strontium-90 source and could have received an extremity exposure in excess of regulatory limits. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations listed in the enclosed Notice are classified in the aggregate as a Severity Level II problem.

The NRC requires its licensees to comply with NRC regulations and the terms and conditions of the NRC license, especially those statements and representations related to its specific program to which the licensee commits to adhere. Overhoff Technology has

been a licensee for over ten years and should fully understand that it is expected to comply with all its license requirements. A licensee cannot choose not to follow certain requirements. If a licensee cannot meet a commitment required by a condition of the license, then the licensee can request relief by way of a license amendment.

We acknowledge your corrective actions presented at the enforcement conference, which included ceasing those activities not authorized by your license, safely storing those materials found to be unsecured during the inspection, and implementing and posting those forms required by your license. Although we allowed you additional time prior to the enforcement conference to perform a complete evaluation of your licensed program, and develop corrective actions and a regulatory improvement plan, as you had requested in your November 24, 1992 letter, your corrective actions were not of sufficient scope to demonstrate how you intended to avoid further violations. Furthermore, at the time of the conference, you had not conducted the required exposure evaluation required by 10 CFR 20.201(b) relative to Violation I.C. We also recognize, as stated in your February 2, 1993 letter, that you have the assistance of Ms. Shirley Small in reviewing your program in order to meet NRC requirements. You also indicated in your letter, that "it is absolutely not the case" that you stated during the enforcement conference that "you knew, or should have known the NRC requirements and license conditions and did not believe that adherence to all of them was warranted." Because the enforcement conference was not transcribed, it is not possible to reconstruct exactly what was said. However, we questioned all NRC participants and there was unanimous agreement that you did say that you were aware of the requirements since you prepared the manual, and that you did not believe that adherence to all of them was warranted.

In summary, to emphasize the need for adhering to NRC regulations, your license conditions and commitments, and to ensure effective management of the radiation safety program, I have decided to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1,200 for the Severity Level II problem. The base value of a civil penalty for a Severity Level II problem is \$800. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was escalated 50 percent for the identification factor because the NRC identified the violations. Your corrective actions were not of sufficient scope to warrant mitigation for the corrective action factor, as discussed above. The other factors in the Enforcement Policy were considered and no further adjustment to the base civil penalty was considered appropriate.

Based on the results of the NRC inspection and enforcement conference, the staff questions whether you are able to possess and use licensed material in accordance with NRC regulatory requirements without the benefit of a consultant health physicist. Based on your statements at the enforcement conference about the financial hardship associated with retaining a consultant health physicist, the staff also questions your financial ability to retain a consultant health physicist. Therefore, you are required to respond to the enclosed Demand for Information in accordance with the instructions provided therein. This information is necessary to determine whether to modify, suspend, or revoke your license.

Two violations not assessed a civil penalty and associated with License No. 34-18214-02G are described in Section II of the enclosed notice involving the failure to (1) provide required documents with devices distributed to generally licensed persons; and (2) properly package, mark, and label transported radioactive material. Since, following the enforcement conference, your consultant identified the failure to submit Material Transfer Reports, we are exercising discretion in accordance with Section VII.B.1 of the Enforcement Policy not to cite this violation.

Additionally, concerns were identified during the inspection regarding the inadequate implementation of your training program, and the use of equipment to analyze leak test samples, which equipment has not been demonstrated capable of detecting 0.005 microcurie of removable contamination. Please address these concerns in your response.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, and your response to the Demand for Information and the above concerns, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your responses will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice and Demand for Information are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Overhoff Technology
Corporation

5

Questions concerning this Notice and Demand for Information should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at (301) 504-2741.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosures:

1. Notice of Violation and Proposed
Imposition of Civil Penalty
2. Demand for Information

cc: James R. Williams
State of Ohio

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Overhoff Technology Corporation
Milford, Ohio

Docket No. 030-14669
Docket No. 030-31687
License No. 34-18214-01
License No. 34-18214-02G
EA 92-219

During an NRC inspection conducted on October 29 and November 5, 1992, violations of NRC requirements were identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violations Associated with License No. 34-18214-01 and Assessed a Civil Penalty

- A. 10 CFR 30.34(c) requires, in part, that each licensee confine his possession and use of byproduct materials to the locations and purposes authorized by the license.

Conditions 6.A., 7.A., 8.A., and 9.A. of License No. 34-18214-01 limit, among other things, the possession and use of hydrogen-3 to 1000 millicuries for research and development as defined in 30.4 of 10 CFR Part 30.

Contrary to the above, at various times between August 1985 and November 1992, the licensee possessed greater than the 1000 millicurie total possession limit permitted by the license. For example, on August 20, 1985, the licensee possessed 1940 millicuries of hydrogen-3 as tritium gas, and, as of April 20, 1988, possessed approximately 1070 millicuries. Further, on numerous occasions from approximately August 22, 1985, through November 5, 1992, the licensee used the tritium gas for calibration of tritium-in-air monitors commercially distributed by the licensee, an activity other than research and development as defined in 30.4 of 10 CFR Part 30.

- B. Condition 20 of License No. 34-18214-01, as contained in Amendment No. 10 dated June 29, 1990, requires, in part, that the licensee conduct its program in accordance with the statements, representations, and procedures contained in a letter dated November 23, 1983, and its enclosures.

1. Section III, "Radioactive Material Storage," of the licensee's radiation safety manual, dated October 1983, and referenced by the November 23, 1983, letter, requires that all radioactive materials be stored in a metal cabinet which is locked and labelled in accordance with 10 CFR 20.203(f).

10 CFR 20.207(a) requires that licensed materials stored in an unrestricted area be secured against unauthorized removal from the place of storage. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on October 29, 1992, licensed material, consisting of approximately 696 millicuries of hydrogen-3, 50 millicuries of strontium-90 and 250 millicuries of krypton-85 was not stored in a locked metal cabinet. Specifically, the licensed material was stored in the northeast corner of the licensee's facilities located at 1160 US Route 50, Milford, Ohio, an unrestricted area, and was not secured against unauthorized removal.

2. Section III, "Radioactive Material Storage," of the licensee's October 1983 radiation safety manual, referenced in the November 23, 1983, letter, requires that a radioactive material tracking sheet be maintained at the entrance to the radioactive material storage area, and any use of radioactive material be recorded on this sheet.

Contrary to the above, as of November 5, 1992, the licensee did not maintain a radioactive material tracking sheet at the entrance to the radioactive material storage area to record any use of radioactive material.

3. Section VIII, "Record Keeping," of the licensee's October 1983 radiation safety manual, referenced in the November 23, 1983, letter, requires that each radioactive item have a separate sheet detailing receipt, inspection, any special or periodic testing, transfer, and disposal of that item. The tracking sheet records radioactive material use, operation location, and personnel involved in any operation requiring the use of radioactive material.

Contrary to the above, as of November 5, 1992, the licensee did not maintain a separate sheet for each radioactive item recording radioactive material use, operation location, and personnel involved in any operation requiring the use of radioactive material.

4. Section V, "Radiation Protection Measures," of the licensee's October 1983 radiation safety manual, referenced in the November 23, 1983, letter, states that weekly radiation surveys are performed in the active working area and the most frequently used work station is wipe tested once each month, and a wipe test of a randomly chosen work station is performed at the same time.

Contrary to the above, from approximately July 12, 1988, through November 5, 1992, the licensee has not performed weekly radiation surveys in the active working areas and has not performed a wipe test in the most frequently used work station and of randomly chosen work stations once each month. Specifically, the licensee has conducted radiation surveys only on those occasions when sealed sources are used and has not conducted wipe tests of any work stations.

5. Section V, "Radiation Protection Measures," Item B, "Radioactive Material Handling Procedures," of the licensee's October 1983 radiation safety manual, referenced in the November 23, 1983, letter, states that prior to any radioactive material handling, the radiation safety officer must be notified.

Contrary to the above, on one occasion between September 5, 1992, and October 4, 1992, an individual handled a sealed source containing approximately 100 millicuries of strontium-90, and did not provide prior notice to the radiation safety officer.

6. Section V, "Radiation Protection Measures," Item B, "Radioactive Material Handling Procedures," of the licensee's October 1983 radiation safety manual, referenced in the November 23, 1983, letter, states that under no circumstances will any radioactive material be touched directly with fingers. Remote handling tools will be used.

Contrary to the above, on one occasion between September 5, 1992, and October 4, 1992, a licensee

employee handled a sealed source containing approximately 100 millicuries of strontium-90 with his fingers.

7. Section V, "Radiation Protection Measures," Item B, "Radioactive Material Handling Procedures," of the licensee's October 1983 radiation safety manual, referenced in the November 23, 1983, letter, states that appropriate shielding will be placed at the work station in such a manner as to reduce the exposure rate to a minimum when working with radioactive material.

Contrary to the above, on one occasion between September 5, 1992, and October 4, 1992, when a sealed source containing approximately 100 millicuries of strontium-90 was used, appropriate shielding was not placed at the work station to reduce the exposure rate to a minimum when working with radioactive material. Specifically, no shielding was placed at the work station.

8. Section II, "Personnel Safety," of the licensee's August 1983 sealed source handling procedures manual, referenced in the November 23, 1983, letter, states that all employees are required to wear film rings and film badges when in the work area.

Contrary to the above, on one occasion between September 5, 1992, and October 4, 1992, when an employee was in the work area and using a sealed source containing approximately 100 millicuries of strontium-90, he did not wear a film ring or film badge.

- C. 10 CFR 20.201(b) requires that each licensee make, or cause to be made, such surveys as may be necessary to comply with the requirements of Part 20 and which are reasonable under the circumstances to evaluate the extent of radiation hazards that may be present. As defined in 10 CFR 20.201(a), "survey" means an evaluation of the radiation hazards incident to the production, use, release, disposal, or presence of radioactive materials or other sources of radiation under a specific set of conditions.

Contrary to the above, as of November 5, 1992, the licensee did not make, or cause to be made, surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the extremities and skin of the whole body. Specifically, the licensee did

not evaluate the radiation exposure to the extremities and skin of the whole body of an individual who did not wear a ring and film badge when he used approximately 100 millicuries of strontium-90, as a sealed source, between September 5, 1992 and October 4, 1992. In addition, the licensee did not evaluate the radiation exposure to the extremities and skin of the whole body of the same individual, who used a sealed source containing an unknown quantity of radioactive material between July 5, 1990, and August 4, 1990, and whose assigned whole body personnel monitoring equipment measured a beta particle radiation exposure of 1960 millirems for that period.

This is a Severity Level II problem (Supplement VI).
Civil Penalty - \$1,200.

II. Violations Associated with License No. 34-18214-02G and Not Assessed a Civil Penalty

- A. Condition 13 of License No. 34-18214-02G dated January 14, 1992, requires that the licensee conduct its program in accordance with statements, representations and procedures contained in an application dated February 5, 1990 (with attachments).

Section V, "Documentation Accompanying the Transmission Gauge," of the licensee's February 5, 1990, application, states that the following documents are distributed with each gauge:

1. A leak test certificate from Overhoff Technology Corporation or from some other NRC or Agreement State approved organization authorized to perform leak testing services.
2. A radiation survey report documenting radiation measurements around the gauge.
3. Radiological safety instructions.
4. Operational manual.
5. A copy of the NRC regulations in 10 CFR 31.5 or the equivalent regulations of an Agreement State.

Contrary to the above, on October 29, 1992, the licensee distributed an Overhoff Technology Model 8100 transmission gauge, containing approximately 15 millicuries of strontium-90, to a recipient located in the State of Georgia, and none of the above documents was distributed with the gauge.

This is a repeat violation.

This is a Severity Level IV violation (Supplement VI).

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside the confines of its plant or other place of use, or delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.101 defines radioactive material as a hazardous material.

49 CFR 171.2(a) requires that no person offer or accept a hazardous material for transportation in commerce unless that material is properly classed, described, packaged, marked, labeled, and in condition for shipment as required by or authorized by 49 CFR Subchapter C - Hazardous Materials Regulations.

Contrary to the above, on October 29, 1992, the licensee transported an Overhoff Technology Model 8100 transmission gauge, containing approximately 15 millicuries of strontium-90, and the material was not packaged, marked and labeled as required by 49 CFR Subchapter C. Specifically, the material was not packaged in accordance with 49 CFR 173.411, marked in accordance with 49 CFR 172.301, and labeled in accordance with 49 CFR 172.403.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, Overhoff Technology Corporation (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violation, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the

Notice of Violation

- 7 -

authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the cumulative amount of the civil penalty proposed above, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

Dated at Rockville, Maryland
this 2nd day of April 1993

**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

In the Matter of	)	Docket No. 030-14669
	)	License No. 34-18214-01
OVERHOFF TECHNOLOGY CORPORATION	)	EA 92-219
Milford, Ohio	)	
	)	

DEMAND FOR INFORMATION

I

Overhoff Technology Corporation (Licensee) holds Byproduct Material License No. 34-18214-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 30. The license, originally issued on December 1, 1978, was last amended in its entirety January 4, 1993, and is due to expire on May 31, 1995.

II

A routine NRC inspection was conducted on October 29 and November 5, 1992. Additional information relevant to the inspection was obtained on November 24, 1992. During the inspection, the NRC inspector identified 10 violations which include failure to: (1) maintain the quantity of licensed material possessed within authorized limits, and limit the use of licensed material to the uses authorized by the license; (2) secure licensed material against unauthorized removal; ((3) and (4)) post and use licensed material tracking sheets; (5) conduct weekly radiation level surveys and monthly contamination surveys; (6) notify the Radiation Safety Officer prior to the use of any radioactive material; ((7) and (8)) use remote handling equipment and shielding when working with sealed sources; (9) wear personnel monitoring equipment when using licensed material; and (10) make surveys to assure compliance with that part of 10 CFR 20.101 that limits the radiation exposure to the extremities and skin of the whole body.

On January 12, 1993, an enforcement conference was conducted between the Licensee and NRC to discuss the apparent violations, their causes, the Licensee's corrective actions, and the Licensee's regulatory improvement plan. During discussions regarding root and contributing causes of the violations, the Licensee acknowledged that a lack of effective management oversight and control existed in the implementation of the Licensee's radiation safety program.

At the conference, the Licensee presented a regulatory improvement plan which it was considering. The plan included, but was not limited to, quarterly health physics surveys and comprehensive annual audits to be conducted by the consulting

health physicist. The plan also "suggested" that after the next NRC inspection, the consulting audits be conducted semi-annually.

In addition, Licensee responses to NRC questions indicated that the Licensee relied strongly on its consultant health physicist to achieve and maintain compliance with NRC requirements. This reliance appears sufficiently strong that without the benefit of a qualified consultant health physicist, it is questionable whether the Licensee could maintain compliance with NRC requirements.

The Licensee indicated that retaining the consultant health physicist has been a financial hardship. This financial hardship could result in the Licensee discontinuing the health physicist's consulting services.

Based on the results of the NRC inspection and enforcement conference, the staff questions whether there is reasonable assurance that the Licensee is able to possess and use licensed material in accordance with NRC requirements so as to protect the health and safety of its employees and the general public, without assistance from persons who are currently outside its organization and who are knowledgeable in the effective management of a licensed radiation safety program. Furthermore, based on the Licensee's statements at the enforcement conference, it is not clear whether the Licensee intends to continue to retain a consultant health physicist.

III

Accordingly, pursuant to sections 81, 161c, 161d, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.204, and 10 CFR 30.32(b), in order for the Commission to determine whether the license should be modified, suspended or revoked, or other enforcement action taken to ensure compliance with NRC regulatory requirements, the Licensee is required to submit to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, within 30 days of the date of this Demand for Information, the following information, in writing and under oath or affirmation:

- A(1) Whether it intends: (a) to utilize the services of a qualified independent consultant health physicist, for a period of three years from the date of this Demand, to perform quarterly health physics program reviews and an annual comprehensive audit at the end of the first year, however, the quarterly health physics reviews may be reduced to semi-annual reviews following NRC approval based on a satisfactory inspection after one year, and (b) to take prompt corrective action to address any deficiencies

identified by the consultant or document the basis for not taking such action;

- A(2) Whether it intends to submit to NRC 60 days prior to the end of the three-year period, a report stating what actions the licensee will take in the absence of a consultant to assure that the licensee and its employees understand Commission requirements and are following them; and
- A(3) Why NRC should not amend the license to require the actions provided in items A(1) and A(2) above.
- B. If it believes that Items A(1), A(2), and A(3) are unnecessary, explain why the NRC should have confidence that the licensee will maintain compliance with NRC requirements without an outside consultant and why Byproduct Material License No. 34-18214-01 should not be modified, suspended, or revoked.

Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address, and the Regional Administrator, NRC Region III, 799 Roosevelt Road, Glen Ellyn, Illinois 60137.

After reviewing your response, the NRC will determine whether further action is necessary to ensure compliance with regulatory requirements.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety,
Safeguards and Operations Support

Dated at Rockville, Maryland
this 2nd day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

March 29, 1993

Docket No. 030-05985
License No. 37-00276-25
EA 93-021

Mr. James E. Ahlberg
Chief Executive Officer
Professional Service Industries, Inc.
510 East 22nd Street
Lombard, Illinois 60148

Dear Mr. Ahlberg:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$7,500
(NRC Inspection Report No. 030-05985/93-001)

This letter refers to the special NRC safety inspection conducted on February 1-2, 1993, at the Medusa Cement Company in Wampum, Pennsylvania, and at your Pittsburgh Testing Laboratory Division office in Pittsburgh, Pennsylvania. The inspection report was sent to you on February 9, 1993. The inspection was conducted to review the circumstances associated with an event that occurred at the Wampum field site on January 17, 1993. The event involved two employees of the cement company walking unimpeded into a high radiation area at that location while your radiographer and radiographer's assistant had left the area for a period because of dusty conditions in the area. During the inspection, five violations of NRC requirements were identified. On March 16, 1993, an enforcement conference was conducted with Mr. Mark Weiland and other members of your staff to discuss the violations, their causes and your corrective actions. A copy of the Enforcement Conference Report is enclosed.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty. The most significant violation involved the failure to maintain direct surveillance of the high radiation area (HRA) so as to protect against any entry into the HRA. The HRA was created when radiography was performed, using a 42-curie uncollimated cobalt-60 source, on welds in a steel vessel at the location. While that HRA existed, two employees of the cement company walked into the radiation area and HRA without being noticed by the radiographer or his assistant. The individuals remained in the HRA for approximately 2.5 minutes, and each received radiation exposures estimated to be about 150 millirem.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The NRC is extremely concerned that the source was in the exposed position for approximately 20 minutes without the radiographer or radiographer's assistant being present. As a result of this lack of surveillance of the HRA, the potential existed for an even greater exposure to the two employees of the cement company had they gone closer to the source, or had they remained in the HRA for a longer period. This failure constitutes a significant violation of NRC requirements. The violation is classified at Severity Level III in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C (Enforcement Policy). The violation is set forth in Section I of the Notice. Four other violations classified at Severity level IV are set forth in Section II of the Notice.

One of the Severity Level IV violations involved the failure of the radiographer and radiographer's assistant to inform your Radiation Safety Officer of the incident once they became aware that the two individuals had entered the HRA. In fact, the RSO only became aware of the event nine days after being informed by the safety officer of the cement company who had discussions with the two employees. The NRC recognizes that you promptly informed the NRC of this event, even though such reporting was not required. Nonetheless, it is imperative that your radiation safety staff is promptly advised of such occurrences to ensure that they are promptly evaluated and effectively corrected to prevent recurrence.

The NRC also recognizes that subsequent to the inspection, actions were initiated to correct the violation and prevent recurrence. These actions, which were described during the inspection, in your letter to the NRC, dated February 26, 1993, and at the enforcement conference, included: (1) suspension of the radiographer and radiographer's assistant pending refresher training and recertification, as well as issuance of a letter of reprimand to the responsible radiographer; (2) conduct of an audit of the individuals in the field after they were permitted to resume activities following successful completion of the retraining and recertification process; (3) conduct of a meeting with all radiography staff to discuss, among other things, this event, as well as issuance of a notice describing the incident to all of your radiographers; and (4) plans to provide respirators to radiographers for dealing with dusty or otherwise degraded conditions.

Notwithstanding these corrective actions, to emphasize the importance of maintaining direct surveillance and access control over the high radiation area generated as a result of a radiographic operation, so as to prevent entry to these areas, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$7,500 for the violation set forth in Section I of the enclosed Notice.

