NUREG/CR-5784
PNL-7795
BHARC-700/91/025

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Fitness for Duty in the Nuclear Power Industry

A Review of the First Year of Program Performance
and an Update of the Technical Issues

Prepared by
N. Durbin, C. Moore, T. Grant, T. Fleming, P. Hunt, R. Martin, S. Murphy, J. Hauth,
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Battelle Human Affairs Research Centers

Pacific Northwest Laboratory

Prepared for
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Manuscript Completed: September 1991
Date Published: September 1991

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Prepared for
Division of Reactor Inspection and Safeguards
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555
NRC FIN I2007

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ABSTRACT

This report presents an overview of the NRC licensees' implementation of the FFD program during the first full year of the program's operation and provides new information on a variety of FFD technical issues. The purpose of this document is to contribute to appropriate changes to the rule, to the inspection process, and to other NRC activities. It describes the characteristics of licensee programs, discusses the results of NRC inspections, updates technical information covered in previous reports, and identifies lessons learned during the first year. Overall, the experience of the first full year of licensees' FFD program operations indicates that licensees have functioning fitness for duty programs devoted to the NRC rule's performance objectives of achieving drug-free workplaces in which nuclear power plant personnel are not impaired as they perform their duties.

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EXECUTIVE SUMMARY

On June 7, 1989, the Nuclear Regulatory Commission (NRC) published a rule in the Federal Register, 54 FR 24468 (10 CFR Part 26, Fitness-for-Duty Programs), requiring that licensees authorized to operate or construct a nuclear power reactor implement a fitness-for-duty (FFD) program for all personnel having unescorted access to the protected areas and for all licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures. This rule became effective on July 7, 1989, with an implementation date of January 3, 1990. This report presents an overview of the NRC licensees' implementation of the FFD program during the first year and provides an update on the technical issues relevant to the rule. It includes a description of licensee programs, a discussion of the results of NRC inspections, an update on new technical information relevant to the NRC's FFD rule, and a discussion of lessons learned during the first year. The purpose of this document is to contribute to appropriate changes to the rule, to the inspection process, or other NRC activities.

Overall, the results of the first year of the rule implementation have been promising. The NRC currently has one of the most extensive, if not the most extensive, fitness-for-duty regulations in the nation. During the past year, the NRC's FFD program has been one of the most rigorous drug and alcohol testing programs applied to any element of the civilian workforce. Implementation of the program has required both the NRC and the industry to be innovative. Given the complexity of implementing the rule, the number of people affected by the rule, and the amount of coordination required both within and between utilities and other organizations (such as HHS certified laboratories), the problems with this program have been minimal.

The experience of the first full year of licensees' FFD program operations indicates that licensees have functioning fitness-for-duty programs devoted to the performance objectives of providing reasonable assurance that nuclear power plant personnel will not be impaired as they perform their duties and that these programs will have the aim of achieving drug-free workplaces. While there were some differences in the means and effectiveness of programs across the industry, the program performance reports submitted by licensees and the NRC's initial FFD inspection efforts disclosed no major problems on an industry-wide level. In particular, some aspects of random testing, program management, worker welfare, licensee audit programs, and FFD program personnel were found to be strengths in many programs across the industry. Deficiencies of varying significance were found in such programmatic areas as random testing coverage of off-normal periods, training of licensee personnel in various aspects of the program, maintenance of specimen chain-of-custody, and protection of workers' interests. While these problems occurred in more than one program, none represented an industry-wide problem.

The updated review of the technical issues reviews the information that has become available since the publication of NUREG/CR 5227, Fitness for Duty in the Nuclear Power Industry: A Review of the Technical Issues (Barnes et al. 1988) and NUREG/CR 5227 Supplement 1, Fitness for Duty in the Nuclear Power Industry: A Review of the Technical Issues (Moore et al. 1989). Based on this updated information, there continues to be evidence that the prevalence of drug use and the efficacy of drug testing indicate that workplace drug testing is an important component of a workplace fitness-for-duty program, and that it is imperative that this testing be but one component in a comprehensive broad-brush program.