The base civil penalty amount for a Severity Level III violation is \$5,000. The escalation and mitigation factors set forth in the enforcement policy were considered, and on balance, the penalty was increased by 50% because: (1) your corrective actions were considered prompt and comprehensive, and therefore, 50% mitigation of the penalty on this factor is warranted; (2) your past enforcement history with respect to the Pittsburgh facility has not been good, as evidenced by several civil penalties issued in the past, including a \$14,000 civil penalty imposed on May 9, 1991, and therefore, 100% escalation of the penalty on this factor is warranted. No credit for identification is provided since the issue was not identified until you were informed of the issue by the safety officer of the cement company. The other escalation/mitigation factors were considered and no further adjustment was deemed warranted.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC's Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition
of Civil Penalty
2. Enforcement Conference Report

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Professional Service Industries, Inc.
Pittsburgh, Pennsylvania 15220

Docket No. 030-05985
License No. 37-00276-25
EA 93-021

During an NRC inspection conducted on February 1-2, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed A Civil Penalty

10 CFR 34.41 requires that during each radiographic operation, the radiographer or radiographer's assistant maintain direct surveillance of the operation to protect against unauthorized entry into a high radiation area, as defined in 10 CFR Part 20, except where the high radiation area is equipped with a control device or alarm system, or locked.

Contrary to the above, on January 17, 1993, at a field site at the Medusa Cement Company in Wampum, Pennsylvania, neither the licensee radiographer nor the radiographer's assistant maintained direct surveillance over the radiographic operation to protect against entry into a high radiation area, and the high radiation area was not equipped with a control device, alarm system, or locked. Specifically, the radiographer did not maintain direct surveillance over the high radiation area created by a 42-curie cobalt-60 source at the No. 2 finish mill at the Medusa facility, in that the radiographer and radiographer's assistant left the building five minutes after the source was exposed and remained outside the building for approximately 20 minutes.

This is a Severity Level III violation. (Supplement VI)

Civil Penalty - \$7,500

II. Violations Not Assessed A Civil Penalty

- A. Condition 18 of License No. 37-00276-25 requires that licensed material be possessed and used in accordance with statements, representations and procedures contained in an application dated March 21, 1986.

Section 13.2.5 of the Operating and Emergency Procedures, which were contained in the application dated March 21, 1986, requires that the Radiation Safety Officer or Assistant Radiation Safety Officer be notified when an unauthorized entry is made into a restricted area.

Contrary to the above, from January 17, 1993 to January 26, 1993, the radiographer and radiographer's assistant failed to notify either the Radiation Safety Officer or the Assistant Radiation Safety Officer that two individuals made an unauthorized entry into the restricted area (High Radiation Area) at a job site at the Medusa Cement Company in Wampum, Pennsylvania. The Radiation Safety Officer was notified of the unauthorized entry into the restricted area by representatives of the Fuller Company and Medusa Cement Company on January 26, 1993.

This is a Severity Level IV violation. (Supplement VI)

- B. 10 CFR 34.42 requires, notwithstanding any provisions in 10 CFR 20.204(c), that areas in which radiography is being performed be conspicuously posted as required by 10 CFR 20.203(b) and (c)(1).

10 CFR 20.203(b) requires that each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION RADIATION AREA."

10 CFR 20.203(c)(1) requires that each high radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol and the words "CAUTION HIGH RADIATION AREA."

Contrary to the above, on January 17, 1993, during radiography performed at a job site at the Medusa Concrete Company in Wampum, Pennsylvania, the licensee did not conspicuously post the radiation area and the high radiation area in which industrial radiography was being performed.

This is a Severity Level IV violation. (Supplement IV)

C. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170-189.

1. 49 CFR 172.203(c)(2) requires that the letters "RQ" be entered on the shipping paper either before or after the basic description required for each hazardous substance. Pursuant to 49 CFR 172.101, radioactive material is classified as a hazardous material.

Contrary to the above, on January 17, 1993, a 42-curie cobalt-60 source, a hazardous material, was transported by the licensee and the letters "RQ" were not entered, either before or after the description, on the shipping paper that the licensee used to accompany the shipment.

This is a Severity Level IV violation. (Supplement V)

2. 49 CFR 172.324(b) requires, in part, for each package containing a hazardous substance, the letters "RQ" shall be marked on the package in association with the proper shipping name.

Contrary to the above, on January 17, 1993, a 42-curie cobalt-60 source, a hazardous material, was transported by the licensee in a package without the letters "RQ" marked on the shipping container.

This is a Severity Level IV violation. (Supplement V)

Pursuant to the provisions of 10 CFR 2.201, Professional Services Industries, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received with the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedures for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless comprised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 475 Allendale Road, King of Prussia, Pennsylvania 19406.

Dated at King of Prussia, Pennsylvania
this 29th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MAR 09 1993

Docket No. 030-32493
License No. 29-28685-01
EA 93-041

Radiation Oncology Center at Marlton
ATTN: Carolyn Horowitz, M.D., Ph.D.
Radiation Safety Officer
750 Route 73 South
Willow Ridge Suite 401
Marlton, New Jersey 08053

Dear Dr. Horowitz:

SUBJECT: CONFIRMATORY ORDER MODIFYING LICENSE (EFFECTIVE
IMMEDIATELY)

The enclosed Order is being issued as a result of apparent violations of NRC requirements related to the implementation of your radiological safety program. This Order follows a Confirmatory Action Letter (CAL No. 1-93-002) issued to you by NRC on February 5, 1993. You agreed to the issuance of the Order in a March 5, 1993 telephone conversation with Mr. Richard Cooper and Ms. Pamela Henderson of the NRC Region I Office.

Under the terms of the Order, you may not receive or use any NRC-licensed material pending further action by the NRC.

Questions concerning this Order may be addressed to James Lieberman, Director, Office of Enforcement at telephone number 301-504-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, the enclosure, and your response will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosure: As Stated

cc w/enclosure:
Jill Lipoti, Ph.D.,
Assistant Director for
Radiation Protection Programs
Division of Environmental Quality
Department of Environmental Protection
CN415
Trenton, New Jersey 08625-0415

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket No. 030-32493
RADIATION ONCOLOGY CENTER	)	License No. 29-28685-01
AT MARLTON	)	EA 93-041
Marlton, New Jersey	)	

CONFIRMATORY ORDER MODIFYING LICENSE
(EFFECTIVE IMMEDIATELY)

I

Radiation Oncology Center at Marlton (licensee) is the holder of NRC License No. 29-28685-01 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Parts 30 and 35. The license authorizes the licensee to possess iridium-192 sealed sources for use in an Omnitron International, Inc. Model 2000 high dose rate (HDR) after-loading brachytherapy unit (HDR) for the treatment of humans. The license initially was issued on January 17, 1992, and is due to expire on January 31, 1997.

II

NRC Region I staff conducted a routine safety inspection of the subject license on February 2 and 4, 1993. During this inspection, apparent violations of NRC requirements related to the implementation of the licensee's radiological safety program were identified. Of particular concern to the NRC was the lack of radiation safety program oversight by the Radiation Safety Officer (RSO) in discharging her licensed responsibilities and the lack of knowledge demonstrated by the RSO/Authorized User and her staff of the license conditions and the routine and emergency

operation of the HDR. The inspectors also determined that the iridium-192 source authorized under the NRC license was removed from the licensee's HDR unit by the manufacturer on February 2, 1993 and subsequently returned to the manufacturer for disposal on February 3, 1993.

III

As a result of concerns expressed by NRC Region I officials over the apparent violations, the licensee agreed to certain actions. By a confirmatory action letter (CAL) dated February 5, 1993, from Richard W. Cooper, II, Director, Division of Radiation Safety and Safeguards, NRC, Region I, to the licensee, the NRC confirmed that the licensee had agreed that:

1. It would not obtain any sources of radioactive material authorized under its license until specifically authorized in writing by the Director, Division of Radiation Safety and Safeguards, NRC, Region I.
2. By February 10, 1993, it would provide the NRC Region I office with a complete printout of the operational data stored in its Omnitron Model 2000 HDR computer memory, including error messages, and a written explanation for each individual code. In addition, by February 18, 1993, the licensee would submit to the NRC Region I office a report

that assessed, for each patient treatment that it had performed using the HDR, whether a misadministration had occurred. In making this determination, the licensee, as a minimum, would compare the HDR computer data with the written patient prescription and calculated doses.

3. It would take actions required by 10 CFR Part 35, including reporting and notification, if its review revealed that a misadministration had occurred.

The CAL provided that the issuance of the CAL did not preclude the issuance of an order formalizing the above commitments.

By letter dated February 9, 1993, the licensee reaffirmed its commitment not to receive any radioactive sources without authorization from Region I and submitted a printout of the operational data stored in its Omnitron Model 2000 HDR computer memory, including error messages, and a written explanation for each individual code. The licensee also stated that an audit of all treatments conducted at its facility would begin on February 12, 1993, and that the results of this audit, including any misadministrations identified, would be forwarded to the NRC. By letter dated February 12, 1993, the licensee submitted the results of the February 12, 1993 audit, concluding that they had

no misadministrations. Both submittals required by Item 2 of the CAL have been received and are under staff review. The licensee also satisfied Item 3.

I find that the licensee's commitment as set forth in Item 1 of the February 5, 1993 letter is still necessary and conclude that with adherence to this commitment, the public health and safety is reasonably assured. For the reasons described above, I have determined that the public health and safety require that the licensee's commitment as set forth in Item 1 of the February 5, 1993 CAL be confirmed by this Order. Pursuant to 10 CFR 2.202, I have also determined that the public health and safety require that this Order be immediately effective. The licensee consented to the issuance of this Confirmatory Order during a March 5, 1993 telephone call between Mr. Richard Cooper and Ms. Pamela Henderson of the NRC Region I Office and Dr. Horowitz, Radiation Safety Officer, acting on behalf of the licensee.

IV

Accordingly, pursuant to sections 81, 161b, 161i, 161o, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202 and 10 CFR Parts 30 and 35, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT LICENSE NO. 29-28685-01 IS MODIFIED AS FOLLOWS:

Pending further action by the NRC: (1) any NRC-licensed material possessed by the licensee shall be placed and maintained in a locked, stored, and shielded condition; and (2) the licensee may not receive any NRC-licensed material. All other requirements of the license continue in force.

The Regional Administrator, Region I, may relax or rescind, in writing, the above condition upon a showing by the licensee of good cause.

V

Any person adversely affected by this Confirmatory Order, other than the licensee, may request a hearing within 20 days of its issuance. Any request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, ATTN: Chief, Docketing and Service Section, Washington, D.C. 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region I, 475 Allendale Road, King of Prussia, PA 19406, and to the licensee. If such a person requests a hearing, that person shall set forth

with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Confirmatory Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), 57 Fed. Reg. 20194 (May 12, 1992), any person other than the licensee adversely affected by this Order, may, in addition to demanding a hearing, at the time the hearing request is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. AN

ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE
EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 9th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011 8084

MAR 25 1993

Docket No. 40-8027
License No. SUB-1010
EA 93-010

Sequoyah Fuels Corporation
(Subsidiary of General Atomics)
ATTN: James J. Sheppard, President
P.O. Box 610
Gore, Oklahoma 74435

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$18,000 (NRC INSPECTION REPORTS 92-30, 92-31 AND 92-32)

This is in reference to NRC inspections related to a November 17, 1992, nitrogen dioxide release from the Sequoyah Fuels Corporation (SFC) Sequoyah Facility in Gore, Oklahoma. Inspection reports describing the circumstances surrounding this event, SFC's corrective actions following the event, and apparent violations of NRC requirements were issued on December 18, 1992; January 21, 1993; and January 29, 1993, respectively. The apparent violations identified during these inspections were discussed with you and other SFC representatives at a March 2, 1993, public enforcement conference in the NRC's Arlington, Texas office. Subsequent to the enforcement conference, SFC provided additional information regarding two issues that were discussed at the conference: personnel accountability and the possible health consequences of the November 17, 1992 release. This information was provided to the NRC in a letter dated March 10, 1993.

The circumstances surrounding the November 17, 1992, event are described in detail in the NRC's December 18, 1992, Augmented Inspection Team (AIT) report. In brief, approximately 23,000 cubic feet of nitrogen dioxide were released from the facility to the environment when nitric acid was added to a digester tank which was believed to have been empty but which contained approximately 8,800 pounds of uranium concentrate. The nitrogen dioxide gas, which was released from the facility over a period of approximately 20 minutes and was dispersed as it traveled in a northwesterly direction, effected facility workers and members of the public in the vicinity of the facility who were exposed to the release. These effects included upper respiratory and eye irritation that, in some cases, lasted for several days. In addition, nitrogen dioxide entered the facility's control room, forcing control room personnel to don respiratory equipment during their response to the emergency.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

The November 17th event was caused, in part, by a failure to adhere to facility procedures requiring that operators ensure the closure of a slide gate valve between the uranium concentrate feed transfer conveyer and a previously used digester tank if a different digester is being placed in service. This failure, which violated a caution statement in the procedure governing this type of operation, permitted uranium concentrate to be inadvertently added to the wrong digester. When nitric acid was added to this digester, an uncontrolled reaction occurred and resulted in the production and release of nitrogen dioxide.

The NRC's inspections also found that other circumstances had contributed to the occurrence of this event. First, the slide gate valve to the digester was essentially inoperable, i.e., it was stuck open, and had not been functioning properly for weeks prior to the event. Although the operators and some supervisors knew of this fact, they failed to inform the Area Manager or initiate a work request to repair the valve. Secondly, the problems with the fume scrubber ejector system on the digestors had caused operators to adopt a practice of starting and stopping the feed transfer conveyer in order to control the chemical reaction. This practice increased the probability that operators would run the conveyer in the wrong direction and add uranium concentrate to the wrong digester, which is what happened in this instance. Finally, SFC failed to take adequate corrective action to resolve deficiencies with the control room ventilation system, following a fluorine intrusion event on June 27, 1992. Though a deficiency report was generated and assigned to engineering for implementation of corrective measures, those measures were insufficient to prevent the intrusion of nitrogen dioxide during the November 17, 1992, event. This is a particular concern because the operations staff had been aware of other gaseous releases that were first detected in the control room.

The violations of NRC requirements and SFC license conditions associated with this event are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violation in Section I concerns the failure to adhere to a caution statement in a facility procedure that required operators to locally ensure the closure of a slide gate valve to a digester. This failure was the direct cause of the nitrogen dioxide gas release. The violations in Section II involve: a failure to ensure that the control room was sealed to prevent the intrusion of contaminants from the process facility during an emergency (Violation II.A); a failure to ensure that all individuals were accounted for following an evacuation of the facility (Violation II.B); a failure of some facility personnel to don appropriate respiratory protective equipment in responding to the emergency (Violation II.C); and a failure to utilize the air horn system in conjunction with the public address system to alert personnel of the emergency (Violation II.D). Each of the violations in Section II had the potential for significant injury or loss of life to site personnel, had conditions (such as wind direction) been slightly different.

During the enforcement conference, you disputed a sixth potential violation involving the classification of the emergency condition. At issue was your guidance that did not adequately address the classification of events involving non-radioactive hazardous materials. However, this item is not being cited because it did not affect the facility's overall response, as the actions that would have been triggered by the classification had already been initiated, and additional guidance was subsequently issued. In addition, during the enforcement conference, you disputed Violation II.C. This violation is being cited because, although you could account for everyone responding to the emergency, the facility's accountability system could not account for all other personnel, i.e., those at the assembly area, because the data was not kept up-to-date.

The regulatory significance that NRC attaches to the violations surrounding this event is increased by the fact that facility operations continued despite the licensee's knowledge of the equipment problems discussed above. SFC management had not provided operators adequate guidance regarding the continuation of facility operations with equipment that was inoperable or malfunctioning. In addition, SFC's efforts to improve adherence to procedures, which has been a recurring problem at the facility, were not effective in this instance. In effect, the entire system of physical and administrative controls that were intended to prevent a significant release of nitrogen dioxide from the digestors failed in this instance.

The failure to (1) follow operating procedures that resulted in the release of toxic gas that had the potential for significant injury or loss of life to site personnel or the general public, and (2) adequately implement all portions of the facility Contingency Plan during an actual emergency is a very significant regulatory concern. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, 57 FR 5791 (February 18, 1992), the violations that led to this event and increased the potential for significant personnel injury have been classified at Severity Level II.

The NRC recognizes that SFC took both immediate and long-term corrective action to restore compliance with license conditions and to resolve the deficiencies revealed by this event. These actions included the resolution of equipment problems, the development of procedures governing facility operations with inoperable equipment and additional training of facility personnel. The NRC issued a Confirmatory Action Letter (CAL) on November 18, 1992, confirming SFC's commitment to delay facility operations until it completed investigations of the event and received the NRC's concurrence on restart. On November 23, 1992, SFC announced that it would not resume operation of the uranium hexafluoride (UF₆) facility and that it would operate the depleted uranium tetrafluoride (DUF₄) facility only until SFC's current contractual obligations were fulfilled. On December 23, 1992, based on inspections to confirm SFC's completion of its corrective action plan, the NRC authorized SFC to resume operations of the DUF₄ facility.

To emphasize the importance of ensuring compliance with requirements that are designed to protect the safety of facility employees and the general public, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$18,000 for the Severity Level II problem described above and in the Notice. The base value of a civil penalty for a Severity Level II problem is \$8,000. The civil penalty adjustment factors in the Enforcement Policy were considered, as discussed below.

The base civil penalty was neither escalated nor mitigated for the identification factor as the violations were identified as the result of a self-disclosing event. After considering SFC's corrective actions, as discussed above, the base civil penalty was mitigated 50 percent. The base civil penalty was escalated 75 percent due to SFC's poor past performance. The full 100 percent escalation was not applied for this factor in recognition of the significant improvements recently implemented in other areas of SFC's operation. In addition, the fact that SFC had knowledge of equipment problems that, if corrected, might have precluded this event, warranted an additional escalation of 100 percent. The other factors were considered and no further adjustments were considered warranted. Therefore, the base civil penalty was escalated a total of 125 percent.

In developing this enforcement action, the NRC considered the pending changes to the status of the SFC facility, as discussed above. Notwithstanding those changes, SFC will still be involved with licensed activities into the foreseeable future that include operation of the DUF4 facility and long term decommissioning activities. Therefore, broad enforcement discretion was not exercised in order to emphasize the continuing responsibility of SFC to comply with all aspects of the NRC's requirements while engaged in those licensed activities.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:
Notice of Violation and Proposed Imposition
of Civil Penalty

cc:
Oklahoma Radiation Control Program Director

Diane Curran, Esq.
Harmon, Curran & Tousley
201 S Street, N.W., Suite 430
Washington, D.C. 20009

Brita Haugland-Cantrell, Esq.
2300 North Lincoln Boulevard
112 State Capitol Building
Oklahoma City, Oklahoma 73105-4894

James Wilcoxon, Esq.
Wilcoxon & Wilcoxon
Attorney for Cherokee Nation
P.O. Box 357
Muskogee, Oklahoma 74402-0357

Newman & Holtzinger, P.C.
ATTN: Maurice Axelrad
1615 L Street, N.W.
Suite 1000
Washington, D.C. 20036

General Atomics
ATTN: R.N. Rademacher
Vice President
Human Resources
P.O. Box 85608
San Diego, California 92138

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Sequoyah Fuels Corporation
Sequoyah Facility
Gore, Oklahoma

Docket No. 40-8027
License No. SUB-1010
EA 93-010

During NRC inspections conducted on December 28, 1992, through January 12, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- I. License Condition 9 of NRC License SUB-1010 authorizes use of licensed materials in accordance with the statements, representations, and conditions contained in Chapters 1 through 8 of the license renewal application dated August 23, 1985, as supplemented. Section 2.7.1 in Chapter 2 of this license renewal application, as supplemented, states, in part, that it shall be the responsibility of the Licensee to see that written operating procedures are established, maintained, and adhered to for all operations and safety-related activities involving source or hazardous materials. A caution statement in Section 4.2.2 of Operating Procedure N-230-1, "Digestion of Yellowcake and Transfer of Slurry," instructs operators to locally ensure that the slide gate valve to a previously used digester is closed if the digester to be placed in service is not the same as the one used to mix the most recent batch.

Contrary to the above, the Licensee did not see that written operating procedures were adhered to for all operations and safety-related activities involving source and hazardous material. Specifically, on November 16 and 17, 1992, SFC operators did not ensure that the slide gate valve to Digestion Tank No. 2, which had previously been used, was closed prior to mixing batches in two different digester tanks.

- II. License Condition 9 of NRC License SUB-1010 authorizes use of licensed materials in accordance with the statements, representations, and conditions contained in Chapters 1 through 8 of the license renewal application dated August 23, 1985, as supplemented. Chapter 8 of the license renewal application states that the Licensee shall implement, maintain, and execute the response measures of the Radiological Contingency Plan submitted to the Commission on August 20, 1986, as supplemented. Further, Chapter 8 states that the Sequoyah Facility Contingency Plan interfaces with several related Contingency documents, particularly the Contingency Plan Implementing Procedures (CPIPs). The detailed instructions for implementation and support of the contingency plan are contained in the CPIP procedures.
 - A. Section 6.1.1 of the Contingency Plan states that the control room is sealed to prevent entry of external contamination from the process area.

Contrary to the above, on November 17, 1992, the control room was not sealed to prevent entry of external contamination from the process area. Specifically, contaminated air was recirculated into the control room from outside the main process building and from the process areas through an air intake and recirculation plenum that was not sealed from potentially contaminated process areas.

- B. Section 4.2.3 of CPIP-22, "Onsite Emergency Monitoring", requires, in part, that monitoring personnel don protective clothing and/or respirators to provide protection equal to or greater than the anticipated hazard.

Contrary to the above, during the November 17, 1992, event, a health & safety technician entered a visibly hazy room (the in-plant H&S office) containing nitrogen dioxide gas without donning any respiratory protection equipment. In addition, another health & safety technician partly entered into another visibly hazy room (the in-plant break room) containing nitrogen dioxide gas without donning any respiratory protection equipment. Measurements of this second area later indicated that airborne concentrations of nitrogen dioxide were above a level that was immediately dangerous to life and health. Rooms that are visibly hazy with nitrogen dioxide gas indicate a hazard that requires respiratory protective equipment.

- C. Section 5.4.2 of the Contingency Plan states that all persons responding to the emergency will be accounted for by the Onsite Emergency Director. All others will be accounted for at the Assembly & Support Center (ASC).

Contrary to the above, on November 17, 1992, the licensee did not and could not account for all personnel who were required to report to the ASC prior to releasing them after the Site Emergency was terminated.

- D. Section 6.3.1 of the Contingency Plan states, in part, that the facility public address system is used in conjunction with the air horn signal system to alert employees and direct them away from hazardous areas. Section 6.3.1 further states that these two systems comprise the onsite emergency notification system and that the air horn signal alerts personnel to an emergency condition.

Contrary to the above, on November 17, 1992, the air horn signal was not sounded upon the declaration of an Unusual Event, an emergency condition as described in the Contingency Plan.

Violations I and II.A through D are a Severity Level II problem
(Supplements VI and VIII).
Civil Penalty - \$18,000

Pursuant to the provisions of 10 CFR 2.201, Sequoyah Fuels Corporation (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved.

If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violations listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g.,

citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Dated at Arlington, Texas
this 25th day of March 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8084

FEB 9 1992

Docket No. 030-32768
License No. 49-27434-01
EA 93-001

Southwest X-Ray Corporation
ATTN: M. McIntire
P.O. Box 24
Rock Springs, Wyoming 82902

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$2,500 (NRC INSPECTION REPORT NO. 030-32768/91-01)

This is in reference to the inspection conducted on October 22, 1991, at Southwest X-Ray Corporation's Rock Springs, Wyoming, field office. This inspection, which was documented in a report issued December 4, 1991, found one violation of NRC requirements, the failure to wear alarm ratemeters during the performance of industrial radiography. In a letter dated March 18, 1993, the NRC informed you that the circumstances surrounding this violation had been reviewed by the NRC's Office of Investigations (OI) to determine whether the violation was committed willfully and that OI's investigation had not produced sufficient evidence to support such a conclusion. On April 2, 1993, you attended an enforcement conference in the NRC's Arlington, Texas office to discuss this violation.

Since January 10, 1991, the NRC has required in 10 CFR 34.33(a) that alarm ratemeters be worn by radiography personnel at all times during radiographic operations. This requirement, which calls for the use of ratemeters that will emit an audible alarm in high radiation fields, was developed to prevent inadvertent and unnecessary exposure to high radiation levels and was based on the NRC's conclusion that most radiation incidents involving radiography activities would be prevented by the use of such devices. Based on the information developed during the inspection and investigation, and the discussions that took place during the enforcement conference, Southwest X-Ray Corporation was in violation of this important requirement from January 10, 1991, until the date of the inspection in October 1991.

Although you apparently were confused about the effective date of the requirement at the time of the NRC's inspection, the radiation safety officer for Southwest X-Ray Corporation at that time indicated to the investigator that the company had received in its Little Rock, Arkansas office, copies of the NRC's correspondence informing licensees of this requirement. Thus, Southwest X-Ray Corporation had notice but failed to comply.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C,

APR - 9 1993

Southwest X-Ray Corporation

- 2 -

Southwest X-Ray Corporation's failure to ensure that radiography personnel wore alarm ratemeters at all times during radiographic operations has been categorized at Severity Level III.

The NRC recognizes that you took immediate actions to come into compliance with this requirement following the inspection. You agreed to suspend radiographic operations on October 22, 1991, and did not resume radiographic operations until the following day, when you obtained alarm ratemeters and provided them to all radiography personnel. An NRC inspection in February 1993 confirmed that you have been complying with this requirement and other NRC requirements since that time.

To emphasize the importance of maintaining an awareness of and complying with all NRC requirements, particularly those that are designed to ensure the safety of radiography personnel and the public, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$2,500 for the Severity Level III violation described above and in the Notice.

The base value of a civil penalty for a Severity Level III violation is \$5,000. The civil penalty adjustment factors in the Enforcement Policy were considered and resulted in a net \$2,500 decrease. In making this decision, the NRC determined: 1) that a 50-percent increase was warranted because this violation was discovered by the NRC, not as the result of audits conducted by Southwest X-Ray Corporation; 2) that a 50-percent decrease was warranted for your corrective actions; 3) that a 100-percent decrease was warranted because this violation is inconsistent with Southwest X-Ray Corporation's compliance history; and 4) that a 50-percent increase was warranted because Southwest X-Ray Corporation had prior notice of this requirement.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

APR - 9 1993

Southwest X-Ray Corporation

- 3 -

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosure:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. Enforcement conference attendance list

cc: State of Wyoming

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Southwest X-Ray Corporation
Rock Springs, Wyoming

Docket 030-32768
License 49-27434-01
EA 93-001

During an NRC inspection conducted on October 22, 1991, a violation of NRC requirements was identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

10 CFR 34.33(a) requires that the licensee not permit any individual to act as a radiographer or a radiographer's assistant unless at all times during radiographic operations, the individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD).

Contrary to the above, on numerous occasions between January 10, 1991, and October 22, 1991, a licensee radiographer did not wear an alarm ratemeter while conducting radiographic operations.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$2,500

Pursuant to the provisions of 10 CFR 2.201, Southwest X-Ray Corporation (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear

Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas, 76011.

Dated at Arlington, Texas
this 9th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
700 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5927

MAR 30 1993

General License
[10 CFR 150.20]
EA 93-048

Standard Nuclear Consultants, Ltd.
ATTN: James Mikowski
Radiation Safety Officer
1 S 016 Donny Hill Road
Elburn, Illinois 60119

Dear Mr. Mikowski:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTY - \$ 500 (INSPECTION REPORT NO. 999-90003/93004)

This refers to the special safety inspection, authorized by 10 CFR 150.20, conducted on February 19, 1993, to review your licensed activities in NRC non-Agreement States. The report documenting this inspection was mailed to you by letter, dated March 5, 1993. A significant violation of NRC requirements was identified during the inspection, and on March 18, 1993, an enforcement conference was held with you in the Region III office.

Through an inspection at an NRC licensed facility, the NRC learned that Standard Nuclear Consultants, Ltd., an Agreement State licensee, was performing licensed activities (e.g. survey instrument calibration, leak tests, source exchanges) in non-Agreement States and had not complied with the reciprocity requirements of 10 CFR 150.20. Specifically, Standard Nuclear Consultants, Ltd., failed to provide proper notification to the NRC that it was performing licensed work in non-Agreement States. NRC inspectors subsequently contacted you and explained the requirements of 10 CFR 150.20. By letter, dated February 23, 1993, you informed the NRC of the number of occasions that licensed activities were performed in non-Agreement States without notifying the NRC (98 times in 1992; 87 times in 1991; and 16 times during November and December 1990), after you terminated your specific NRC Byproduct Material License in October 1990. The violation of 10 CFR 150.20 is described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) and is categorized at Severity Level III in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C.

The root cause of the violation and the subsequent corrective action were discussed during the March 18, 1992, enforcement conference. The major factor contributing to the violation

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

appeared to be your misunderstanding of the conditions of your State of Illinois specific license pertaining to temporary job sites and the reciprocity process. The NRC recognizes that you immediately corrected the violation and that you plan to inform the NRC of regularly scheduled visits to NRC non-Agreement States and also update the NRC as your schedule changes.

The NRC relies on an Agreement State licensee to notify the NRC whenever licensed activities are performed in a non-Agreement State. This violation is a serious matter because it denied the NRC opportunities to inspect your activities while working in non-Agreement States, thereby removing the NRC's ability to perform its function of verifying that licensed activities are performed in a safe manner. To emphasize the need for the importance of appropriate management attention to ensure adherence to all regulatory requirements, I am issuing the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$ 500 for this Severity Level III violation.

The base value of a civil penalty for a Severity Level III violation is \$ 500. The civil penalty adjustment factors in the Enforcement Policy were considered. The civil penalty was initially increased 50 percent because the NRC identified the violation. The civil penalty was increased an additional 100 percent because of the multiple times the violation occurred. These increases were offset by reductions of 50 percent for your timely and extensive corrective actions and 100 percent for your past good performance (no events or significant enforcement actions since you first possessed licensed material in 1984). The remaining factors in the enforcement policy were considered and no further adjustment to the base civil penalty was considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management

Standard Nuclear Consultants

-3-

and Budget as required by the Paperwork Reduction Act of 1980,
Public Law No. 96-511.

Sincerely,

A handwritten signature in cursive script, appearing to read "A Bert Davis".

A. Bert Davis
Regional Administrator

Enclosure:
Notice of Violation and
Proposed Imposition of Civil Penalty

cc w/enclosure:
DCD/DCB(RIDS)
State of Illinois, Department
of Nuclear Safety

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Standard Nuclear Consultants, Ltd.
Elburn, Illinois

General License
[10 CFR 150.20]
EA 93-048

During an NRC inspection conducted on February 19, 1993, a violation of NRC requirements was identified. In accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

10 CFR 150.20(b)(1) requires, in part, that, when engaging in activities in non-Agreement States under the general license granted by 10 CFR 150.20(a), four copies of Form NRC-241 (revised) and four copies of the Agreement State specific license must be filed with the Regional Administrator of the appropriate Nuclear Regulatory Commission Regional Office at least three days prior to engaging in such activity.

Contrary to the above, from November 1990 to December 31, 1992, the licensee engaged in activities in non-Agreement States under the general license granted in 10 CFR 150.20(a). Specifically, the licensee performed licensed service activities (e.g. instrument calibrations, shutter checks and leak tests) on numerous occasions in non-Agreement States without filing Form NRC-241 or the Agreement State specific license with the Regional Administrator of the appropriate Nuclear Regulatory Commission Regional Office, as required by 10 CFR 150.20(b)(1). For example, on at least 75 occasions, from February 18, 1992, to December 31, 1992, the licensee did not file the required forms.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$ 500.

Pursuant to the provisions of 10 CFR 2.201, Standard Nuclear Consultants (Licensee) is hereby required to submit a written statement of explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a demand for information may be issued

Notice of Violation

- 2 -

as to why the license should not be modified, suspended, or revoked or why such other actions as may be proper should not be taken.

Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U. S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section V.B of 10 CFR Part 2, Appendix C (1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The responses noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk,

Notice of Violation

- 3 -

Washington, D.C. 20555 with a copy to the Regional Administrator,
U.S. Nuclear Regulatory Commission, Region III, 799 Roosevelt Road,
Glen Ellyn, Illinois 60137.

FOR THE NUCLEAR REGULATORY COMMISSION

A. Bert Davis
Regional Administrator

Dated at Glen Ellyn, Illinois
this 30th day of March 1993

**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V**

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

FEB 19 1993

Docket No. 030-13425
License No. 53-17839-01
EA 92-259

Wahiawa General Hospital
128 Lehua Street
Wahiawa, Hawaii 96786

Attention: David L. Hill
President

**SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY - \$1250
(NRC Inspection Report No. 030-13425/92-02)**

This refers to the inspection conducted on December 3, 18 and 28, 1992, of Wahiawa General Hospital, Wahiawa, Hawaii. The results of the inspection were reported in NRC Inspection Report No. 030-13425/92-02, dated January 14, 1993. Four violations of NRC requirements were identified as a result of the alarm of a radiation monitor at a solid waste disposal facility. The violations, their causes, and your corrective actions were discussed with you during an Enforcement Conference on February 3, 1993. The results of the Enforcement Conference were documented in NRC Inspection Report 93-01, and are enclosed.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). Collectively, the four violations set forth in the enclosed Notice represent a breakdown in your management system designed to provide adequate control of radioactive materials.

The violations include failures to: (1) use Department of Transportation (DOT) shipping papers for the Mo/Tc generator shipped on September 24, 1992; (2) use DOT package labels for the Mo/Tc generator shipped on September 24, 1992; (3) perform package contamination surveys on Mo/Tc generators shipped on September 24, 1992 and November 23, 1992; and (4) designate the November 23, 1992 Mo/Tc generator shipment as a limited quantity.

The incident involving the unauthorized radioactive Mo/Tc generator waste detected at the H-Power disposal facility and the associated transportation violations summarized above are considered especially significant because the NRC previously notified licensees of the potential for such incidents. On October 23, 1981, we issued NRC Information Notice No. 81-32 entitled "Transfer and/or Disposal of Spent Generators" to advise licensees of their responsibilities to properly control the transfer of spent generators. This Information Notice contained specific information which, if followed, would most likely have prevented the H-Power incident.

As a result of the above violations, personnel employed by several state and local agencies responded to the H-Power incidents. The laborious search of large quantities of trash for the sources of the unauthorized radioactivity required the expenditure of extensive resources by government agencies and created unnecessary risks to these personnel. In addition to the potential for radiation exposure, state and local personnel also had to contend with the risks posed by chemical and biological hazards.

The number of violations, their consequences, and your failure to implement the corrective actions described in the 1981 NRC Information Notice denote a breakdown in the control of the radiation safety program by licensee management. Collectively, these violations represent a potentially significant lack of attention toward licensed responsibilities. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

To emphasize the need for effective management oversight of your radiation safety program, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$1250 for the Severity Level III problem. The base value of a civil penalty for a Severity Level III problem is \$500. The escalation and mitigation factors in the Enforcement Policy were considered.

The base civil penalty was increased by 50% for inadequate corrective action, as evidenced by your untimely and minimal commitment to develop and strictly follow revised procedures for the disposal of Mo/Tc generators. In this regard, the NRC is concerned by the apparent lack of involvement of your Radiation Safety Officer (RSO) in achieving prompt and effective corrective action for this violation. It was only at the specific request of the NRC that the RSO attended the enforcement conference, and even then, his participation was brief and seemingly indifferent. The penalty was also increased 50% due to your weak performance during the last two NRC inspections, as evidenced by six violations of NRC requirements. The penalty was also increased by 50% for the prior opportunity to prevent this incident as afforded by the prior NRC notification described above. The other factors listed in the Enforcement Policy were also considered, but no further adjustments were deemed appropriate. Therefore, based on the above, the base civil penalty has been increased by 150 percent.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice and report are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:

Notice of Violation and Proposed Imposition of Civil Penalty
NRC Enforcement Conference Report 93-01

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Wahiawa General Hospital
Wahiawa, Hawaii

Docket No. 030-13425
License No. 53-17839-01
EA 92-259

During an NRC inspection conducted on December 3, 18 and 28, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

- A. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.200(a) requires, with exceptions not applicable here, that each person who offers a hazardous material for transportation describe the hazardous material on the shipping paper in the manner required by subpart C of 49 CFR Part 172. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on September 24, 1992, the licensee offered a molybdenum-99/technetium-99m generator containing 27 millicuries of molybdenum-99 to a carrier for transport and did not include with the shipment, a shipping paper describing the material.

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.403 requires, in part, with exceptions not applicable here, that each package of radioactive material be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label. The contents, activity, and transport index must be entered in the blank spaces on the label; and each package must have two labels, affixed to opposite sides of the package.

Contrary to the above, on September 24, 1992, the licensee delivered to a carrier for transport a molybdenum-99/technetium-99m generator containing 27 millicuries of molybdenum-99, without the appropriate RADIOACTIVE WHITE-I label.

- C. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475 requires, in part, that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate test that the external radiation and contamination levels are within the allowable limits specified in 49 CFR Parts 171-177.

Contrary to the above, on September 24, 1992, and November 23, 1992, the licensee delivered to a carrier for transport packages of radioactive material without ensuring by examination or appropriate test that removable surface contamination levels were within allowable limits.

- D. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.421 excepts radioactive materials in certain limited quantities, defined therein, from the specification packaging, shipping paper and certification, marking, and labeling requirements of subpart H, 49 CFR Part 173.

49 CFR 173.421-1(a) requires, in part, that a "limited quantity" of radioactive material, shipped as excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the package list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material, limited quantity, n.o.s., UN 2910."

Contrary to the above, on November 23, 1992, the licensee delivered to a carrier for transport a package which contained a molybdenum-99/technetium-99m generator with 10 millicuries of molybdenum-99, as a "limited quantity", excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, and did not have a notice enclosed in or on the package, included with the package list, or otherwise forwarded with the package, with the required statement concerning the consignor conformance of the package.

Violations A through D above constitute a Severity Level III problem (Supplement V).

Civil Penalty - \$1250.

Pursuant to the provisions of 10 CFR 2.201, Wahiawa General Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Commission may issue an order or a demand for information as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region V, 1450 Maria Lane, Walnut Creek, California 94596.

Dated at Walnut Creek, California
this 19 day of February 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

JUN 02 1993

Docket No. 030-13425
License No. 53-17839-01
EA No. 92-259

Wahiawa General Hospital
128 Lehua Street
Wahiawa, Hawaii 96786

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$750

This refers to your letter dated March 17, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated February 19, 1993. Our letter and Notice described four violations identified by the NRC during a special reactive inspection conducted on December 3, 18, and 28, 1992, as a result of the alarm of a radiation monitor at a solid waste disposal facility. To emphasize the need for effective management oversight of your radiation safety program, a civil penalty of \$1,250 was proposed.

In your response you agreed that the violations occurred as stated, but requested remission of the Civil Penalty. After consideration of your response, we have concluded (for the reasons given in the Appendix attached to the enclosed Order Imposing Civil Monetary Penalty) that, while remission of the Civil Penalty is not warranted, some mitigation is appropriate. Specifically, the NRC staff has withdrawn the proposed escalation of the civil penalty for corrective action and also for prior notice. Accordingly, we hereby serve the enclosed Order on Wahiawa General Hospital imposing a civil monetary penalty in the amount of \$750.

In your reply, you expressed the opinion that you are not required to retain NRC Information Notices (INs). You are not legally required to retain INs. However, you are required to comply with Commission requirements. NRC issues INs for issues it considers significant so that licensees will examine their programs to avoid similar problems. Therefore, NRC considers violations that were preventable based on the information provided in INs to be significant regulatory concerns. Licensees who have achieved a high degree of compliance and safety are normally pro-active in identifying and correcting their own violations. Periodic review of pertinent INs during program reviews and training is an important aspect of this process and assures a degree of continuity when personnel are replaced. Therefore, you should consider maintaining a file of pertinent INs as an element of management control over licensed activities.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Wahiawa General Hospital

2

In your response to this letter and Order, please describe any plans that you have to retain INS in the future.

We will review the effectiveness of your corrective actions during a subsequent inspection.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.,
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosures: As Stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	
Wahiawa General Hospital	)	Docket No. 030-23425
Wahiawa, Hawaii	)	License No. 53-17839-01
	)	EA No. 92-259

ORDER IMPOSING CIVIL MONETARY PENALTY

I

Wahiawa General Hospital (Licensee) is the holder of Materials License No. 53-17839-01 issued by the Nuclear Regulatory Commission (NRC or Commission) on August 10, 1992. The license authorizes the Licensee to use radioactive materials for medical purposes, as described in 10 CFR 35.100, 35.200, and 35.300, in accordance with the conditions specified in the license.

II

An inspection of the Licensee's activities was conducted on December 3, 18, and 28, 1992. The results of this inspection indicated that the Licensee had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated February 19, 1993. The Notice states the nature of the violations, the provisions of the NRC's requirements that the Licensee had violated, and the amount of the civil penalty proposed for the violations.