ACKNOWLEDGMENTS

Preparation of this report has been made possible through the contributions of numerous people. First and foremost we would like to thank Mr. Loren Bush, the NRC lead engineer for this project, for his extensive contributions. Mr. Brian Grimes has consistently provided clear and insightful ideas as well as overall management to this effort. Other NRC staff, including Mr. Phil McKee, Ms. Elaine Koup, and Mr. Gene McPeck have been very helpful in providing information and feedback. We would like to thank Ms. Nancy Sutherland, research librarian, and the staff of the Alcohol and Drug Abuse Institute in Seattle, Washington for providing invaluable resources and assistance. We are grateful for efforts by Ms. Susan Czamy, who was instrumental in the preparation of this report, and Ms. Charleen Sager, who devoted a great deal of time to editing. Finally, we would like to acknowledge the major contributions of nuclear licensee management and, in particular, the fitness-for-duty staff members who gathered additional data and participated in phone interviews to provide much of the information found in this report. We regret that these licensees and staff must remain anonymous and cannot be thanked individually here.

The accuracy of the information and the views presented in this report are the responsibility of the authors and do not necessarily represent the opinion of the NRC or of any particular individuals or licensees.

1 INTRODUCTION

On June 7, 1989, the Nuclear Regulatory Commission (NRC) published a rule in the Federal Register, 54 FR 24468 (10 CFR Part 26, Fitness-for-Duty Programs), requiring that licensees authorized to operate or construct a nuclear power reactor implement a fitness-for-duty (FFD) program for all personnel having unescorted access to the protected areas and to licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures. This rule became effective on July 7, 1989, with an implementation date of January 3, 1990.

The NRC adopted the rule in response to the nationwide concern over drug and alcohol abuse and in recognition that the safety-sensitive nature of work within protected areas creates a serious concern regarding drug and alcohol abuse among nuclear power plant workers. Thus, the drug and alcohol testing program became a central element of the required FFD program. During the past year, the NRC's FFD program has been one of the most rigorous drug and alcohol testing programs applied to any element of the civilian workforce. This report presents an overview of the NRC licensees' implementation of the FFD program during the first year. It includes a description of licensee programs, a discussion of the results of NRC inspections, an update on new technical information relevant to the NRC's FFD rule, and lessons learned from the first year.

1.1 Background

Since the late 1970s, the NRC has been concerned with the public health and safety impact of fitness-for-duty problems in commercial nuclear power plants. This concern was shared by many members of the nuclear industry, and most nuclear utilities voluntarily implemented FFD programs during the 1980s. The NRC, however, remained concerned about the comprehensiveness and effectiveness of some of these programs and the failure of some utilities to adopt any significant program. In response to this concern, the NRC published a policy statement in August of 1986 outlining the need for utilities to implement programs to eliminate fitness-for-duty problems--including illegal drug use, alcohol abuse, abuse of legal drugs, and any other mental or physical problems that could impair job performance. An evaluation of utility programs following the implementation of the policy statement still indicated a wide range in the quality and comprehensiveness of FFD programs in the nuclear industry. This prompted the NRC to conduct an assessment of alternative approaches to addressing FFD concerns, and, after publishing a draft rule and responding to comments on this draft rule, the NRC published the final rule in the Federal Register on June 7, 1989. In addition, the Commission requested that the NRC staff continue to analyze licensee programs, assess the effectiveness of the rule, and recommend appropriate improvements or changes. This report provides background information needed to assist in this evaluation.

1.2 Outline of the Report

Following this introduction, the report has two main sections.

- **Section 2 describes the program characteristics of utility fitness-for-duty programs and some of the strengths and problems associated with each program element; describes the violations, non-cited violations, and unresolved items identified during the initial inspections of licensee fitness-for-duty programs; and summarizes for each section of the rule the relevant information from each of the previous sections, from Section 3, and from NUREG/CR 5758, Volume 1. The purpose of this section is to contribute to the discussion of appropriate changes to the rule, the inspection process, or other NRC activities.**
- **Section 3 provides an update on the technical issues relevant to the rule, including a summary of the results of the first year of drug testing under 10 CFR Part 26.**

2 INDUSTRY PRACTICE IN IMPLEMENTING THE RULE

This section summarizes the industry experiences in implementing the major programmatic elements of the Commission's fitness-for-duty rule (10 CFR Part 26) during 1990.

2.1 Overview

This section provides an overview of licensee fitness-for-duty programs based on the available information. It combines information from a number of sources to describe the outcomes of the first year of implementation of the NRC's fitness-for-duty rule. These descriptions and analyses, along with information available from other staff activities, provide the Commission with some of the information it needs to assess: (1) the progress of the industry in meeting the program objectives, and (2) the ability of the rule to assure the appropriate level of progress and performance. In addition, the analyses may identify certain good practices that could be more uniformly adopted by the industry and areas of general programmatic weakness that may suggest revisions to the rule.

Because information is available on only a subset of issues and because there is variation in the degree to which detailed information exists, some topics are discussed in greater detail than others. The topics for which information is presented in this section and the level of detail presented in this section for a given category reflect the available data rather than relative importance of a particular area.

This report does not attempt to analyze the social and work factors that give rise to or inhibit fitness-for-duty problems. Data required for such analyses are not readily available. Nor does the report represent an attempt to analyze the relationship between the effectiveness of FFD programs and plant safety.

Following this overview, Section 2 is divided into five additional subsections: Section 2.2 provides information on the data and methodology used in this section; Section 2.3 presents an overview of pre-rule drug testing programs; Section 2.4 describes current fitness-for-duty program elements; Section 2.5 summarizes the results of inspection efforts; and Section 2.6 provides a summary and analysis of the first year of rule implementation.

2.2 Data and Methodology

Four primary sources of data are used in this report. The first source is the program performance reports that licensees are required by 10 CFR 26.71(d) to submit every six months. These data provide information on the drugs included in the test panel and cutoff levels for each drug, size of the population tested, numbers of tests and proportions of positive tests, and the number of confirmed positive tests for specific substances. Licensee assessments of lessons learned during implementation and summary information concerning management actions, such as number of referrals to the Employee Assistance Program (EAP) and the number of workers who have had their access restored after being sanctioned for FFD violations, are also provided in the program performance reports. These reports will eventually

provide information on changes that occur over time in the drug testing programs, allowing NRC staff to track changes in a number of key measures (e.g., percentage of positive test results for illegal drugs and alcohol). The primary analysis of this data source is contained in NUREG/CR 5758. This report uses information from the program performance reports on program characteristics in Section 2.4, and refers to the findings from these data in Section 2.6.

The second data source is inspection efforts, including inspections of FFD training (TI 2515/104) conducted by NRC resident inspectors, and 24 initial inspections (TI 2515/106) and 3 special inspections conducted by NRC regional inspectors. Data from these inspections are documented in inspection reports, and additional qualitative case study data are available from site visits conducted by staff from both the NRC and Battelle Human Affairs Research Centers as part of these inspection efforts. The regional inspection efforts provide information regarding program implementation at those sites for which inspection reports were published as of March 1, 1991.

The third source of data is comprised of utility responses to two surveys. Each survey was conducted by contacting relevant personnel for nine programs. The first survey obtained information on MRO qualifications and screening test results. The second survey obtained information on pre-rule testing programs and more detailed information on positive drug test results. These surveys were designed to answer questions regarding specific issues of interest to the Commission. The survey results are presented in Sections 2.3 and 2.4, and the implications are discussed in Section 2.6. A more detailed discussion of these surveys, including the interview protocol, is provided in Appendix A.