The Licensee responded to the Notice in a letter dated March 17, 1993. In its response, the Licensee agreed with the violations, but requested remission of the civil penalty based on: (1) the alleged unacceptability of an NRC Information Notice as the basis for escalation for prior opportunity to have identified and prevented the violations, (2) the alleged improper placement of responsibility on the Licensee for actions taken by an individual who delivered radioactive materials for a centralized radiopharmacy, and (3) the alleged promptness of the Licensee's corrective actions.

III

After consideration of the Licensee's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violations occurred as stated, but that mitigation of the proposed civil penalty is appropriate, and that a penalty in the amount of \$750 should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee pay a civil penalty in the amount of \$750 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

V

The Licensee may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing" and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, with a copy to the Commission's Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region V, 1450 Maria Lane, Walnut Creek, California 94596-5368.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If the Licensee fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event the Licensee requests a hearing as provided above, the issue to be considered at such hearing shall be whether, on the basis of the violations admitted by the Licensee, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.,
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Dated at Rockville, Maryland
this 2nd day of June 1993

APPENDIX

EVALUATIONS AND CONCLUSION

On February 19, 1993, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection conducted on December 3, 18 and 28, 1992. Wahiawa General Hospital responded to the Notice on March 17, 1993, admitting the violations but requesting remission of the civil penalty. The NRC's evaluation and conclusion regarding the licensee's request are as follows:

Restatement of Violations

- A. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.200(a) requires, with exceptions not applicable here, that each person who offers a hazardous material for transportation describe the hazardous material on the shipping paper in the manner required by subpart C of 49 CFR Part 172. Pursuant to 49 CFR 172.101, radioactive material is classified as hazardous material.

Contrary to the above, on September 24, 1992, the licensee offered a molybdenum-99/technetium-99m generator containing 27 millicuries of molybdenum-99 to a carrier for transport and did not include with the shipment a shipping paper describing the material.

- B. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 172.403 requires, in part, with exceptions not applicable here, that each package of radioactive material be labeled, as appropriate, with a RADIOACTIVE WHITE-I, a RADIOACTIVE YELLOW-II, or a RADIOACTIVE YELLOW-III label. The contents, activity, and transport index must be entered in the blank spaces on the label; and each package must have two labels, affixed to opposite sides of the package.

Contrary to the above, on September 24, 1992, the licensee delivered to a carrier for transport a molybdenum-99/technetium-99m generator containing 27 millicuries of

molybdenum-99, without the appropriate RADIOACTIVE WHITE-I label.

- C. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.475 requires, in part, that before each shipment of any radioactive materials package, the shipper ensure by examination or appropriate test that the external radiation and contamination levels are within the allowable limits specified in 49 CFR Parts 171-177.

Contrary to the above, on September 24, 1992, and November 23, 1992, the licensee delivered to a carrier for transport packages of radioactive material without ensuring by examination or appropriate test that removable surface contamination levels were within allowable limits.

- D. 10 CFR 71.5(a) requires that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 173.421 excepts radioactive materials in certain limited quantities, defined therein, from the specification packaging, shipping paper and certification, marking, and labeling requirements of subpart H, 49 CFR Part 173.

49 CFR 173.421-1(a) requires, in part, that a "limited quantity" of radioactive material, shipped as excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, be certified as being acceptable for transportation by having a notice enclosed in or on the package, included with the package list, or otherwise forwarded with the package. This notice must include the name of the consignor or consignee and the statement: "This package conforms to the conditions and limitations specified in 49 CFR 173.421 for excepted radioactive material, limited quantity, n.o.s., UN 2910."

Contrary to the above, on November 23, 1992, the licensee delivered to a carrier for transport a package which contained a molybdenum-99/technetium-99m generator with 10

millicuries of molybdenum-99, as a "limited quantity", excepted from specification packaging, shipping paper and certification, marking, and labeling requirements, and did not have a notice enclosed in or on the package, included with the package list, or otherwise forwarded with the package, with the required statement concerning the consignor conformance of the package.

Summary of Licensee's Request for Mitigation

Prior Opportunity to Identify:

Licensee Response:

The licensee argued that the NRC's escalation of the civil penalty based on NRC Information Notice (IN) 81-32, "Transfer and/or Disposal of Spent Generators" was improper because previous NRC guidance on records retention has never mentioned Information Notices, and the cited IN did not state that it was to be retained in a permanent file.

NRC Evaluation:

The NRC Enforcement Policy, Section VI.B.2.d, specifically includes the information in an NRC notification as an example of an opportunity to identify a potential violation. The Policy states that escalation by as much as 100% of the base civil penalty may be applied for cases where the licensee should have identified the violation sooner as a result of such opportunity. In this case, however, given the age of this IN, personnel responsible for compliance with NRC regulatory requirements were not aware of the information in it. Therefore, based on the specific facts of this case, the NRC staff is withdrawing the proposed escalation based on prior opportunity to identify.

Corrective Action:

Licensee Response:

The licensee challenges the NRC's 50% escalation for corrective action on two grounds. First, the licensee states that it took prompt corrective action, instructing its technologist not to send spent generators to the centralized radiopharmacy immediately after it was learned that a Wahiawa generator column contributed to the H-Power incident. Second, in response to the NRC's escalation of the civil penalty based on the licensee's failure to modify its procedures, the licensee states that it interpreted the statements in the NRC's January 14, 1993 letter that an Enforcement Conference would "... provide an opportunity for you to present your proposed corrective actions ..." to

mean that the licensee should not finalize modified procedures until after the conference, in case changes were suggested by the NRC.

NRC Evaluation:

The NRC did not intend that the licensee delay the implementation of its corrective actions until the enforcement conference. However, since immediate corrective actions were taken, NRC is withdrawing the proposed escalation based on corrective action.

Additional Considerations:

Licensee Response:

The licensee challenges the civil penalty as the improper placement of responsibility on Wahiawa General Hospital for the actions taken by an individual who delivered radioactive materials for a centralized radiopharmacy, arguing that the pharmacy was fully aware of the potential source of radiation exposure from undecayed columns, and that the presence of shipping papers or a shipping container would not have altered the actions of the pharmacy employee.

NRC Evaluation:

The licensee is responsible for ensuring that radioactive materials are properly transported in accordance with NRC and DOT regulations. The generators that the Licensee delivered to the radiopharmacy employee for transport on September 24 and November 23, 1992 contained 27 millicuries of Mo-99 and 10.1 millicuries of Mo-99 respectively. The pharmacy employee dismantled both generators in order to salvage the lead shielding for his own use and threw one generator column in the non-radioactive trash, which led to the H-Power Facility alarm incident. The pharmacy employer stated that, based on discussions with the Licensee's nuclear medicine technologist, the pharmacy employee was under the impression that he was collecting non-radioactive generators which had decayed to background.

Had the Licensee properly packaged and labeled the generators in accordance with NRC and DOT regulations, there could have been no confusion on the part of the pharmacy employee as to the radioactive content of the generators. Based on the facts of this case, the violations on the part of the Licensee could or did result in a significant failure on the part of the pharmacy employee to identify the radioactive content of the shipment. Therefore, in accordance with the NRC Enforcement Policy, Supplement V.C.3, the failures on the part of the Licensee were

classified as a Severity Level III problem, and the civil penalty was assessed accordingly.

NRC Conclusion

The NRC staff has concluded that the violations did occur as stated, but that escalation of the base civil penalty should be reduced from 150% to 50%. Consequently, a civil penalty in the amount of \$750 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

JUN 01 1993

Docket No. 030-14870
License No. 29-18334-01
EA No. 93-093

Ms. Lisa Goldstein, Vice President
and Chief Operating Officer
Wayne General Hospital
224 Hamburg Turnpike
Wayne, New Jersey 07470

Dear Ms. Goldstein:

Subject: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL
PENALTIES - \$6,250
(NRC Inspection Report No. 030-14870/93-001)

This letter refers to the NRC inspection conducted on April 13 and 14, 1993, at your facility located in Wayne, New Jersey, of activities authorized by NRC License No. 29-18334-01. The inspection report was sent to you on May 11, 1993. During the inspection, thirteen apparent violations of NRC requirements were identified, including a violation of Quality Management (QM) Program requirements. As a result, a Confirmatory Action Letter (CAL) (No. 1-93-005) was issued by the NRC on April 16, 1993, which confirmed your commitment to immediately suspend radiopharmaceutical treatment in your Radiation Therapy Department. In addition, on May 19, 1993, an enforcement conference was conducted with you and other members of the management and staff at your facility to discuss the apparent violations, their causes and your corrective actions. A copy of the enforcement conference report is enclosed (Enclosure 2).

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) (Enclosure 1). The violation of the QM program requirements involved the failure to prepare a written directive prior to the administration of iodine-131 on one occasion, as well as having a written directive signed by a physician who was not an authorized user on another occasion. Although this violation did not result in any misadministration of materials, this violation is of particular concern because such violations create the potential for a misadministration. In addition, an audit performed by your staff in July 1992 identified significant problems related to the implementation of the written directive requirement (i.e., several instances were identified where a written directive was not prepared). However, the corrective actions taken since that time which included, implementing a form to be used for written directives by the authorized users, were not effective in that they did not prevent these two additional instances from occurring.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

JUN 01 1993

The other twelve violations identified during the inspection include, but are not limited to: (1) failure to require a supervised individual to follow written procedures; (2) failure to obtain prior radiation dose records for new employees; (3) multiple failures to perform adequate surveys; (4) failure to hold radioactive waste for decay for a minimum of ten half-lives; (5) failure to include a representative of the nursing service on the Radiation Safety Committee (RSC); (6) failure to have a required quorum for a RSC meeting; (7) failure to make a record of brachytherapy source use; and (8) failure to submit the QM program to the NRC as required by the NRC regulations. The large number of these violations collectively represent a breakdown in the control of licensed activities.

The NRC license issued to Wayne General entrusts responsibility for radiation safety, and requires effective oversight of the licensed programs by the management of the hospital. Therefore, incumbent upon each NRC licensee is the responsibility of management in general, and the RSC and Radiation Safety Officer (RSO) in particular, to protect the public health and safety by ensuring that all requirements of the NRC license are met and that any potential violations of NRC requirements are identified and expeditiously corrected. The violation of QM program requirements is of significant regulatory concern to the NRC since each of the specific program requirements provides a safety barrier that, if not adhered to, could result in a misadministration. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation is classified at Severity Level III and is set forth in Section I of the enclosed Notice. The twelve other violations that collectively represent a breakdown in the control of licensed activities are also categorized in the aggregate as a Severity Level III problem, and are set forth in Section II of the enclosed Notice.

The NRC recognizes that, in response to the CAL, you have suspended all radiopharmaceutical patient treatments in your Radiation Therapy Department that required implementation of the QM program until specifically authorized by the NRC. You have also reviewed all radiopharmaceutical patient treatments performed in the Radiation Therapy Department since January 27, 1992, and submitted a report of this review to the NRC Region I Office. A review of this report confirmed that no misadministrations had occurred.

JUN 01 1993

The NRC also recognizes that actions were taken or planned to correct the violations and effect improvements in the control and implementation of the radiation safety program. These actions, which were described at the enforcement conference, include, but are not limited to: (1) submitting your QM program; (2) designating one physicist as having the sole responsibility for implementing the QM program at your facility under the oversight and monitoring of the RSO; (3) certifying or recertifying all authorized users of iodine-131 regarding the written directive requirement; (4) vesting the RSO with necessary authority and independence to carry out and oversee all radiation safety program responsibilities including the QM program requirements and use of written directives; (5) independent periodic evaluation of the radiation safety program by a qualified consultant; (6) appointment of a senior management representative to the RSC who will attend all RSC meetings; (7) more active participation of the nursing representative in the RSC, including attending meetings; (8) scheduling quarterly RSC meetings earlier in the calendar quarter to ensure the opportunity to have a quorum; (9) expanding the scope of the RSC to review all necessary aspects of the program; (10) requisitioning the prior quarter dose of the newly employed technologists so that it could be verified that their exposure did not exceed regulatory limits; (11) developing an improved survey program; and (12) implementation of a computer program to ensure radioactive waste is held in storage for at least ten half lives. At the time of the enforcement conference, most of these corrective actions were in place or planned to be completed within a short time frame.

Notwithstanding those actions, to emphasize the importance of (1) adequate implementation of the QM program, and (2) aggressive management oversight of the radiation safety program, so as to ensure that licensed activities are conducted safely and in accordance with requirements, and violations, when they exist, are promptly identified and corrected, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalties (Notice) in the amount of \$6,250 for the violations set forth in Sections I and II of the enclosed Notice.

With respect to the violation of the QM program requirement, the base civil penalty amount for this Severity Level III violation is \$2,500. A basis exists for 50% escalation of the penalty because the violation was identified by the NRC, as well as 50% mitigation of the penalty because your corrective actions were prompt and extensive. In addition, you had a prior opportunity to prevent the violation of the "written directive" QM requirement because your audit of the QM program in July 1992 identified the failure to prepare a written directive on several occasions. Therefore, 50% escalation on this factor is warranted. Full 100% escalation on this factor was not applied because the audit was done on your own initiative, and corrective actions were taken, although they were not effective in preventing recurrence of the violation. Therefore, on balance, 50% escalation of the base civil penalty is warranted. The other escalation/mitigation factors were considered and no further adjustment is warranted.

JUN 01 1993

Wayne General Hospital

4

With respect to the remaining violations that were classified in the aggregate at Severity Level III, the base civil penalty amount of \$2,500 has been escalated by 50% because the violations were identified by the NRC, and mitigated 50% because your corrective actions were prompt and extensive. Therefore, on balance, no adjustment to the civil penalty for this Severity Level III problem is warranted. The other escalation/mitigation factors were considered and no further adjustment is considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In this response, please address how you plan to enhance management oversight to ensure compliance with the requirements. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition
of Civil Penalties
2. Enforcement Conference Report

ENCLOSURE 1

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTIES

Wayne General Hospital
Wayne, New Jersey

Docket No. 030-14870
License No. 29-18334-01
EA No. 93-093

During an NRC inspection conducted on April 13 and 14, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose civil penalties pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalties are set forth below:

I. Violation of the QM Program Requirements

10 CFR 35.32(a)(1)(iii) and (iv) require, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any brachytherapy radiation dose and any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

10 CFR 35.2 defines a written directive for an administration of quantities greater than 30 microcuries of either sodium iodide iodine-125 or iodine-131 as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical and which contains the dosage.

Item 1 of the licensee's written quality management program (revised July 30, 1992), requires that only an authorized user is permitted to administer radioactive materials as delineated in the NRC license and that the user date and sign a written directive prior to the administration of the radioactive dose. In addition, Item 6 of the licensee's written quality management program requires that the authorized user, Radiation Oncologist, date and sign a written directive prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either sodium iodide iodine-125 or iodine-131.

Contrary to the above, a written directive signed and dated by the authorized user was not prepared prior to the administration of therapeutic dosage of a radiopharmaceutical or dosage of quantities greater than 30 microcuries of sodium iodide iodine-131. Specifically, on January 4, 1993, a dosage of 99.1 millicuries of iodine-131 was administered to a patient and no written directive was prepared. In addition, on November 24, 1992, a dosage of 28.5 millicuries of iodine-131 was administered to a patient and the written directive was signed by a physician who is not an authorized user.

This is a Severity Level III violation (Supplement VI).

Civil Penalty - \$3,750.

II. Violations Representative of a Breakdown in Control of Licensed Activities

- A. 10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one-half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on March 30, 1993, the licensee's Radiation Safety Committee met and conducted business and the Radiation Safety Officer was not present.

- B. 10 CFR 35.22(a)(1) requires that the membership of the Radiation Safety Committee consist of at least three individuals and include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor the Radiation Safety Officer.

Contrary to the above, as of April 14, 1993, the membership of the licensee's Radiation Safety Committee did not include a representative of the nursing service.

- C. 10 CFR 35.92(a) permits a licensee to dispose of byproduct material with a physical half-life of less than 65 days in ordinary trash, provided, in part, that the licensee first holds such byproduct material for decay a minimum of ten half-lives.

Contrary to the above, on February 3, 1993, the licensee disposed of radioactive waste containing iodine-131 in ordinary trash without first holding this material for decay a minimum of ten half-lives. Specifically, iodine-131 waste was only held for 27 days, a period of time of less than ten half-lives for iodine-131.

- D. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the use of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the instructions of the supervising authorized user.

The instructions of the supervising authorized user, entitled "Procedures for Receipt, Handling and Disposal of Radioactive Material", dated June 22, 1992, require, in part, that prior to opening the container, the exposure rates at three feet from the container surface and at the surface be measured and recorded.

Contrary to the above, on January 4, 1993, the physicist, an individual under the supervision of the licensee's authorized user, opened a package containing 99.1 millicuries of iodine-131 prior to measuring the dose rates at three feet and at the surface of the package. Specifically, the physicist stated that he removed the vial containing the iodine-131 from the package and shielded container and then performed the surveys.

- E. 10 CFR 35.59(h) requires, in part, that a licensee in possession of a sealed source or brachytherapy source measure the ambient dose rates quarterly in all areas where such sources are stored.

Contrary to the above, from August 21, 1992 until April 14, 1993, a period in excess of a calendar quarter, the licensee did not measure the ambient dose rates in the Radiation Therapy Hot Lab, an area where sealed sources and brachytherapy sources were stored.

- F. 10 CFR 35.315(a)(7) requires that, for each patient receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75, a licensee survey the patient's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters.

Contrary to the above, on January 8, 1993, the licensee did not conduct a survey for removable contamination before assigning another patient to room No. 612, the room of a patient who had received radiopharmaceutical therapy and had been hospitalized for compliance with 10 CFR 35.75.

- G. 10 CFR 35.406(b) requires that a licensee make a record of brachytherapy source use, including: (1) the names of the individuals permitted to handle the sources, (2) the number and activity of sources removed from storage, the patient's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; and (3) the number and activity of sources returned to storage, the patient's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

Contrary to the above, as of April 14, 1993, the licensee's record of brachytherapy source usage for November 23, 1992, did not include the number and activity of the sources in storage after removal, the number and activity of the sources returned to storage, nor the number and activity of sources in storage after the return.

- H. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste are stored.

Contrary to the above, during the weeks of October 15, 1992 to March 10, 1993, the licensee did not survey with a radiation detection survey instrument the hot lab of the Radiation Therapy Department, an area where radiopharmaceuticals and radiopharmaceutical waste are stored.

- I. 10 CFR 35.70(e) requires that a licensee survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored.

Contrary to the above, during the weeks of October 15, 1992 to March 10, 1993, the licensee did not survey for removable contamination in the hot lab of the Radiation Therapy Department, an area where radiopharmaceuticals were routinely prepared and administered.

- J. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, on numerous occasions from October 15, 1992 until March 10, 1993, the licensee did not survey with a radiation detection instrument at the end of the day areas of the hot lab where radiopharmaceuticals were routinely prepared for use and administered. For example, no such survey was performed on March 10, 1993.

- K. 10 CFR 20.102(a) requires, in part, that each licensee require any individual, prior to first entry of the individual into the licensee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose in excess of 25 percent of the applicable standards specified in 10 CFR 20.101(a) to disclose in a written, signed statement, either: (1) that the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during that specifically identified current calendar quarter from sources of radiation possessed or controlled by other persons.

Contrary to the above, the licensee did not require any individual, prior to first entry of the individual into the licensee's restricted area during each employment or work assignment under such circumstances that the individual will receive or is likely to receive in any period of one calendar quarter an occupational dose of 25 percent of the applicable standards specified in 10 CFR 20.101(a) to disclose in a signed statement, either: (1) that the individual had no prior occupational dose during the current calendar quarter, or (2) the nature and amount of any occupational dose which the individual may have received during that specifically identified current calendar quarter from sources of radiation possessed or controlled by other persons. Specifically, since July 1992, two nuclear medicine technologists have been working in the nuclear medicine department, a restricted area, and as of April 14, 1993, the licensee had not required the individuals to furnish their prior radiation dose record.

- L. 10 CFR 35.32(f)(2) requires, in part, that each existing licensee submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992, a written certification that the quality management program has been implemented along with a copy of the program.

Contrary to the above, as of April 14, 1993, the licensee did not submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6, a written certification that the quality management program had been implemented along with a copy of the program.

These violations are categorized in the aggregate as a Severity Level III problem (Supplements IV and VI).

Civil Penalty - \$2,500.

Pursuant to the provisions of 10 CFR 2.201, Wayne General Hospital (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalties (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalties by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalties in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalties will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalties, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation(s) listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalties should not be imposed. In addition to protesting the civil penalties in whole or in part, such answer may request remission or mitigation of the penalties.

In requesting mitigation of the proposed penalties, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing civil penalties.

Upon failure to pay any civil penalties due which subsequently have been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalties, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalties, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I.

Dated at King of Prussia, Pennsylvania
this 15 day of June, 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8084

DEC 28 1992

Docket No. 150-00030
General License (10 CFR 150.20)
EA 92-216

Western Technologies, Inc.
ATTN: Mr. Craig Johnson
Vice President
P.O. Box 21387
Phoenix, Arizona 85036

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION
OF CIVIL PENALTY - \$8,000 (NRC INSPECTION
REPORT 150-00030/92-01)

This is in reference to the NRC's inspection of Western Technologies, Inc. (Western Technologies), during radiographic operations performed at the White Sands Missile Range, New Mexico, on October 28, 1992. The results of this inspection were discussed with Western Technologies' former radiation safety officer on November 2, 1992, and were documented in a report issued on November 17, 1992.

NRC's inspectors observed Western Technologies personnel performing radiography without wearing alarm ratemeters as required by 10 CFR 34.33(a). Based on the significance of this violation, an enforcement conference was held between Western Technologies and NRC personnel on December 1, 1992, in NRC's Arlington, Texas office. A list of attendees is enclosed.

Western Technologies, which holds New Mexico and Arizona State licenses for its radiography activities, was performing licensed activities in NRC jurisdiction pursuant to the general license authorized by NRC in 10 CFR 150.20. The general license authorizes the performance of radiography in accordance with the terms and conditions specified in a specific license issued by an Agreement State and with the NRC regulations listed in 10 CFR 150.20(b).

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Western Technologies, Inc. - 2 -

In addition to finding Western Technologies personnel conducting radiography without required alarm ratemeters, NRC's inspectors found that the radiographers did not recharge their pocket dosimeters prior to beginning work, also a violation of 10 CFR 34.33(a); that the radiographers were not listed on the New Mexico license utilized by Western Technologies in gaining the authority to work in NRC jurisdiction; and that the shipping papers used in transporting the radiographic equipment did not include certain required information.

With regard to the failure to wear alarm ratemeters, NRC concludes that the radiographers knowingly violated this requirement because they acknowledged that they were aware of the requirement and that they had been aware of the fact that they did not have alarm ratemeters at the job site when they began radiographic operations. This violation, which was the focus of the enforcement conference discussions, is a serious violation of NRC requirements. This requirement was adopted to prevent significant radiation exposures by providing greater assurance that radiography personnel do not expose themselves or others to unexpectedly high radiation fields. The seriousness of this violation is compounded by the fact that it was committed knowingly.

The NRC recognizes that, as a result of the NRC inspection, Western Technologies personnel discontinued radiography operations at White Sands until alarm ratemeters were obtained, and that Western Technologies later took disciplinary action against the individuals involved. During the enforcement conference, you indicated that complacency for safety requirements may have contributed to the occurrence of this violation and that company management may not have been placing the appropriate emphasis on strict compliance with such requirements. The NRC acknowledges your efforts to eliminate this complacent attitude. Important among these efforts is the message you have conveyed in your training sessions following the NRC inspection. Personnel have been instructed that radiography work is not to be performed unless all required safety equipment is present and that employees should contact the home office to obtain any necessary equipment before beginning work.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the failure to wear alarm ratemeters during radiography operations has been categorized as a Severity Level II violation. This type of violation is normally classified at Severity Level III; however, the severity level was increased in this case because the radiographers knowingly violated this requirement.

Western Technologies, Inc. - 3 -

To emphasize the seriousness of willful violations, the importance of strict compliance with safety requirements, and the importance of developing mechanisms to ensure that company personnel are complying with such requirements, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$8,000 for the Severity Level II violation described above and in the Notice.

The base value of a civil penalty for a Severity Level II violation is \$8,000. The civil penalty adjustment factors in Section VI.B.2 of the Enforcement Policy were considered and, on balance, resulted in no adjustment. In considering these factors, the NRC concluded that your corrective actions warranted a reduction in the penalty by 50 percent of the base value. However, this was offset by the fact that the violation was identified by the NRC as opposed to having been discovered by Western Technologies through its own audit programs. The remaining civil penalty adjustment factors were considered, but did not result in any further adjustments.

The violations involving incomplete shipping papers and the use of personnel not listed on your New Mexico license have been classified at Severity Level IV and V, respectively, and have not been assessed a civil penalty.

Western Technologies is required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. In addition, you should describe the actions that Western Technologies will take before working in NRC jurisdictions to assure that you fully understand and comply with current NRC requirements; and to assure that your employees comply with all NRC requirements, not just those that they elect to follow. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

DEC 28 1992

Western Technologies, Inc. - 4 -

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. List of Enforcement Conference attendees

cc w/ enclosures:

State of New Mexico Radiation Control Program Director
State of Arizona Radiation Control Program Director

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Western Technologies, Inc.
Phoenix, Arizona

Docket No. 150-00030
General License, 10 CFR 150.20
EA 92-216

During an NRC inspection conducted on October 28, 1992, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

10 CFR 34.33(a) requires, in part, that: (1) a licensee not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, the individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD); and (2) pocket dosimeters be recharged at the start of each shift.

Contrary to the above, on October 28, 1992, two radiographers employed by Western Technologies, Inc. (Licensees), did not wear alarm ratemeters while conducting radiographic operations at the White Sands Missile Range, New Mexico, and did not recharge their direct reading pocket dosimeters at the start of the shift.

This is a Severity Level II violation (Supplement VI).
Civil Penalty - \$8,000.

II. Violations Not Assessed a Civil Penalty

A. 10 CFR 71.5(a) requires, in part, that a licensee who transports licensed material outside of the confines of its plant or other place of use, or who delivers licensed material to a carrier for transport, comply with the applicable requirements of the regulations appropriate to the mode of transport of the Department of Transportation (DOT) in 49 CFR Parts 170 through 189.

49 CFR 177.817(a) requires that a carrier not transport a hazardous material unless it is accompanied by a shipping paper prepared in accordance with 49 CFR 172.200-203. Pursuant to

Notice of Violation

- 2 -

49 CFR 172.101, radioactive material is classified as hazardous material.

49 CFR 172.203(c)(2) requires that the letters "RQ" (Reportable Quantity) be entered on the shipping paper either before or after the basic description required for each hazardous substance.

Contrary to the above, on October 28, 1992, while conducting radiographic operations at the White Sands Missile Range, New Mexico, the Licensee transported approximately 22 curies of iridium-192, a reportable quantity, and the letters "RQ" were not entered either before or after the description of the hazardous material on the shipping paper that accompanied the shipment.

This is a Severity Level IV violation (Supplement V).

- B. 10 CFR 150.20(b)(4) requires that the licensee comply with all terms and conditions of the specific license issued by an Agreement State except such terms or conditions as are contrary to the requirements of 10 CFR Part 150.

License Condition 11.B of the Licensee's State of New Mexico Radioactive Material License (Number IR244-21) specifies, in part, those individuals authorized to act as radiographers or radiographer's assistants as defined in Part 5-120, New Mexico Radiation Protection Regulations.

Contrary to the above, on October 28, 1992, while conducting radiographic operations at the White Sands Missile Range, New Mexico, the Licensee permitted an individual to act as a radiographer who was not listed as an authorized radiographer or radiographer's assistant on the Licensee's State of New Mexico Radioactive Material License (Number IR244-21).

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, the Licensee is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1)

Notice of Violation

- 3 -

admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above or may protest imposition of the civil penalty, in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty, in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205, regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or

DEC 28 1992

Notice of Violation

- 4 -

mitigated, may be collected by civil action pursuant to Section 234(c) of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

Dated at Arlington, Texas
this 28th day of December 1992

DEC 28 1992

Enclosure 2

Attendance List
December 1, 1992, Enforcement Conference
(EA 92-216)

Western Technologies, Inc.

Craig Johnson, Vice President & Managing Director
Alex Zuran, Director, NDT

Nuclear Regulatory Commission

John Montgomery, Deputy Regional Administrator
Johns Jaudon, Deputy Director, Division of Radiation Safety
& Safeguards (DRSS)
William Brown, Regional Counsel
Chuck Cain, Chief, Nuclear Materials Inspection Section
(NMIS), DRSS
Mark Shaffer, Radiation Specialist, NMIS, DRSS
Gilbert Guerra, Radiation Specialist, NMIS, DRSS
Gary Sanborn, Regional Enforcement Officer
Joe DelMedico, Enforcement Specialist, Office of Enforcement
(by telephone)

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D C 20555-0001

MAR 2 1993

Docket 150-00030
General License (10 CFR 150.20)
EA 92-216

Western Technologies, Inc.
ATTN: Mr. Craig Johnson
Vice President
Post Office Box 21387
Phoenix, Arizona 85036

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$8,000

This refers to your letter dated January 26, 1993, in response to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent to you by our letter dated December 28, 1992. Our letter and Notice described a violation of 10 CFR 34.33(a), i.e., a failure to wear alarming ratemeters during radiography operations.

To emphasize the seriousness of willful violations, the importance of strict compliance with safety requirements, and the importance of developing mechanisms to ensure that company personnel are complying with such requirements, a civil penalty of \$8,000 was proposed.

In your response, you admitted this violation but requested full mitigation of the proposed penalty based on a number of factors. A summary of the reasons for your request for mitigation is contained in the enclosed Order.

After consideration of your request for mitigation, we have concluded for the reasons given in the appendix to the enclosed Order Imposing Civil Monetary Penalty that the full amount of the penalty should be imposed by Order. Accordingly, we hereby serve the enclosed Order on Western Technologies, Inc., imposing a civil monetary penalty in the amount of \$8,000. The NRC will review the effectiveness of your corrective actions during future inspections.

Western Technologies, Inc. - 2 -

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosure will be placed in the NRC's Public Document Room.

Sincerely,

Hugh L. Thompson, Jr.
Deputy Executive Director for
Nuclear Materials Safety, Safeguards,
and Operations Support

Enclosure: As Stated

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of	)	
	)	Docket 150-00030
WESTERN TECHNOLOGIES, INC.	)	General License
Phoenix, Arizona	)	EA 92-216

ORDER IMPOSING CIVIL MONETARY PENALTY

I

On October 28, 1992, Western Technologies, Inc. (WTI) conducted radiography activities pursuant to the general license authorized by the Nuclear Regulatory Commission (NRC or Commission) in 10 CFR 150.20. The general license authorizes the performance of radiography in accordance with the terms and conditions specified in a specific license issued by an Agreement State and with the NRC regulations listed in 10 CFR 150.20(b).

II

An inspection of WTI activities in NRC jurisdiction was conducted on October 28, 1992, at White Sands Missile Range in New Mexico. The results of this inspection indicated that WTI had not conducted its activities in full compliance with NRC requirements. A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon WTI by letter dated December 28, 1992. The Notice described the nature of the violations, the provisions of the NRC's requirements that WTI had violated, and the amount of the civil penalty proposed for one of the violations.

WTI responded to the Notice in a letter dated January 26, 1993. In its response, WTI admitted the violation which resulted in the proposed civil penalty, but requested full mitigation for reasons that are summarized in the Appendix to this Order.

III

After consideration of WTI's response and the statements of fact, explanation, and argument for mitigation contained therein, the NRC staff has determined, as set forth in the Appendix to this Order, that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

WTI pay a civil penalty in the amount of \$8,000 within 30 days of the date of this Order, by check, draft, money order, or electronic transfer, payable to the Treasurer of the United States and mailed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555.

WTI may request a hearing within 30 days of the date of this Order. A request for a hearing should be clearly marked as a "Request for an Enforcement Hearing," and shall be addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555. Copies also shall be sent to the Assistant General Counsel for Hearings and Enforcement at the same address and to the Regional Administrator, NRC Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011.

If a hearing is requested, the Commission will issue an Order designating the time and place of the hearing. If WTI fails to request a hearing within 30 days of the date of this Order, the provisions of this Order shall be effective without further proceedings. If payment has not been made by that time, the matter may be referred to the Attorney General for collection.

In the event WTI requests a hearing as provided above, the issue to be considered at such hearing shall be:

- 4 -

Whether, on the basis of the violation admitted by WTI, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Material Safety, Safeguards
and Operations Support

Dated at Rockville, Maryland
this 22nd day of March 1993

APPENDIX

EVALUATION AND CONCLUSION

On December 28, 1992, a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued for violations identified during an NRC inspection. Western Technologies, Inc., (WTI) responded to the Notice on January 26, 1993. WTI admitted the violation that resulted in the proposed civil penalty, but requested full mitigation. The NRC's evaluation and conclusion regarding WTI's request are as follows:

Restatement of Violation

I. Violation Assessed a Civil Penalty

10 CFR 34.33(a) requires, in part, that: (1) a licensee not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, the individual wears a direct reading pocket dosimeter, an alarm ratemeter, and either a film badge or a thermoluminescent dosimeter (TLD); and (2) pocket dosimeters be recharged at the start of each shift.

Contrary to the above, on October 28, 1992, two radiographers employed by Western Technologies, Inc. (Licensee), did not wear alarm ratemeters while conducting radiographic operations at the White Sands Missile Range, New Mexico, and did not recharge their direct reading pocket dosimeters at the start of the shift.

This is a Severity Level II violation (Supplement VI).
Civil Penalty - \$8,000.

Summary of WTI's Request for Mitigation

In its January 26, 1993, letter, WTI admitted the above violation but requested full mitigation of the penalty, citing the following reasons: 1) There was no radiation hazard to persons in the area and no harm was done to any person; 2) The involved radiographers were disciplined and all radiographers were reminded that they are not to operate without required safety equipment; 3) This is the only violation that Western Technologies, Inc. has received and the company has an excellent record in the state of Arizona; 4) This was an isolated occurrence and the company's audit programs have not identified any other infractions; 5) The company has spent considerable money to investigate and ensure against a recurrence, including the cost of attending the NRC enforcement conference; and 6) The NRC's announcement of its enforcement action has done considerable damage to the company's reputation and should count as a monetary value against the fine.

NRC Evaluation of WTI's Request for Mitigation

The NRC's evaluation of WTI's arguments for mitigation follows:

1. The NRC agrees with WTI that no actual harm was done. However, the severity level of the violation and the civil penalty amount were determined in accordance with the NRC's Enforcement Policy and the enforcement action was consistent with action taken for similar violations. The NRC has placed great importance on wearing alarm ratemeters because they are designed to prevent significant radiation exposures to radiographers and persons in the vicinity of radiography work. Thus the violation is of significant regulatory concern and given its willful nature was properly categorized at Severity Level II.
2. The NRC recognized the corrective actions taken by WTI and gave WTI the maximum amount of credit permitted by the Enforcement Policy, i.e., a reduction in the penalty by 50 percent of the base value.
3. Regarding WTI's regulatory performance in the Agreement State of Arizona, the guidance in the Enforcement Policy, Section VI.B.2.(c), does provide that mitigation of the base civil penalty may be appropriate where past regulatory performance has been good. However, given the willful nature of the violation, the NRC staff, as an exercise of discretion, did not find that there was an adequate basis for mitigation of the penalty based on the licensee performance factor. The exercise of such discretion in cases involving willfulness is permitted under the Enforcement Policy in Section VII, and is intended to reflect the level of NRC's concern regarding the willful violation and ensure that the enforcement action conveys the appropriate message to the licensee.
4. WTI argues that it has an audit program and that this was an isolated occurrence. However, the central fact in applying the factor for identification is that the NRC inspector identified the violation to the involved radiographers. The NRC escalated the penalty by 50% in accordance with its Enforcement Policy, which provides for such an increase when violations are identified by the NRC, to emphasize that licensees should be identifying and correcting their own violations. By definition (10 CFR 34.2), a radiographer is an individual who is responsible to the licensee for assuring compliance with the requirements of the Commission's regulations. In the case at hand, the radiographers knew that they did not have the required alarm ratemeters; however, they conducted the operation anyway.

5. The NRC recognizes that Western Technologies, Inc., has spent money to investigate the incident, develop corrective actions and attend the enforcement conference. However, corrective actions are expected and required and, as discussed above, were considered in applying the civil penalty adjustment factors. With regard to the expense of attending the enforcement conference, development of corrective actions, and licensee investigation of violations, the Enforcement Policy does not provide for using such expenses as a factor in determining the amount of a civil penalty.
6. The NRC announced its proposed enforcement action consistent with NRC practices for keeping the public informed of regulated activities. While the NRC understands that such announcements may possibly harm a licensee's reputation, this may provide an additional incentive to take lasting corrective action. The NRC Enforcement Policy does not provide for considering the impact of negative publicity as a factor in determining the amount of a civil penalty.

NRC Conclusion

The NRC has concluded that neither an adequate basis for a reduction of the severity level of the violation nor for mitigation of the civil penalty was provided by WTI. Consequently, the proposed civil penalty in the amount of \$8,000 should be imposed.

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

APR 23 1993

Docket No. 70-1151
License No. SNM-1107
EA 93-044

Westinghouse Electric Corporation
ATTN: Mr. J. A. Fici, Manager
Columbia Plant
Commercial Nuclear Fuel Division
Drawer R
Columbia, South Carolina 29250

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$18,750 (NRC INSPECTION REPORT NOS. 70-1151/92-04 AND 70-1151/93-01)

This refers to the Nuclear Regulatory Commission (NRC) Operational Safety Assessment (OSA) conducted on August 17-28, 1992, and the followup inspections conducted on October 28-29, 1992 and February 15-19, 1993, at the Westinghouse Electric Corporation's Commercial Nuclear Fuel Division (CNFD) located in Columbia, South Carolina. The OSA assessed overall facility operations and its possible impact on public and employee health and safety. The report documenting the OSA was sent to you by letter dated November 25, 1992. You were advised at that time that any potential enforcement issues would be addressed separately. As a result of the followup inspections, violations of NRC requirements were identified. An enforcement conference was held on March 17, 1993, in the NRC Region II office to discuss the violations, their cause, and your corrective actions to preclude recurrence. A summary of this conference was sent to you by letter dated March 23, 1993.

The violations are described in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice). The violation in Part I concerns your failure to perform several required nuclear criticality safety (NCS) analyses. The first example involved the installation and use of a non-favorable geometry (NFG) sump in the diked area of the uranyl nitrate storage tank pad. No NCS analysis had been performed to justify use of the NFG sump and to establish appropriate administrative controls. This issue was identified by the OSA when the team noted that a non-favorable slab thickness could be generated in the sump if one of the 7500 gallon tanks leaked or failed. The root cause of this problem was the failure to establish and implement adequate controls to ensure that an appropriate NCS analysis was performed prior to installation of the sump.

The second example in the violation involved the use of numerous NFG containers throughout the chemical area of the plant. The OSA team identified that NFG containers, such as 55-gallon drums and other large volume containers, were being used without having had an NCS analysis performed. The root cause

APR 23 1993

of this problem was your failure to establish and implement adequate controls to ensure a safety review prior to the introduction of NFG containers in areas of the plant utilizing SNM.

Although there are non-specific administrative controls that, if adhered to, should reduce the likelihood of a criticality accident, the fact that no specific NCS analyses had been performed to analyze the process upset conditions in these instances is of significant concern to the NRC. The development and documentation of required specific administrative controls is an inherent part of ensuring that a criticality safety incident does not occur and that adequate NCS controls are established and maintained. In that regard, we recognize that there was a low probability of a nuclear criticality. Nevertheless, under certain conditions, there could have been such an accident as a result of using the NFG containers. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation with two examples has been categorized at Severity Level III.

In order to emphasize the importance of ensuring that appropriate NCS analyses are performed to ensure that operational activities are conducted safely and in accordance with requirements, I have been authorized, after consultation with the Director, Office of Enforcement, and the Deputy Executive Director for Nuclear Materials Safety, Safeguards, and Operations Support, to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) in the amount of \$18,750 for the Severity Level III violation. The base civil penalty for a Severity Level III violation is \$12,500. The escalation and mitigation factors in the Enforcement Policy were considered as discussed below.

The base civil penalty was escalated by 50 percent because the violation was identified by the NRC. Neither escalation nor mitigation was warranted for corrective action. The staff recognizes that once the problem involving the NFG containers was identified, you initiated immediate corrective action to resolve this deficiency and develop a comprehensive plan to minimize NFG containers and provide the appropriate nuclear criticality controls on those remaining. However, the timely completion of that plan was not vigorously pursued. Mitigation of 100 percent was warranted for licensee performance as evidenced by a good enforcement history, the self-initiated response to developing industry issues, and your generally proactive approach to problems. However, escalation of 100 percent was warranted for your prior opportunity to identify this potential problem. NRC Information Notice No. 89-24, "Nuclear Criticality Safety," discussed potential problems resulting from inadequate administration and application of the double contingency principle in establishing NCS limits and controls, and specifically discussed the use of 55-gallon drums. The base civil penalty was not escalated for the factors of multiple examples or duration, because these were considered at arriving at the severity level of the violation. Therefore, based on the above, the base civil penalty has been increased by 50 percent.