2.3 Pre-Rule Drug Testing Programs

All licensees had some type of drug testing prior to the implementation of 10 CFR Part 26. No programs, however, contained all of the elements specified in the rule. In most cases, licensees conducted pre-access or pre-employment drug testing. Some licensees also used periodic testing and a few licensees included random testing.

Data on pre-rule and post-rule testing programs were gathered in a survey of nine programs. Overall, comparison of outcomes for pre- and post-rule programs is not possible since the pre-rule programs usually differed substantially from the post-rule programs. In particular, few programs included random drug testing in pre-rule programs. The sections below summarize the information provided in a survey of nine licensees.

2.3.1 Background

Nine plants were randomly selected from plants that were believed to have conducted random or periodic drug testing in addition to pre-access or pre-employment drug testing prior to the

implementation of 10 CFR Part 26.¹ FFD managers or administrators were interviewed by telephone and asked to send additional information if it could not be provided in the telephone survey. Each telephone call was followed immediately by a letter thanking them for participating and again requesting the additional information. Reminder telephone calls were made to all of the utilities not responding within two weeks. Respondents were assured anonymity.

2.3.2 Results

The initial telephone interview provided information on the majority of interview questions (these questions are provided in Appendix A). Eight of the nine plants followed up with responses to the requests for additional information. The level of detail provided on pre-rule testing programs varied across the plants that provided additional information. Two plants indicated that some or all of the additional information requested on pre-rule drug testing data was confidential or had not been maintained in the detail requested.

Table 2.1 summarizes important findings from the study regarding pre-rule drug testing programs. All of the pre-rule drug programs operated by the nine plants were established between 1984 and 1986. During this time, eight of the nine plants established an EAP. The majority of the plants assessed were already using pre-employment, pre-access, and for-cause testing prior to the rule. Similarly, most plants tested for all drugs included in the NRC's rule drug panel in their pre-rule drug testing programs. Prior to the rule, the majority of plants were using EMIT and GC/MS to screen and confirm drug test results. Several plants had drugs tested at a lab, although NIDA certification processes were not in place prior to 1989.

Implementation of the NRC FFD rule served to standardize many of the early drug testing programs. Apart from the effect of standardizing programs across the industry, most FFD managers interviewed commented that the single greatest post-rule change in drug testing was the incorporation of random testing as defined by the NRC. Prior to the rule, only four of the nine plants conducted random testing (see Table 2.2). Within these four plants, sampling rates varied with some testing 20 percent of their employees annually and others testing only 3-5 percent of their employees annually.

Due, in part, to the flexibility allowed by the rule, little change occurred in the types of drugs tested and in the cutoff levels used following implementation of the rule. Eight of the nine plants continued to test for the same drugs. Four plants used the NRC cutoff levels in their pre-rule drug testing programs. In some instances, plants opted to use stricter cutoff levels

¹The survey revealed that one of the licensees in the sample did not include either periodic or random testing in its pre-rule drug testing program. This licensee remained in the survey. Hence, only eight of the nine plants in the survey had random or periodic tests prior to 10 CFR Part 26.