APR 23 1977

The violations in Part II of the Notice involved the failure to 1) perform an adequate review of safety-related procedures, 2) follow procedures related to ensuring supplemental operating instructions are properly controlled, 3) include all required information on Regulatory Affairs Review Requests for Change as required by procedure, 4) perform independent verifications of sample results, 5) post and follow criticality signs, 6) follow procedures related to ensuring compliance with criticality control parameters and instructions, and 7) ensure review and approval of all portions of a test plan prior to its use. The first six violations were categorized at Severity Level IV, while the last one was categorized at Severity Level V. These violations, all of which share a procedure related commonality, are of concern to the NRC because they indicate management inattention to detail relative to ensuring procedural compliance.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebner
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl: (see next page)

Westinghouse Electric Corporation 4

APR 23 1993

cc w/encl:
Heyward G. Shealy, Chief
Bureau of Radiological Health
South Carolina Department of Health
and Environmental Control
2600 Bull Street
Columbia, SC

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Westinghouse Electric Corporation
Commercial Nuclear Fuel Division
Columbia, South Carolina

Docket No. 70-1151
License No. SNM-1107
EA 93-044

During NRC inspections conducted on August 17-28, 1992, and February 15-19, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed A Civil Penalty

Condition 9 of Special Nuclear Material (SNM) License Number 1107 (SNM-1107) requires that licensed material be used in accordance with the statements, representations, and conditions contained in Chapters 2, 3, and 4 of the license application dated March 26, 1984, and supplements thereto.

Chapter 2, Minimum Specifications and Capabilities, Section 2.3.1.10 of the license application states that where practicable, reliance will be placed on equipment design in which dimensions are limited rather than on administrative controls for nuclear criticality safety. When non-favorable geometry is used, Westinghouse shall justify the proposed use of non-favorable geometry and establish appropriate administrative controls. After justifying the need for non-favorable geometry equipment, the analysis must take into consideration identified contributing causes of criticality accidents, demonstrate that such causes will be subject to administrative controls, and demonstrate compliance with the double contingency principle. Contributing causes to be addressed will include process upsets.

Contrary to the above:

1. As of August 28, 1992, the licensee did not meet the minimum specifications and capabilities specified in the license application. Specifically, the licensee did not justify use of a non-favorable geometry sump, which was added to the diked or curbed area underneath uranyl nitrate storage tanks at some point in time during or after installation/construction of the tanks. No nuclear criticality safety analysis was performed to consider the contributing causes of criticality accidents, establish appropriate administrative controls, and demonstrate compliance with the double contingency principle. As a consequence, appropriate administrative controls were not established.
2. Attachment RA-301-1, "Floor Storage Plan," of Procedure RA-301, "Nuclear Criticality Control Criteria," Revision 6, dated

January 10, 1990, authorized the use of non-favorable geometry containers (55-gallon drums) without requiring justifications for the containers nor a criticality analyses of the various applications of the containers which considered the contributing causes of process upsets.

This is a Severity Level III violation (Supplement VI).
Civil Penalty - \$18,750.

II. Violations Not Assessed A Civil Penalty

Condition 9 of License SNM-1107 requires that licensed material be used in accordance with statements, representations, and conditions contained in Chapters 2, 3, and 4 of the license application dated March 26, 1984, and supplements thereto.

- A. Chapter 3, Section 3.1.2.3 (11) of the license application requires the Radiation Protection Component to review and approve all site procedures specifically related to radiation protection, nuclear criticality safety, emergency planning and SNM safeguards.

Contrary to the above, as of August 28, 1992, the Radiation Protection Component failed to perform an adequate review of safety-related procedure RO-06-003, "Ambient Environmental Air Monitoring for Radioactivity," Revision 5, dated July 9, 1992. The review was inadequate in that the procedure revision eliminated the self-absorption factor in the calculations for alpha activity, which could result in lower than actual (non-conservative) radioactive measurements of routine environmental air samples.

This is a Severity Level IV violation (Supplement VI).

- B. Chapter 2, Section 2.6 of the license application states that special nuclear material (SNM) processing shall be conducted in accordance with approved written procedures or instructions.

Procedure TA-005, "S.O.I. and P.I.F. Preparation and Distribution," Revision 3, dated February 27, 1992, establishes the procedure for the preparation, approval and distribution of Supplementary Operating Instructions (SOI) and SOI acknowledgement sheets. SOIs establish or modify written approved procedures or instructions for SNM processing. Section 6, requires, in part, that SOIs and SOI Acknowledgement Sheets be distributed and maintained in their respective areas. Section 7 requires, in part, that an expiration date be designated for each SOI, and the date of issuance is entered on each SOI and SOI Acknowledgement Sheet.

Form TAF 005-B, Supplementary Operating Instructions Acknowledgement Sheet," Part C., "Supervisor's Instructions," Part 1 states that the supervisor is to complete the SOI acknowledgement process within

five (5) working days which includes having all the operators read and sign the SOI with the supervisor signing last to indicate that all operators' names are on the sheet.

Contrary to the above, during the Operational Safety Assessment (OSA) conducted during the period from August 17 through 28, 1992, the licensee failed to control the preparation and distribution of SOIs and SOI Acknowledgement Sheets, as evidenced by the following:

1. SOIs C-142, C-143, and C-144, contained in the ammonium diuranate (ADU) conversion area control room SOI log, had no date of issuance nor expiration. Several of the supervisor acknowledgement sheets were missing from the respective area logbook, despite the fact the SOI had not expired.
2. SOI Acknowledgement Sheets that did not receive a complete supervisor sign off within the five days included SOI I-087, SOI I-123, and SOI IDR-0100.
3. SOI PEL-340 and the SOI logbook for the indirect dry route (IDR) area FA-2 could not be located. In addition, SOI PEL-358, which had an expiration date of August 21, 1992, had not been removed by August 24, 1992.

This is a Severity Level IV violation (Supplement VI).

- C. Chapter 2, Section 2.3.1.1 of the license application states that written procedures describing general nuclear criticality control requirements shall be maintained in the Regulatory Affairs Procedures Manual by the Radiation Protection Component. This section also states that operations shall be conducted in accordance with these procedures to ensure compliance with NRC regulations and license conditions.

Procedure RA-104, "Regulatory Affairs Review Requests," Revision 6, dated March 3, 1992, requires, in part, that the person originating the requested change(s) complete Section I of Form RA-104-1 by providing sufficient information including accurate red-lined drawings or sketches to adequately describe the change(s); that Regulatory Engineering review the proposed changes, determine applicable radiological and nuclear criticality safety requirements (which generally entails performing criticality safety analyses) and complete RA-104-1, Section II by signing the form. Once the form, RA-104-1, is completed, the originator is to implement the required radiological and nuclear criticality safety controls established by Regulatory Engineering and have existing working drawings revised and/or new drawings prepared and submitted to Regulatory Engineering for final review and approval. Procedure RA-104 then requires Regulatory Engineering to sign the appropriate drawings to ensure implementation of all required control criteria.

Contrary to this requirement, a review of selected Regulatory Affairs Review Requests for Change (facility change requests) by the OSA team during the period August 17-28, 1992, and during the inspection the week of February 15-19, 1993, indicated that some of the change requests did not contain all the information required by procedure in that:

1. Concerning the nuclear safety analysis for RA-104-1-754:
 - a. the form did not indicate who performed the analysis or who did the second party review, i.e., there were no signatures,
 - b. there were no equipment drawings or literature of the equipment involved and no updated drawings, and
 - c. the accident or upset conditions used in the nuclear criticality safety analysis were not identified.
2. Concerning the nuclear safety analysis for RA-104-1-783:
 - a. the analysis did not indicate who performed the original analysis, i.e., there was no signature, and
 - b. there were no drawings of equipment or layout drawings accompanying the package.

This is a Severity Level IV violation (Supplement VI).

- D. Chapter 2, Section 2.2.15.3 of the license application requires supervisor or chief operator verification of Uranium-235 concentration and free acid content in adjustment tanks prior to transfer.

Contrary to the above, during the OSA conducted during the period from August 17-28, 1992, the OSA team determined that the licensee failed to perform an adequate verification of Uranium-235 concentration and free acid content in adjustment tanks prior to transfer. Specifically, the supervisor or chief operator did not independently verify that the operators received and recorded the correct sample results for the contents of tanks about to be transferred. Rather, the supervisors and chief operators relied on the operators obtaining the correct sample results via telephone.

This is a Severity Level IV violation (Supplement VI).

- E. Chapter 2, Section 2.3.1.1 of the license application requires, in part, that operations shall be conducted in accordance with the written procedures maintained in the Regulatory Affairs Procedures Manual which describe general nuclear criticality control requirements.

Procedure RA-302, "Criticality Signs," Revision 5, dated April 21, 1989, requires, in part, that criticality signs identifying applicable

criticality control parameters and instructions shall be conspicuously posted, maintained and complied with, in areas or on equipment where SNM is present as required by Regulatory Engineering.

Contrary to this procedure, during the OSA conducted during the period from August 17-28, 1992, the licensee failed to follow this procedure in that:

1. The Rod Reclamation Hood (Reject Rod Unloading Station) was in use but no criticality sign was posted.
2. The criticality sign located on the tray elevator in the conversion dissolver area was not conspicuously posted in the front of the work station and was not available for reference by workers when required.
3. The following posted criticality signs were not complied with:
 - a. Several 9.5 inch diameter polypacks containing 3.8 percent enriched uranium "hardscrap" were stored on a rack in the Rotary Blender Area which was limited, according to the posted sign, to 3.7 percent enriched "hardscrap",
 - b. The twelve inch spacing between SNM, required by postings, on storage racks and in an array of drums containing SNM standards was not maintained, and
 - c. A storage rack in the Rod Loading Area contained trays of fuel pellets with a posting limiting the tray to a slab thickness of 4 inches. Several instances were noted where the 4 inch slab thickness was exceeded.

This is a Severity Level IV violation (Supplement VI).

- F. Chapter 2, Section 2.3.1.1 of the license application requires, in part, that operations shall be conducted in accordance with the written procedures maintained in the Regulatory Affairs Procedures Manual which describe general nuclear criticality control requirements.

Procedure RA-301, "Nuclear Criticality Control Criteria," Revision 6, dated January 10, 1990, requires, in part, that a minimum of one foot spacing shall be maintained between counters, racks, carts and equipment containing SNM under moderation control, and that greater separation distances may be required in areas containing interacting SNM which have "surface density" areas [yellow exclusion areas] assigned to them.

Procedure RA-302, "Criticality Signs," Revision 5, dated April 21, 1989, requires, in part, that criticality signs identifying applicable criticality control parameters and instructions shall be conspicuously posted on equipment or in areas where SNM is present as required by Regulatory Engineering.

Contrary to the above, during the OSA conducted during the period from August 17-28, 1992, a work table, used for the repair and cleaning of pumps and other pieces of equipment and located adjacent to a vertical safe geometry tank in the ADU conversion area, was situated over a portion of the yellow exclusion area for this tank and no restrictions or guidance was given for placement of SNM on the portion of the table that was above the exclusion area nor upon placing SNM on the shelf of the table located about six inches above the exclusion area.

This is a Severity Level IV violation (Supplement VI).

- G. Chapter 2, Section 2.3.1.1 of the license application requires, in part, that operations shall be conducted in accordance with the written procedures maintained in the Regulatory Affairs Procedures Manual which describe general nuclear criticality control requirements.

RA-104, "Regulatory Affairs Review Requests," Revision 6., dated March 3, 1992, a procedure which describes general nuclear criticality safety requirements for proposed additions or modifications, requires in part that Regulatory Engineering complete Section II of RA-104-1.

Review Request RA-104-1-782, "IDR Vaporization Process, Liquid Level Probe/Gravity Drain," Section II, required, in part, that the test engineer document the initial interlock verification using test data sheets in procedure RA-109, "Safety Significant Interlock Test Documentation."

Contrary to the above, on September 2, 1992, Review Request RA-104-1-782 was signed off as complete although, as of February 19, 1993, procedure RA-109, "Safety Significant Interlock Test Documentation," had not been approved and issued.

This is a Severity Level V violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Westinghouse Electric Corporation, Commercial Nuclear Fuel Division (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further

violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C (57 FR 5791, February 18, 1992), should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN:

Notice of Violation

8

Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia.

Dated at Atlanta, Georgia
this 25th day of April 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET NW
ATLANTA GEORGIA 30323

MAY 14 1993

Docket No. 030-03308
License No. 45-01589-01
EA 93-090

Winchester Medical Center
ATTN: Mr. David Goff
Administrator
Post Office Box 3340
Winchester, Virginia 22601

Gentlemen:

SUBJECT: NOTICE OF VIOLATION AND PROPOSED IMPOSITION OF CIVIL PENALTY -
\$1250 (NRC INSPECTION REPORT NO. 45-01589-01/93-01)

This refers to the Nuclear Regulatory Commission (NRC) inspection conducted by Mr. J. Henson on March 30-31, 1993, at the Winchester Medical Center, Winchester, Virginia. The inspection included an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. The report documenting this inspection was sent to you by letter dated April 28, 1993. During the inspection, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), 10 CFR Part 2, Appendix C, a licensee is provided an opportunity for an enforcement conference prior to an NRC determination of the appropriate enforcement action.

On April 22, 1993, Mr. D. Collins, Chief, Nuclear Materials Safety and Safeguards Branch, Division of Radiation Safety and Safeguards, NRC Region II, contacted you by telephone to arrange an enforcement conference to discuss the apparent violation associated with your failure to fully implement a quality management program. During that telephone conversation, you indicated that you did not see the benefit of participating in an enforcement conference because the NRC had been provided all the relevant information concerning the violation including your corrective actions. After reviewing this matter, we agree that we have all the information needed to determine the appropriate enforcement action.

We have completed our review of this matter. Violation I.A in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice) involved the failure to establish a written quality management program that included written policies and procedures to cover the administration of sodium iodide I-125 or I-131 in the range of 30 microcuries to 30 millicuries. On seven occasions between June 18, 1992 and March 31, 1993, administrations of between 3 and 5.5 millicuries of sodium iodide I-131 were made to patients for whole body scans and were performed without the required written directive. Additionally, your staff failed to identify the patient by more than one method on these seven occasions. During discussions with the Radiation Safety

Officer (RSO), he indicated to the inspector that he was not aware that a quality management program was required for administrations in the range of 30 microcuries to 30 millicuries and consequently did not prepare a written program for administrations within that dose range. Failure to establish and implement a written quality management program for the seven administrations for whole body scans is considered a significant failure to implement regulations. This failure is of concern because a contributing factor was a basic misunderstanding of the requirements associated with 10 CFR 35.32 for a Quality Management Program. Therefore, in accordance with the Enforcement Policy, this violation has been categorized at Severity Level III.

The staff recognizes that once the nature of the violation and attending requirements were understood, immediate corrective action was taken to prepare and implement a written quality management program for administrations in the range of 30 microcuries to 30 millicuries.

To emphasize the importance of ensuring the implementation of an adequate quality management program and complying with regulatory requirements and license conditions, I have been authorized to issue the enclosed Notice of Violation and Proposed Imposition of Civil Penalty in the amount of \$1,250 for the Severity Level III violation set forth in Part I of the enclosed Notice. The base civil penalty for a Severity Level III violation is \$2,500. The escalation and mitigation factors in the Policy were considered as discussed below.

Escalation of 50 percent was applied for the factor of identification because the violation in Part I of the Notice was identified by the NRC. Mitigation of 50 percent was warranted for good corrective action that included the immediate initiation of a review of all nuclear medicine records to establish the corrective action in cases involving the administration of doses greater than 30 microcuries, establishing a program to monitor future administrations to ensure compliance with the quality management program, and thoroughly briefing the nuclear medicine staff on program requirements. Mitigation of 50 percent was applied for the factor of licensee performance based on the results of two previous inspections conducted by the NRC. The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate. Therefore, based on the above, the base civil penalty has been decreased by 50 percent.

Although not identified for escalated enforcement, violation II.B in the enclosed Notice involved three occasions where the Radiation Safety Committee met and conducted business without a management representative present. This violation is of concern because the NRC expects licensee management to be involved fully in the Radiation Safety Program. Having a management representative attend Radiation Safety Committee meetings is an important element of that involvement. Violation II.C involved the failure to routinely conduct certain radiation surveys at the end of the day in areas where radiopharmaceuticals were prepared for use and administered.

MAY 12 1993

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebnetter
Regional Administrator

Enclosure:
Notice of Violation and Proposed
Imposition of Civil Penalty

cc w/encl:
Commonwealth of Virginia

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

Winchester Medical Center
Winchester, Virginia

Docket No. 030-03308
License No. 45-01589-01
EA 93-090

During an NRC inspection conducted on March 30-31, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the Nuclear Regulatory Commission proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violations and associated civil penalty are set forth below:

I. Violation Assessed a Civil Penalty

- A. 10 CFR 35.32(a) requires, in part, that each licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objectives that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, and that prior to each administration the patient's identity is verified by more than one method as the individual named in the written directive.

Contrary to the above, as of March 31, 1993, the licensee had not established a written quality management program that included written policies and procedures to cover the administration of sodium iodide I-125 or I-131 in the range of 30 microcuries to 30 millicuries, or a procedure for verifying a patient's identity by more than one method. Specifically, on seven occasions between June 18, 1992 and the date of the inspection, March 31, 1993, the licensee administered 3-5.5 millicuries of sodium iodide I-131 for whole body scans without the benefit of a written directive for such administrations and without verifying the identity of the patient by more than one method.

This is a Severity Level III violation. (Supplement VI).
Civil Penalty - \$1,250

II. Violations Not Assessed a Civil Penalty

- B. 10 CFR 35.22(a)(3) requires that to establish a quorum and conduct business, at least one half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

Contrary to the above, on March 6, September 18, and December 18, 1992, the licensee's Radiation Safety Committee met and conducted business without the management representative's presence.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, as of March 31, 1993, the licensee did not survey with a radiation detection instrument at the end of the day areas where radiopharmaceuticals were routinely prepared for use and administered. Specifically, daily radiation surveys were not performed on days when weekly contamination surveys were performed.

This is a Severity Level IV violation. (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Winchester Medical Center (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each alleged violation: (1) admission or denial of the alleged violation, (2) the reasons for the violation if admitted, and if denied, the reasons why, (3) the corrective steps that have been taken and the results achieved, (4) the corrective steps that will be taken to avoid further violations, and (5) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Consideration may be given to extending the response time for good cause shown. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Within the same time as provided for the response required above under 10 CFR 2.201, the Licensee may pay the civil penalty by letter addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a check, draft, money order, or electronic transfer payable to the Treasurer of the United States in the amount of the civil penalty proposed above, or the cumulative amount of the civil penalties if more than one civil penalty is proposed, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission. Should the Licensee fail to answer within the time specified, an order imposing the civil penalty will be issued. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be

clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice in whole or in part, (2) demonstrate extenuating circumstances, (3) show error in this Notice, or (4) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the factors addressed in Section VI.B.2 of 10 CFR Part 2, Appendix C, should be addressed. Any written answer in accordance with 10 CFR 2.205 should be set forth separately from the statement or explanation in reply pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty due which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c.

The response noted above (Reply to Notice of Violation, letter with payment of civil penalty, and Answer to a Notice of Violation) should be addressed to: Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region II, Atlanta, Georgia.

Dated at Atlanta, Georgia
this 14th day of May 1993

**II.B. MATERIALS LICENSEES, SEVERITY LEVEL III VIOLATION,
NO CIVIL PENALTY**

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION V

1450 MARIA LANE
WALNUT CREEK, CALIFORNIA 94596-5368

MAY 7 1993

Docket No. 030-17088
License No. 53-19179-01
EA No. 93-084

C&R Laboratories
2248 Aumakua Street
Pearl City, Hawaii 96782

Attention: Roland Watson
Owner/Radiation Safety Officer

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT No. 030-17088/93-02)

This refers to the inspection conducted on March 18, 30, and April 13, 1993, at your facility in Pearl City, Hawaii. The results of the inspection were reported in NRC Inspection Report No. 030-17088/93-01, dated April 23, 1993. The inspectors identified five apparent violations of NRC requirements. The violations, their causes, and your corrective actions were discussed with you during a telephone enforcement conference on April 29, 1993. The results of the Enforcement Conference are documented in NRC Inspection Report 93-02, and are enclosed.

Violation A in the enclosed Notice of Violation (Notice), involved the failure to wear an alarm ratemeter preset to alarm at 500 mR/hr between December 5, 1992, and March 18, 1993. The root cause of Violation A appears to be inadequate knowledge of the operation and limitations of the GS-15 chirper used by the Owner/RSO of the company. The purpose of the alarm ratemeter is to warn the radiographer if he/she approaches an unshielded source. Alarm setpoints are required to be set at 500 mR/hr to prevent the alarm ratemeter from alarming under normal radiographic conditions. If alarm ratemeters are set at lower levels, the frequent alarming of the device could be considered an annoyance by the radiographer, and the alarm ratemeter might be turned off. Therefore, this violation has been categorized at Severity Level III.

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy) 10 CFR Part 2, Appendix C, a civil penalty is considered for a Severity Level III violation. However, I have been authorized not to impose a civil penalty in this case based on the application of the civil penalty adjustment factors described below.

The base civil penalty was escalated 50% due to the NRC Inspectors' identification of the violation. The base civil penalty was mitigated 50% based on your prompt corrective action to remove the GS-15 chirper from service, which included locking the device in a storage cabinet, training radiographic personnel in the correct use of alarm ratemeters, and purchasing an additional RA-500 alarm ratemeter. Additionally, the base civil penalty

was mitigated 100% based on your past performance during the last two NRC inspections, which resulted in one non-cited violation.

The other adjustment factors in the Policy were considered and no further adjustment to the base civil penalty is considered appropriate.

Violations B and C in the enclosed Notice involve the use of a DOI Type B overpack which did not conform to the specifications of the Certificate of Compliance (COC) in violation of 10 CFR 71.12(2)(c), and the failure to provide periodic training to radiographic personnel every twelve months, as required by Section D of the Administrative Manual, which was submitted with your letter to NRC dated April 29, 1985. Violations B and C indicate a need for you to maintain more effective oversight of the Radiation Safety Program in order to ensure that personnel are trained in the proper use of safety related equipment.

The failure to specify the correct activity of Iridium-192 sealed sources on shipping papers as required by 49 CFR 172.203(d) is not being cited because the criteria specified in Section VII.B of the Enforcement Policy were satisfied. Based on your timely resubmittal of the 1992 personnel monitoring report, the apparent violation of 10 CFR 20.407 was withdrawn.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

John B. Martin
Regional Administrator

Enclosure:
Notice of Violation
NRC Enforcement Conference Report 93-02

NOTICE OF VIOLATION

C&R Laboratories
2248 Aumakua Street
Pearl City, Hawaii 96782

Docket No. 030-17088
License No. 53-19179-01
EA No. 93-084

During an NRC inspection conducted on March 18, 30, and April 13, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 34.33(a) and (f) require, in part, that the licensee not permit any individual to act as a radiographer or a radiographer's assistant unless, at all times during radiographic operations, the individual wears an alarm ratemeter set to give an alarm signal at a preset dose rate of 500 mR/hr.

Contrary to the above, on approximately forty occasions between December 5, 1991, and March 18, 1993, a licensee radiographer did not wear an alarm ratemeter set to give an alarm at a preset dose rate of 500 mR/hr while conducting radiographic operations.

This is a Severity Level III violation (Supplement VI).

- B. 10 CFR 71.12 states, in part, that a general license to transport licensed material, or to deliver licensed material to a carrier for transport, applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of 10 CFR 71, and complies with the terms and conditions of the certificate of compliance (COC).

Contrary to the above, between January 1 and March 18, 1993, the licensee transported licensed material under the general license pursuant to 10 CFR 71.12, and the licensee did not comply with the terms and conditions of the COC for the DOT Type B overpack, DOT 6717, used to transport Specification Type 7A radiographic devices. Specifically, the Type B overpack did not conform to the drawing and the "snug-fitting" requirements of the COC.

This is a Severity Level IV violation (Supplement V).

- C. License Condition 17 requires in part that the licensee possess and use licensed material in accordance with the statements, representations, and procedures contained in a letter to NRC dated April 29, 1985.

Section D of the Administrative Manual, submitted with your letter to NRC dated April 29, 1985, requires periodic training for all radiographic personnel every 12 months.

Contrary to the above, two radiographers had not received periodic training between December 5, 1991, and March 18, 1993, a period of 15 months.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, C&R Laboratories is hereby required to submit a written statement or explanation to the Regional Administrator, Region V, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, the Commission may issue an order or a demand for information as to why the license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Where good cause is shown, consideration may be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Walnut Creek, California
this 7th day of May, 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

MAY 04 1993

Docket No. 030-07551
License No. 37-00448-19
EA 93-083

Mr. Brian Finestein, Associate General
Director, Administration
Albert Einstein Medical Center
York and Tabor Roads
Philadelphia, Pennsylvania 19141

Dear Mr. Finestein:

Subject: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-07551/93-001)

This letter refers to the routine NRC inspection conducted on March 3-4, 1993, at your facility in Philadelphia, Pennsylvania, of activities authorized by NRC License No. 37-00448-19. The inspection report is enclosed. During the inspection, three violations of NRC requirements were identified, including a violation of the NRC Quality Management (QM) requirements. During a telephone conversation with Dr. Ronald Bellamy of the Region I office on April 15, 1993, you were provided an opportunity for an enforcement conference to discuss these violations. However, you decided that a conference was not needed.

The violations are described in the enclosed Notice of Violation (Notice) and consisted of: (1) the failure to prepare a written directive, as required by the QM rule, prior to the administration of 5.43 millicuries of iodine-131 to a patient in January 1993, as well as the failure to fully prepare other written directives during brachytherapy implants on other occasions (for example, on two occasions, the respective target organ, as well as the isotope to be used, were not specified); (2) failure to measure the thyroid burden of individuals involved in the administration of radioactive material to a patient; and (3) the failure to test your dose calibrator for linearity over the entire range of use of material.

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

MAY 04 1993

The NRC is particularly concerned with the violation of the QM program requirements. Although this violation did not result in any misadministration of materials to a patient, this violation is of particular concern because the failure to prepare a written directive creates the potential for a misadministration. Each of the specific QM requirements, including the written directive, provides a safety barrier which, if not adhered to, could result in a misadministration. Therefore, in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, this violation is classified at Severity Level III. The violation, along with two other violations that are classified at Severity Level IV, is set forth in the enclosed Notice.

The NRC recognizes that subsequent to this event, actions were taken to correct the QM violation and preclude recurrence. These actions included: (1) counseling staff, including authorized users, on your written QM procedures and requirements; (2) revising your brachytherapy patient treatment forms to include all required information; (3) revising your QM audit procedures to require cross checking written directives with your radiopharmaceutical dose administration records; (4) revising your QM program for brachytherapy to require audits at least every 12 months; and (5) initiating an audit of your brachytherapy QM program.

Notwithstanding these corrective actions, the NRC considered issuance of a civil penalty in this case to emphasize the importance of proper conduct of licensed activities at the facility, including strict adherence to QM requirements. However, after consideration of the escalation/mitigation factors in this case, I have decided to mitigate the penalty in its entirety. While a basis exists for escalation of the penalty by 50% because the violation was identified by the NRC, a basis also exists for 150% mitigation of the penalty based on your prompt and comprehensive corrective actions, as well as your prior good enforcement history. The other factors were considered and no further adjustment was warranted.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions, and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

Albert Einstein Medical Center

3

MAY 04 1993

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. 96-511.

Sincerely,

Thomas T. Martin
Regional Administrator

Enclosures:

1. Notice of Violation
2. Inspection Report No. 030-07551/93-001

ENCLOSURE 1

NOTICE OF VIOLATION

Albert Einstein Medical Center
Philadelphia, Pennsylvania

Docket No. 030-07551
License No. 37-00448-19
EA 93-083

During an NRC inspection conducted on March 3-4, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the particular violations are listed below:

- A. 10 CFR 35.32(a) requires, in part, that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of sodium iodide (iodine-131) and any brachytherapy radiation dose.

10 CFR 35.2 defines a written directive for an administration of quantities greater than 30 microcuries of either sodium iodine, iodine-131 or iodine-125, as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical, and which contains the dosage. For a brachytherapy procedure, the written directive for a specific patient, dated and signed by an authorized user, must contain, in part, the treatment site and the isotope to be used.

Items I.A.1 and I.A.3 of the licensee's "Quality Management Program for the Therapeutic Use of Radiopharmaceuticals," also written to comply with 10 CFR 36.32(a) and submitted on January 21, 1992, require in part, that "a written directive (order) will be filled out for each patient using the appropriate form" and that "the written directive be checked prior to the administration and will be followed precisely."

Item 1 of the licensee's "Quality Management Program for Brachytherapy Procedures," written to comply with 10 CFR 35.32(a) and submitted on January 21, 1992, requires that, "before any brachytherapy application of radioactive isotopes takes place, a written directive should be given, in a specified format (directive form), by an authorized user. The directive should be duly signed and dated."

Contrary to the above, a written directive signed and dated by the authorized user was not prepared prior to the administration of 5.43 millicuries of iodine-131 to a patient on January 29, 1993. In addition, written directives were not fully prepared as required by 10 CFR 35.2 for certain brachytherapy procedures performed prior to March 4, 1993. For example, the written directives that were prepared for brachytherapy implants on February 10, 1992, and August 5, 1992, did not specify the treatment site or the isotope that was to be used.

This is a Severity Level III violation (Supplement VI).

- B. 10 CFR 35.315(a)(8) requires, in part, that a licensee measure the thyroid burden of each individual who helped prepare or administer dosages of iodine-131 in amounts that required the patient to be hospitalized for compliance with 10 CFR 35.75, and that the measurements be performed within three days after the administration of the dosage.

Contrary to the above, on July 7, 1992, and February 19, 1993, the licensee administered patient doses of 200 millicuries and 190 millicuries of iodine-131, respectively, dosages which require hospitalization for compliance with 10 CFR 35.75, and, as of March 4, 1993, the licensee did not measure the thyroid burden of the individuals involved in the preparation and administration of the dosage on July 7, 1992, nor the individual who administered the dosage on February 19, 1993, a period of time, in each case, in excess of three days.

This is a Severity Level IV violation (Supplement VI).

- C. 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity over the range of its use between the highest dosage that will be administered to a patient and 10 microcuries.

Contrary to the above, the licensee's dose calibrator linearity test performed on December 7, 1992, covered only the range between 193 millicuries and 3.1 microcuries, and the highest dosage that the licensee administered to a patient on January 29, 1993, was a dosage of 246 millicuries.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Albert Einstein Medical Center is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at King of Prussia, Pennsylvania
this 4th day of May 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION II
101 MARIETTA STREET, N.W.
ATLANTA, GEORGIA 30323

APR 22 1993

Docket No. 030-06580
License No. 45-08890-02
EA 93-080

Froehling and Robertson, Inc.
ATTN: Mr. Sam Kirby
President
Post Office Box 27524
Richmond, Virginia 23261

Gentlemen:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT NO. 45-08890-02/93-01)

This refers to the inspection conducted by W. Loo of this office on March 30, 1993. The inspection included a review of activities authorized for your Roanoke, Virginia facility. At the conclusion of the inspection, the findings were discussed with Mr. Donald Sipher, Manager.

The inspection was an examination of activities conducted under your license with respect to radiation safety and compliance with NRC regulations and the conditions of your license. It included selective examinations of procedures and representative records, interviews with personnel, and direct observations by the inspector.

Based on the results of this inspection, certain of your activities appeared to be in violation of NRC requirements, as specified in the enclosed Notice of Violation (Notice). Violation A in the enclosed Notice involved the failure to maintain constant surveillance and immediate control of licensed material at a temporary job-site on or about October 1, 1992. The licensed material consisted of approximately 8 millicuries (mCi) of cesium-137 and 40 mCi of americium-241 contained in a portable moisture-density gauge. Because the gauge was not under constant surveillance and immediate control of the licensee at the temporary job-site, a bulldozer hit and damaged the gauge.

This violation is of particular concern to the NRC because it could have resulted in unnecessary exposure of individuals to radiation had the gauge's source been severely damaged and radioactive material released. Although the probability that the licensed material posed any significant risk to the public health and safety was minimal because the damage to the gauge was not to the sealed source but the source rod handle, the NRC nevertheless considers this to have been a serious event. The violation indicates a serious lapse of attention on the part of the authorized user which could have resulted in significant radiological consequences due to the failure to follow established procedures. Therefore, this violation has been classified as a Severity Level III violation.

APR 22 1993

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), 10 CFR Part 2, Appendix C, Severity Level III violations generally are considered for escalated enforcement action. Prior to taking escalated enforcement action, the NRC normally holds an enforcement conference to discuss the violation, its cause and safety significance, and the corrective action to preclude recurrence. On April 8, 1993, the Enforcement Policy relative to enforcement conferences was discussed with you by telephone. On April 13, 1993, Mr. William Briody of your staff informed the NRC by telephone that Froehling and Robertson agreed that the NRC had all the relevant information concerning the violation and that an enforcement conference was not needed in this case.

Although the NRC considers a civil penalty for Severity Level III violations, I have decided, after considering the civil penalty adjustment factors set forth in the NRC's Enforcement Policy, that a civil penalty will not be proposed in this case because of your prompt and extensive corrective actions, and your good prior performance.

Violation B in the enclosed Notice involved the failure of licensee personnel to follow emergency procedures. Your emergency procedures specifically require that when a gauge is damaged, the individual using the gauge will post a guard on the area, call the Radiation Safety Officer (RSO) as soon as possible, await instructions and make no attempt to move the damaged equipment until advised to do so. Instead of following the emergency procedures, the user of the gauge damaged on or about October 1, 1992, had the damaged gauge repaired by an unauthorized facility and continued to use the gauge without notifying the RSO of the incident. This violation was classified as a Severity Level IV violation. This violation indicates the need to ensure that personnel receive the appropriate training to ensure that emergency procedures are properly implemented.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and any reply will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Froehling and Robertson, Inc.

3

APR 22 1993

Should you have any questions concerning this letter, please contact us.

Sincerely,

Stewart D. Ebner
Regional Administrator

Enclosures:

1. Notice of Violation
2. Inspection Report

cc w/encs:
Commonwealth of Virginia

ENCLOSURE 1

NOTICE OF VIOLATION

Froehling and Robertson, Inc.
Richmond, Virginia

Docket No. 030-06580
License No. 45-08890-02
EA 93-080

During an NRC inspection conducted March 30, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 20.207(b) requires that licensed materials in an unrestricted area and not in storage be tended under constant surveillance and immediate control of the licensee. As defined in 10 CFR 20.3(a)(17), an unrestricted area is any area access to which is not controlled by the licensee for purposes of protection of individuals from exposure to radiation and radioactive materials.

Contrary to the above, on or about October 1, 1992, licensed material consisting of approximately 8 millicuries (mCi) of cesium-137 and 40 mCi of americium-241, contained in a portable moisture-density gauge located at a construction site in Blacksburg, Virginia, an unrestricted area, was not under constant surveillance and immediate control of the licensee's authorized user and the gauge was struck by a bulldozer and damaged.

This is a Severity Level III violation (Supplement IV).

- B. License Condition No. 19 of NRC License No. 45-08890-02 requires, in part, that the licensee possess and use licensed material in accordance with the statements, representations and procedures contained in the license application dated May 29, 1991.

Section 8.1.2.4 of the "Administrative Control and Radiation Protection Procedures Manual" submitted under Item 10.6 of the application requires, in part, that upon damage of a gauge the authorized user will post a guard on the area, call the Radiation Safety Officer (RSO) as soon as possible, await instructions and make no attempt to move the damaged equipment until advised to do so.

Contrary to the above, on or about October 1, 1992, a portable moisture-density gauge was damaged at a construction site located in Blacksburg, Virginia, and a licensee employee, an authorized user, failed to post a guard on the area or call the RSO. In addition, the user transported the damaged equipment to an unauthorized repair facility and had the gauge repaired.

This is a Severity Level IV violation (Supplement IV).

Froehling and Robertson, Inc.
Richmond, Virginia

2

Docket No. 030-06580
License No. 45-08890-02

Pursuant to the provisions of 10 CFR 2.201, Froehling and Robertson, Inc. is hereby required to submit a written statement or explanation to the Regional Administrator, Region II, with a copy to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or demand for information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

Dated at Atlanta, Georgia
This 22nd day of April, 1993

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV

611 RYAN PLAZA DRIVE SUITE 400
ARLINGTON TEXAS 76011-8084

JUN 25 1993

Docket No. 030-10133
License No. 49-15978-01
EA 93 163

Iverson Memorial Hospital
ATTN: Thomas A. Nord, CEO
255 North 30th Street
Laramie, Wyoming 82070

SUBJECT: NOTICE OF VIOLATION (NRC INSPECTION REPORT NO. 30 10133/93 01)

This refers to the inspection conducted on May 18, 1993, at Iverson Memorial Hospital (IMH), Laramie, Wyoming. A report describing the results of this inspection was issued on June 4, 1993. On June 15, 1993, you and Dr. Robert Knight participated in a telephonic enforcement conference with the NRC to discuss the hospital's failure to implement a Quality Management Program (QMP) as required by 10 CFR 35.32. A list of the participants in that enforcement conference is enclosed (Enclosure 2).

As discussed during the enforcement conference, 10 CFR Part 35 was revised in January 1992 to require NRC medical licensees to establish and maintain written QMPs to provide high confidence that byproduct material or radiation from byproduct material would be administered as directed by an authorized user. The rule requires, in part, that a written directive be prepared prior to the administration of iodine-131 in quantities greater than 30 microcuries, and prior to any therapeutic administration of other radiopharmaceuticals. Additionally, the QMP should be reviewed by the licensee within 12 months of the implementation of the program on January 27, 1992.

The NRC's inspection determined that IMH administered sodium iodide I-131 in quantities greater than 30 microcuries for diagnostic whole body scans on three occasions in 1992 and 1993. However, written directives were not prepared prior to the administrations as required by the rule. In addition, the inspection determined that IMH had not conducted an annual review of its QMP as required by NRC regulations and by its own QMP.

In a letter dated June 14, 1993, IMH informed the NRC that its radiation safety officer had, about one week prior to the inspection, identified the fact that written directives were required for diagnostic whole body scans and had scheduled this item for discussion at a radiation safety committee meeting that took place one day after the NRC inspection. The letter stated that corrective action was deferred because no iodine-131 whole body scans were scheduled between the radiation safety officer's finding and the date of the committee meeting. This information was discussed thoroughly during the enforcement conference and has been considered in determining the enforcement action (see discussion below).

In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, a

JUL - 5 1993

substantial failure to implement the QMP is classified at Severity Level III. Thus, violations A and B in the enclosed Notice of Violation (Notice) are classified in the aggregate as a Severity Level III problem. The remaining violation has been categorized at Severity Level IV.

A civil penalty is considered for a Severity Level III problem. The base value for a Severity Level III problem is \$2,500. The civil penalty adjustment factors in Section VI.B.2 were considered and resulted in full mitigation of the penalty. Identification of a violation by NRC would normally result in an increase equal to 50 percent of the base value. However, the NRC has accepted your explanation, as discussed above, that IMH's radiation safety officer identified the failure to use written directives for diagnostic whole body scans using iodine-131. IMH's identification of this violation warrants a decrease equal to 50 percent of the base value. NRC acknowledges that IMH took prompt action to restore compliance following the identification of the apparent violations, and submitted a response to each of the apparent violations prior to the enforcement conference, thus warranting a decrease of 50 percent of the base value. The remaining adjustment factors were considered, but no further adjustments were considered appropriate.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further NRC enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be placed in the NRC Public Document Room.

The responses directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Pub. L. No. 96-511.

Sincerely,

James L. Milhoan

Regional Administrator

Enclosures:

1. Notice of Violation
2. Enforcement Conference Participants

cc w/enclosures:
State of Wyoming

NOTICE OF VIOLATION

Ivinson Memorial Hospital
Laramie, Wyoming

Docket No. 30-10133
License No. 49-15978-01
EA 93-163

During an NRC inspection conducted on May 18, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 35.32(a), which became effective on January 27, 1992, states in part, that a licensee shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the specific objective that, prior to administration, a written directive is prepared for any administration of quantities greater than 30 microcuries of sodium iodide I-125 or I-131.

10 CFR 35.2 specifies, in part, that a written directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical. For the administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, the written directive must include the dosage.