Table 2.1 Summary of results from pre-rule drug testing program survey

DRUGS TESTED			PRE RULE				
PLANT	DRUG PROGRAM START	PRE-1990	POST-1990	TEST TYPES	TEST METHODS	WHERE DID TESTING TAKE PLACE?	EAP?
1	Missing data	Missing data	NRC-5	Random, pre-access, pre-employment, for-cause	(GC/MS) (EMIT)	Local labs, not NIDA certified	Yes
2	1986	Amphetamines, barbiturates, benzodiazepines, cocaine, methaqualone, opiates, phencyclidine, THC, alcohol	NRC-5; pre-employment barbiturates, benzodiazepines, methaqualone	Pre-access, pre-employment	(Syva-Emit) (GCMS)	Outside lab	No
3	November 1985	Alcohol, amphetamines, barbiturates, benzodiazepines, THC, cocaine, opiates, phencyclidine, methaqualone	NRC-5	Pre-employment; for-cause; periodic (1988)	Lab; pre-screen and GCMS	Sent to labs	Yes
4	1985	NRC-5 plus barbiturates, methaqualone, benzodiazepines	NRC-5 plus barbiturates, methaqualone, and benzodiazepines January 1991 - NRC-5	Pre-access, for-cause, (1987) random (3-5% annually of population.)	EMIT	Missing data	Yes
5	1986	Cocaine, opiates, THC, amphetamines, phencyclidine, alcohol	Same as pre-1990	Pre-access, pre-employment, periodic (2 times per year), for-cause	Missing data	Missing data	Yes
6	1985	Amphetamines, barbiturates, cocaine, methaqualone, opiates, THC, phencyclidine, propoxyphene, hydromorphone, pentazoline, phemetrazine, phenothizines, quinine, meperidine	After positive test, same drugs as in pre-1990 10 drug panel	For-cause, pre-employment, yearly with physical, promotion, follow-up (after 1st positive)	EMIT/GCMS	Sent to labs	Yes
7	1986	NRC-5	NRC-5	Pre-employment (1986); for-cause (1986); random (1989)	EMIT (for-cause on-site)	Sent to lab (for-cause on site)	Yes
8	1984	NRC-5	NRC-5	Pre-employment, pre-access, for-cause, random (20%)	On-site (1988), EMIT (1989), EMIT (84-88 at local university)	1984-88 local university; 1988 on-site	Yes
9	1984	Amphetamines, barbiturates, benzodiazepines, cocaine, methadone, methaqualone, opiates, phencyclidine, propoxyphene, THC	10 drugs; Aug. '90 - stopped testing for methaq.	Pre-access, annual, for-cause	Pre-screen using EMIT, GC/MS used as available	Off-site	Yes

Table 2.2 Types of pre-rule drug testing conducted at a sample of plants

	Random	Pre-Access	Pre-Employ	For-Cause	Periodic
Plant 1	Yes	Yes	Yes	Yes	
2		Yes	Yes		
3			Yes	Yes	Yes
4	Yes	Yes		Yes	
5		Yes	Yes	Yes	Yes
6			Yes	Yes	Yes
7	Yes		Yes	Yes	
8	Yes	Yes	Yes	Yes	
9		Yes		Yes	

than prescribed in the NRC rule. In particular, six out of eight plants (one plant did not report levels) currently use lower cutoff levels for marijuana than those required by the NRC rule.

In general, post-rule drug testing programs have resulted in higher numbers of positive drug tests for workers than did pre-rule drug testing programs. Survey respondents reported that this is primarily due to the inclusion of random drug testing.

Each respondent was asked to compare the major differences between the pre- and post-rule drug testing programs. The following summarizes the respondents' comments.

Perceptions of the rule:

- viewed as a positive addition by the majority of FFD managers interviewed
- seen as beneficial in helping to gain worker acceptance
- caused the testing program to be more systematic and to achieve a higher level of quality due to audit, inspection, and reporting requirements
- alcohol is thought to be difficult to include as the rule does not clearly indicate specific sanctions for alcohol.

Problems associated with random drug testing:

- viewed as expensive
- caused logistical problems when more than one site is included in a program
- it is difficult to maintain confidentiality when testing in a remote area with only a few people.

Detailed results of the survey are provided in Appendix A. This appendix includes a comparison of the pre- and post-rule drug testing cutoff levels (Appendix A, Table A.1); a description of the current plant practices (Table A.2); summaries of the sanctions employed by different plants in response to positive tests (Table A.3); and limited information on the results of drug testing prior to and following the rule for employees and contractors (Table A.4). In addition, case study descriptions of each utility included in this survey are provided in Appendix A.

2.3.3 Summary of Survey Results on Pre-Rule FFD Programs

In summary, these data do not allow a full comparison of pre-rule and post-rule drug testing results. They do, however, show that for the plants sampled, adoption of the 1990 NRC FFD rule did not cause great difficulty. In some cases, the NRC rule actually made it easier to conduct testing by creating greater worker acceptance of the program.