Contrary to the above, between January 27, 1992, and May 18, 1993, the licensee failed to establish and maintain a quality management program that ensured that a written directive was prepared prior to the administration of sodium iodide I-131 in quantities greater than 30 microcuries. Specifically, an authorized user failed to prepare a written directive for two doses of sodium iodide I-131 administered on February 28, 1992, and April 5, 1993, to patients in quantities greater than 30 microcuries.

- B. 10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user shall require the supervised individual to follow the written quality management procedures established by the licensee.

The licensee's Quality Management Program, dated January 21, 1992, contains a written policy and procedure for administration of I-125 or I-131 which specifies that prior to administration a written directive will be prepared for any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131. The Quality Management Program also specifies that each administration will be in accordance with the written directive.

JUN 25 1993

Contrary to the above, an individual working under the supervision of the authorized user failed to verify that a written directive was made prior to administering two doses of sodium iodide I-131 on February 28, 1992, and April 5, 1993, to patients in quantities greater than 30 microcuries.

These violations represent a Severity Level III problem (Supplement VI).

- C. 10 CFR 35.32(b) requires, in part, that: (1) a licensee develop procedures for and conduct a review of the QM program including an evaluation of a representative sample of patient administrations and all recordable events to verify compliance with all aspects of the QM program at intervals no greater than 12 months; (2) evaluate these reviews to determine the effectiveness of the QM program; and (3) retain records of each review, including the evaluations and findings of the review, in an auditable form for 3 years. A recordable event is defined in 10 CFR 35.2 as the administration of a radiopharmaceutical without a written directive where a written directive is required.

The licensee's QM program submitted January 21, 1992, states that on an annual basis, the Radiation Safety Officer will conduct a review of the QM program including an evaluation of a representative sample of patient administrations and all recordable events, evaluate each review to determine the effectiveness of the QM program, and retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

Contrary to the above, as of May 18, 1993, the licensee had not conducted a review of the QM program to include a representative sample of patient administrations and all recordable events since the program was implemented on January 27, 1992. Recordable events had occurred on February 28, 1992, and April 5, 1993, when the licensee failed to provide written directives for the administration of 8 and 10 millicuries of I-131, respectively.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Iverson Memorial Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region IV, 611 Ryan Plaza Drive, Suite 400, Arlington, Texas 76011, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice,

JUN 25 1993

an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

Dated at Arlington, Texas,
this 25th day of June 1993

Enforcement Conference Participants

June 15, 1993 Enforcement Conference*

NRC Region IV representatives

John M. Montgomery, Deputy Regional Administrator, Region IV
L. Joseph Callan, Director, Division of Radiation Safety and Safeguards
(DRSS)
Charles L. Cain, Chief, Nuclear Materials Inspection Section, DRSS
William L. Brown, Regional Counsel
Gilbert L. Guerra, Radiation Specialist

Ivinson Memorial Hospital representatives

Thomas A. Nord, CEO
Robert Knight, MD, Radiation Safety Officer

*Conference conducted telephonically

UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
700 ROOSEVELT ROAD
GLEN ELLYN, ILLINOIS 60137-5027
June 4, 1993

Docket No. 030-02669
License No. 34-01055-01
EA 93-113

Riverside Methodist Hospital
ATTN: Marian Hamm
Senior Vice President
3535 Olentangy River Road
Columbus, Ohio 43214

Dear Ms. Hamm:

SUBJECT: NOTICE OF VIOLATION
(NRC INSPECTION REPORT 030-02669/93001)

This refers to the inspection conducted from March 10 to March 12, 1993, at Riverside Methodist Hospital, Columbus, Ohio, to review the circumstances surrounding the misadministration of cesium-137 to a patient being treated for adenocarcinoma of the cervix. The patient was treated for 35 hours instead of the 51 hours needed to deliver the intended dose. Therefore, the total dose administered was 2201 rads instead of the prescribed 3248 rads. The report documenting this inspection was sent to you by letter dated March 26, 1993. Significant violations of NRC requirements were identified during the inspection, and on May 25, 1993, an enforcement conference was held in the Region III office. Attending the conference were you, Mr. William Axelson, Deputy Director, Division of Radiation Safety and Safeguards, and other members of our respective staffs.

On February 10-12, 1992, a patient underwent an intracavitary brachytherapy source implant procedure as part of a treatment for stage 1 adenocarcinoma of the cervix. An appropriate written directive was executed and signed by one of your authorized users prior to initiation of the treatment. The directive initially specified an approximate dose rate range to a specific location, a treatment time, and listed cesium-137 as the radioisotope. Based on this initial information, a physicist generated a recommended source and dose rate distribution with the aid of a treatment planning computer. After physician approval of the source distribution and dose rate, the total dose was calculated and the written directive completed. The physician reviewed and approved the isodose distribution and dose rate results generated by the treatment planning computer. However, neither the physician nor any other qualified person independently reviewed all treatment planning calculations, including the computer printout information. The physicist involved in the treatment planning calculation self-checked the calculations and the computer printout, but failed to

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

June 4, 1993

discover that iridium-192 was mistakenly selected and listed on the computer printout as the treatment radioisotope rather than the required cesium-137, as prescribed. As a result of this error, the dose rate and consequently the total dose prescribed were based on nine, iridium-192 sources of 19.79 millicuries each, rather than on cesium-137. Since cesium-137 sources were actually used in the implant procedure, the total dose administered to the patient was 32 percent less than the prescribed dose because of the treatment time of 35 hours rather than the necessary 51 hours.

The error and the misadministration were identified by your medical physicists on February 25, 1993, during an audit of your Quality Management Plan (QMP) pursuant to 10 CFR 35.32(b). You then reported the misadministration to the NRC by telephone, as required, and submitted a written report by letter dated March 8, 1993.

Two violations of NRC requirements were identified relative to this misadministration and are described in the enclosed Notice of Violation (Notice). The first violation pertains to the failure to adequately verify that the radioisotope to be used agreed with the written directive and treatment plan, as required by your QMP. The second violation pertains to the failure to independently verify treatment time calculations as required by a license condition and your operating procedures. These violations, taken collectively, represent a significant programmatic problem with your QMP. More importantly you estimated that only 30 percent of the low dose rate brachytherapy administrations were independently verified. We acknowledge that you have since checked all such administrations and have not found any similar events. Nonetheless, your QMP requires independent verification to preclude mistakes such as the one that occurred during February 1992. Although there was little safety significance of this particular misadministration, such errors could just as easily result in overexposures as well as underexposures. Therefore, in accordance with the "Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy) 10 CFR Part 2, Appendix C, the violations are classified in the aggregate as a Severity Level III problem.

The root causes of the violations and your subsequent corrective actions were discussed during the May 25, 1993, enforcement conference. A major factor contributing to the violations appeared to be your misunderstanding that the QMP took precedence over your existing license conditions, and that the related license conditions and operating procedures were no longer applicable.

We acknowledge your immediate and substantial corrective actions after the misadministration was identified. Your first corrective

June 4, 1993

action consisted of modifying the treatment planning computer radioisotope selector to remove six isotopes which are no longer in use and rekeying iridium-192 and cesium-137, to key positions '1' and '3,' respectively, which will allow sufficient separation to prevent an error by selecting the wrong key stroke when the dosimetrist inserts the desired isotope by key number. Your second corrective action was to begin requiring independent checks of treatment calculations even before you realized that you were required to do so. The third corrective action was to review the independent verification procedures with all four physicists and a new employee was given thorough training on each of the steps required. Your fourth corrective measure was to change your procedures such that henceforth, independent verifications will always be required without any exceptions, including emergencies, weekends or holidays. Finally, all personnel have been trained on the revised operating procedures.

In accordance with the Enforcement Policy, a civil penalty is normally considered for a Severity Level III problem. However, I have decided that a civil penalty will not be proposed in this case because of your extensive corrective actions and your recent good performance. However, you are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. In your response, you should document the specific actions taken and any additional actions you plan to prevent recurrence. After reviewing your response to this Notice, including your proposed corrective actions and the results of future inspections, the NRC will determine whether further enforcement action is necessary to ensure compliance with NRC regulatory requirements.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be placed in the NRC Public Document Room.

The response directed by this letter and the enclosed Notice are not subject to the clearance procedures of the Office of Management and Budget as required by the Paperwork Reduction Act of 1980, Public Law No. 96-511.

Sincerely,

J. B. Martin,
Regional Administrator

Enclosure:
Notice of Violation

NOTICE OF VIOLATION

Riverside Methodist Hospital
Columbus, Ohio

Docket No. 030-02669
License No. 34-01055-01
EA 93-113

During an NRC inspection conducted from March 10-12, 1993, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

- A. 10 CFR 35.32(a)(3) requires that each licensee establish and maintain a written quality management program to provide high confidence that byproduct material will be administered as directed by the authorized user. The quality management program must include, in part, written policies and procedures to meet the objective that the final plans of treatment and related calculations are in accordance with the written directive.

10 CFR 35.25(a)(2) requires, in part, that a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b), shall require the supervised individual to follow the instructions of the supervising authorized user and follow the written radiation safety and quality management procedures established by the licensee.

Items 3 and 5 of the licensee's quality management program entitled "Low dose Rate Selectron/Conventional Brachytherapy" require that: (1) the radioisotope be confirmed by the person administering the treatment to verify agreement with the written directive and plan of treatment; and (2) an authorized user or a qualified person under the supervision of an authorized user verify that the radioisotope to be used is in agreement with the written directive and plan of treatment before implanting the sources.

Contrary to the above, on February 10, 1992, the supervised individual administering the treatment (physicist) failed to adequately verify that the radioisotope agreed with the written directive and treatment plan. In addition, the authorized user or other qualified person under the supervision of the authorized user failed to adequately verify that the radioisotope to be used agreed with the written directive and treatment plan before implanting the sources. Specifically, both the physicist and the authorized user failed to adequately verify that the radioisotope to be used was cesium-137 rather than iridium-192.

- B. 10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures. The licensee's operating procedures for its Selectron LDR remote afterloader unit are provided, in part, in letters dated October 26, 1987, and January 8, 1990, and were approved by License Condition No. 18. These letters both state in Item VI.A.vi of an enclosure entitled "Operating Procedures," that treatment time calculations will be independently verified.

Contrary to the above, on February 10, 1992, and routinely on numerous other occasions in 1992 and 1993 through February 26, 1993, the licensee failed to independently verify treatment time calculations associated with patients treated using its LDR remote afterloader unit.

These violations represent a Severity Level III problem (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, Riverside Methodist Hospital is hereby required to submit a written statement or explanation to the U. S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region III, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, this response shall be submitted under oath or affirmation.

FOR THE NUCLEAR REGULATORY COMMISSION

J. B. Martin
Regional Administrator

Dated at Glen Ellyn, Illinois
this 4 day of June, 1993

III. INDIVIDUAL ACTIONS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 4, 1993

IA 93-001

Mr. Richard J. Gardecki
(Address)

Dear Sir:

SUBJECT: ORDER PROHIBITING INVOLVEMENT IN CERTAIN NRC-LICENSED
ACTIVITIES (EFFECTIVE IMMEDIATELY)

The enclosed Order is being issued because of your violations of 10 CFR 40.10 of the Commission's regulations as described in the Order.

Failure to comply with the provisions of this Order may result in civil or criminal sanctions.

Questions concerning this Order should be addressed to Mr. James Lieberman, Director, Office of Enforcement, who can be reached at (301) 504-2741.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice", a copy of this letter and the enclosures will be placed in the NRC's Public Document Room.

Sincerely,

A handwritten signature in dark ink, appearing to read "Hugh L. Thompson, Jr.", is written over the typed name.

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety,
Safeguards and Operations
Support

Enclosure: As stated

cc: Allied-Signal, Inc.
All Agreement States
SECY

UNITED STATES
NUCLEAR REGULATORY COMMISSION

In the Matter of
Richard J. Gardecki

)
)
)
)

IA 93-001

ORDER PROHIBITING INVOLVEMENT IN CERTAIN
NRC-LICENSED ACTIVITIES
(EFFECTIVE IMMEDIATELY)

I

Richard J. Gardecki was recently employed by Allied-Signal, Inc., Metropolis, Illinois. Allied-Signal, Inc. (Licensee) holds License No. SUB-526 issued by the Nuclear Regulatory Commission (NRC or Commission) pursuant to 10 CFR Part 40. The license authorizes possession and conversion of uranium in accordance with the conditions specified therein. Mr. Gardecki was employed by the Licensee from about June 1991 through December 1992 in the position of Assistant Health Physicist, with responsibilities involving compliance with NRC requirements for radiation protection. Under the Licensee's organization and qualifications requirements, as specified in License Condition No. 9, an Assistant Health Physicist is required to hold a bachelor's degree. Failure to have a bachelor's degree holder in that position constitutes a violation of License Condition No. 9.

II

On October 5-7, 1993, an inspection was conducted at the Licensee's facility at Metropolis, Illinois, as a result of concerns raised within the NRC staff as to the education and experience of Richard J. Gardecki. As a result of information

developed in that inspection, an investigation was conducted in November and December 1992 by the Office of Investigations (OI). The inspection and investigation revealed that Mr. Gardecki intermittently took courses at the University of Delaware between 1962 and 1967 and in 1978, but did not accumulate sufficient credits to earn a bachelor's degree. While employed at the University of Delaware between 1977 and 1981, Mr. Gardecki prepared a transcript that falsely reflected sufficient hours of credit at that University to entitle him to a Bachelor of Science degree.

Mr. Gardecki subsequently used the false transcript to obtain employment at the University of Nebraska in about 1983, at Westinghouse Radiological Services Division in about 1985, at Environmental Testing Inc., in 1988, and at the Licensee in about June 1991. In each of these positions, Mr. Gardecki was involved in activities licensed by the NRC or an Agreement State, pursuant to an agreement with the NRC under section 274 of the Atomic Energy Act of 1954, as amended.

In addition, Mr. Gardecki obtained employment as a Radiation Specialist at the NRC in 1987 by submitting a Standard Form 171 (SF171), Application for Federal Employment, which contained the same false information regarding a bachelor's degree at the University of Delaware. He was allowed to resign his NRC employment following identification of the falsehood. Also,

during the OI investigation, he admitted that he had provided false information to the NRC regarding prior employment by General Dynamics in Denver, Colorado.

Further, in a transcribed sworn statement on December 1, 1992, Mr. Gardecki deliberately provided false information to OI investigators when he stated that he graduated from the University of Delaware in 1961. When asked about the University records indicating that he had not received a degree, Mr. Gardecki fabricated a story about the University having mixed his record with that of his brother. He also deliberately provided false information as to the accuracy of a University of Delaware transcript that he had submitted to the Licensee. In a transcribed, sworn statement to OI investigators on December 14, 1992, Mr. Gardecki admitted that he had provided false information in his sworn statements previously given to OI investigators on December 1, 1992 concerning his academic record and applications for employment.

III

Based on the above, Mr. Gardecki engaged in deliberate misconduct, which through his employment (from about June 1991 through December 1992) in a position with educational requirements that Mr. Gardecki did not meet, caused the Licensee to be in violation of the organization and qualifications

requirements of License Condition No. 9. This is a violation of 10 CFR 40.10. Mr. Gardecki also deliberately provided to NRC investigators information that he knew to be inaccurate and was in some respects material to the NRC which also constitutes a violation of 10 CFR 40.10. As an Assistant Health Physicist for the Licensee, Mr. Gardecki was responsible for performance of required surveys and keeping of required records, all of which provide evidence of compliance with Commission requirements. The NRC must be able to rely on the Licensee and its employees to comply with NRC requirements, including the requirement to provide information and maintain records that are complete and accurate in all material respects. Mr. Gardecki's deliberate actions in causing this Licensee to be in violation of License Condition No. 9, a violation of 10 CFR 40.10, and his violation of 10 CFR 40.10 caused by his deliberate misrepresentations to the NRC have raised serious doubt as to whether he can be relied upon to comply with NRC requirements and to provide complete and accurate information to the NRC or to an employer. Mr. Gardecki's misconduct (repeated on several occasions over several years with several employers) caused this Licensee to violate a Commission requirement; and his false statements to Commission officials demonstrate conduct that cannot and will not be tolerated.

Consequently, I lack the requisite reasonable assurance that licensed activities in NRC jurisdiction can be conducted in

compliance with the Commission's requirements and that the health and safety of the public will be protected, if Mr. Gardecki were permitted at this time to be named as a Radiation Safety Officer (RSO) on an NRC license or permitted to supervise licensed activities (i.e., being responsible in any respect for any individual's performance of any licensed activities) for an NRC licensee or an Agreement State licensee while conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20.

Therefore, the public health, safety and interest require that Mr. Gardecki be prohibited from being named on an NRC license as an RSO or from supervising licensed activities (i.e., being responsible in any respect for any individual's performance of any licensed activities) for an NRC licensee or an Agreement State licensee while conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20 for a period of five years from the date of this Order. In addition, for the same period, Mr. Gardecki is required to give notice of the existence of this Order to a prospective employer engaged in licensed activities, described below (Section IV, paragraph 2), to assure that such employer is aware of Mr. Gardecki's previous history. Mr. Gardecki is also required to notify the NRC of his employment by any person engaged in licensed activities, described below (Section IV, paragraph 2), so that appropriate inspections can be performed. Furthermore, pursuant to 10 CFR 2.202, I find that the significance of the conduct described above is such that the

public health, safety and interest require that this Order be immediately effective.

IV

Accordingly, pursuant to sections 61, 81, 103, 161b, 161i, 182 and 186 of the Atomic Energy Act of 1954, as amended, and the Commission's regulations in 10 CFR 2.202, 10 CFR 40.10, and 10 CFR 150.20, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

1. Richard J. Gardecki is prohibited for five years from the date of this Order from being named on an NRC license as a Radiation Safety Officer or from supervising licensed activities (i.e., being responsible in any respect for any individual's performance of any licensed activities) for an NRC licensee or an agreement state licensee while conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20.
2. Should Richard J. Gardecki seek employment with any person engaged in licensed activities during the five year period from the date of this Order, Mr. Gardecki shall provide a copy of this Order to such person at the time Mr. Gardecki is soliciting or negotiating employment so that the person is aware of the Order prior to making an employment decision. For the

purposes of this paragraph licensed activities include licensed activities of 1) an NRC licensee, 2) an Agreement State licensee conducting licensed activities in NRC jurisdiction pursuant to 10 CFR 150.20, and 3) an Agreement State licensee involved in distribution of products that are subject to NRC jurisdiction.

3. For a five year period from the date of this Order, Richard J. Gardecki shall provide notice to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, of the name, address, and telephone number of the employer, within 72 hours of his acceptance of an employment offer, involving licensed activities described in paragraph 2, above.

The Director, Office of Enforcement, may, in writing, relax or rescind any of the above conditions upon demonstration by Mr. Gardecki of good cause.

In accordance with 10 CFR 2.202, Richard J. Gardecki must, and any other person adversely affected by this Order may, submit an answer to this Order, and may request a hearing on this Order, within 20 days of the date of this Order. The answer may consent to this Order. Unless the answer consents to this Order, the

answer shall, in writing and under oath or affirmation, specifically admit or deny each allegation or charge made in this Order and shall set forth the matters of fact and law on which Richard J. Gardecki or other person adversely affected relies and the reasons as to why the Order should not have been issued. Any answer or request for a hearing shall be submitted to the Secretary, U.S. Nuclear Regulatory Commission, Attn: Chief, Docketing and Service Section, Washington, DC 20555. Copies also shall be sent to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555, to the Assistant General Counsel for Hearings and Enforcement at the same address, to the Regional Administrator, NRC Region III, 799 Roosevelt Rd., Glen Ellyn, IL 60137, and to Richard J. Gardecki, if the answer or hearing request is by a person other than Richard J. Gardecki. If a person other than Richard J. Gardecki requests a hearing, that person shall set forth with particularity the manner in which his or her interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.714(d).

If a hearing is requested by Richard J. Gardecki or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

Pursuant to 10 CFR 2.202(c)(2)(i), Richard J. Gardecki, or any other person adversely affected by this Order, may, in addition to demanding a hearing, at the time the answer is filed or sooner, move the presiding officer to set aside the immediate effectiveness of the Order on the ground that the Order, including the need for immediate effectiveness, is not based on adequate evidence but on mere suspicion, unfounded allegations, or error.

In the absence of any request for hearing, the provisions specified in Section IV above shall be final 20 days from the date of this Order without further order or proceedings. AN ANSWER OR A REQUEST FOR HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

FOR THE NUCLEAR REGULATORY COMMISSION

Hugh L. Thompson, Jr.
Deputy Executive Director
for Nuclear Materials Safety,
Safeguards and Operations Support

Dated at Rockville, Maryland
this 4th day of May 1993

END

**DATE
FILMED**

11/10/93