Results from this survey indicate that the rule was successful in producing a more unified approach to drug testing. Plants formerly used a broad range of testing combinations and now uniformly use the five prescribed by the NRC rule. In addition, a more effective and systematic approach is taken to random drug testing, which includes extensive recordkeeping and data analysis, conducting program reviews, and employing quality control measures.

The overall effect of the rule on the licensees in this survey may differ from the effect on other licensees, however. This may be the case because the plants in the sample had adopted a drug testing program prior to the rule that included many of the guidelines suggested by the NRC in its 1986 policy statement, thus making for a smoother transition to the 1990 rule.

2.4 Specific FFD Program Elements

This section summarizes information pertaining to each of the general program elements provided for in 10 CFR Part 26. The section is organized in general conformance with the rule, but does not reference sections of the rule for which information about implementation was not available. The information summarized here is based on available information obtained from site visits to utilities in conjunction with inspection activities, from inspection reports, and from small surveys of utilities.

2.4.1. Written Policy and Procedures

Section 26.20 of the rule contains specific requirements concerning written policies and procedures to support fitness-for-duty programs. The development of policies and procedures for a new program is a process that requires substantial effort--and one where revisions and additions are expected as the program matures. In addition, due to the nature of the inspection effort (inspectors reviewed the policies and procedures prior to each inspection), this is an area of program implementation that received particularly careful scrutiny. Hence, it is not surprising that a substantial number of problems in the area of policy and procedures were identified by licensees or during the inspection process. It should also be noted that lack of complete written

procedures did not necessarily mean that the program was not functioning correctly. The information regarding procedures and policies is organized into three general areas: overall fitness-for-duty policy, test collection procedures, and requirements for fitness-for-duty personnel.

2.4.1.1 Overall Fitness-for-Duty Policy

Section 26.20(a) of the rule requires licensees to provide an overall description of their fitness-for-duty policy. One inspection report mentioned the thoroughness of a licensee's implementing procedures. Other inspection reports noted that licensee policies were missing a complete and/or clear description of one or more areas of the FFD program. In several instances, licensees did not fully clarify important employee issues, such as sanctions, the appeals process, or the protocol for employees to use to evaluate their fitness-for-duty when called to work an unscheduled shift. In a few instances, licensees did not have a policy or procedure addressing over-the-counter or prescribed drugs. Other, more general policy problems included insufficient implementing procedures, or procedures that did not reflect the actual practices of the FFD program. In addition to the items described above, four licensees did not have a complete policy regarding the appeals process.

2.4.1.2 Test Collection Procedures

Developing and instituting test collection procedures was one of the most extensive efforts associated with implementing 10 CFR Part 26. Procedure problems concerning the test collection process were noted in a number of the inspection reports. The most serious of these problems involved test sample collection procedures that were inadequate to ensure specimen integrity. Other problems included cases involving other testing facility processes, such as the keeping of a permanent record book, lack of a verification procedure for couriers, and problems with other security procedures.

2.4.1.3 Personnel Requirements and Procedures

Licensees varied in the department that was assigned responsibility for FFD management. Inspection reports identified the department that assumed FFD management responsibilities in 16 of the 24 initial inspections conducted prior to March 1, 1991. Of these 16 sites, the FFD responsibilities were most frequently assigned to human resources departments (seven sites). In other sites, FFD responsibilities were assigned to Administrative Services (three sites), Security (two sites), Occupational Safety and Health (one site), Employee Relations and Public Affairs (one site), Nuclear Protection Services (one site), an FFD Task Force (one site), Site Access Services Supervisor (one site), and Operations (one site).

The inspection reports also collected information on whether licensee Medical Review Officers (MROs) were employees of the utility or persons under contract to the utility. Of the eight sites in which the inspection report noted MRO contract arrangements, MRO services were provided by a contractor at seven sites and by a utility employee at one site. Information on contract or employment arrangements was not provided in the inspection reports for the remaining 16 sites.

FFD personnel strengths were noted in inspection reports for 17 sites. The majority of these reports cited the professionalism, competency, and dedication of the FFD staff in general, and many of these reports also noted strengths in individual positions, such as the MRO and the FFD administrator. Reports also commended licensees for excellent day-to-day program oversight by FFD administrators, and noted the qualification of the sample collection staff and the medical facility staff. In addition to the personnel strengths noted, 10 inspection reports noted management support of and involvement in the FFD programs as a strength.

The majority of problems pertaining to FFD personnel centered around the job descriptions and procedures for these personnel. At three sites inspectors noted that the FFD manager had too many responsibilities, resulting in ineffective program oversight. In three other cases, ambiguities were noted in the job description and procedures specific to the MRO. The remaining problems concerned ambiguities in job descriptions for other fitness-for-duty personnel, such as the test collection staff and office personnel.

2.4.2 Policy Communications and Awareness Training

As stated in Section 26.21 of the rule, licensees are required to provide all workers training in general policy awareness and must provide additional training in policy awareness for supervisors and escorts. In many cases, licensees combined escort training with employee awareness training and/or supervisor training. This section describes the overall content and quality of training programs. NRC resident inspectors evaluated training programs for employee awareness, escorts, and supervisors at 69 sites. Data from these training evaluations provide detailed information on required training areas.

Guidance for resident inspectors' evaluation of licensee training programs was provided in Temporary Instruction (TI) 2515/104. Inspectors indicated whether the licensee training programs covered specific topics in awareness, escort, and supervisory training, as well as information about:

- Training session length
- Attendance, and whether it was taken
- Type of training media used
- Whether there was a test on the material presented
- Whether there was a question/answer period.

According to the rule, the employee awareness training program must:

. . . provide employees with appropriate training to ensure that they understand:

- (1) Licensee policy and procedures, including the methods that will be used to implement the policy;
- (2) The personal and public health and safety hazards associated with abuse of drugs and misuse of alcohol;

- (3) The effect of prescription and over-the-counter drugs and dietary conditions on job performance and on chemical test results, and the role of the Medical Review Officer;
- (4) Employee assistance programs provided by the licensees; and
- (5) What is expected of them and what consequences may result from lack of adherence to the policy. (10 CFR 26.21)

According to the resident inspectors' observations, there were several elements of the employee awareness training that were covered by almost all licensee training programs (more than 95% of the programs). These included:

- Overview of FFD requirements and program objectives
- Responsibilities of licensee employees, contractors, and vendors
- Licensee policies concerning on-site and off-site use, sale, or possession of illegal drugs
- Licensee policies concerning alcohol consumption and use
- The role of the Medical Review Officer
- Employee Assistance Programs and mechanisms for referral.

Some topic areas were not covered in training by at least 20 percent of the licensees and, in some cases, were not covered by as many as 30 percent of the licensees. These included:

- Indicators of mental stress, fatigue, and illness
- Federal and administrative cutoff levels for alcohol and drugs
- Notification methods, testing rates, and schedules for employees
- Provisions for individuals selected for drug testing when absent
- The appeals process.

A number of these topics relate to the administration of testing. The lack of attention given to these topics may be due to the fact that the details of test administration and notification were being revised as training began.

Overall, 64 percent of the employee training programs were rated by resident inspectors as good and an additional 18 percent were rated excellent. Most training programs used a format that included both lectures (87%) and videos (81%), and almost all (99%) included a question-and-answer period. The average training program length was a little more than 2 hours.

The FFD inspections performed by regional inspectors (TI #2515/106) also provided information on licensee training. The reports noted six program strengths for policy awareness training. Three reports referred to general employee training, and two reports commented on training for FFD personnel. In addition, one report noted the amount of general employee retention of information concerning the licensee's FFD program and procedures.

The inspection reports also noted 10 deficiencies in the area of policy training. In six of these cases, licensees did not provide employees with sufficient training on topics of worker welfare (such as the Employee Assistance Program), test results, and appeals. The remaining four problems concerned training records and procedures. Two licensees had insufficient requalification training procedures, and another two licensees failed to keep current training records.

2.4.3 Training of Supervisors and Escorts

Section 26.22(a) of the rule requires that managers and supervisors be provided with appropriate training to ensure they understand:

- (1) Their role and responsibilities in implementing the program;
- (2) The roles and responsibilities of others, such as the personnel, medical, and employee assistance program staffs;
- (3) Techniques for recognizing drugs and indications of the use, sale, or possession of drugs;
- (4) Behavioral observation techniques for detecting degradation in performance, impairment, or changes in employee behavior; and
- (5) Procedures for initiating appropriate corrective action, to include referral to the employee assistance program.

Resident inspectors noted whether supervisor training included 18 specific topic areas, broken down from the 5 above. Eleven of the topic areas were covered by more than 90 percent of the licensees. There were three areas of training required by 10 CFR 26.22(a) that one-quarter to one-half of the licensees did not include in their programs. These were:

- Description of drug paraphernalia associated with drug use
- Methods and places normally used to hide drugs
- Techniques for recognizing the use, sale, or possession of illegal drugs and alcohol.

As will be discussed below, these omissions are somewhat consistent with those occurring in the escort training courses.

Of the training presentations for supervisors, 30 percent were rated as excellent, while another 57 percent were seen as good. Lectures and videos were the predominate forms of presentation. The training sessions ranged from one and one-half hours to 16 hours and averaged about four and one-half hours (including question-and-answer time). Fewer than half (44%) of the programs tested supervisors on the content of the presentation.

Section 26.22(b) of the rule requires that "persons assigned to escort duties shall be provided appropriate training in techniques for recognizing drugs and indications of the use, sale, or possession of drugs, techniques for recognizing aberrant behavior, and the procedures for reporting problems to supervisory or security personnel."

The form used by the resident inspectors to evaluate escort training covered 12 topic areas. Ten of the 12 were different topics than those required for employee awareness training and only two were not included for supervisory training. As mentioned previously, many licensees combined escort training with employee awareness training or with supervisor training. Thus, inspectors evaluated escort training by considering the employee awareness and supervisor training topics that overlap with escort training topics.

The inspections indicated that 90 percent of the escort training sessions included the following topics:

- Overview of FFD requirements and program objectives
- Physical indicators of acute or chronic alcohol and drug use
- Procedures for reporting FFD concerns to supervisory personnel.

Two topics areas were covered by only about half of the escort training programs. These were:

- Methods and places normally used to hide drugs and alcohol
- Techniques for recognizing indications of the use, sale, or possession of drugs.

A majority (65%) of the programs were rated as good by resident inspectors, while 25 percent were rated only fair. Escort training lasted an average of about two hours and used lecture and video training methods. About half (51%) of the programs tested escorts on the content of the presentation, and 27 percent used drug equipment displays.

FFD inspection reports identified two strengths and seven problems pertaining to supervisor and escort training. Two reports noted the quality and quantity of supervisor training, particularly in the area of behavioral observation. The seven problems all concerned inadequacies with behavioral observation training for supervisors. In some cases procedures were not in place to ensure that all supervisors received behavioral observation training, while in other cases the training in place was deemed insufficient for supervisors to adequately perform behavioral observation.

2.4.4 Chemical Testing

Chemical testing covers a broad range of issues, including the issues associated with developing and implementing chemical testing procedures discussed above (Section 2.4.2). Many of the specific requirements for chemical testing are covered in Appendix A of the rule. These specific requirements are discussed in this section under the more general requirements of the rule.

2.4.4.1 Types of Testing

Section 26.24(a) of the rule states requirements for fitness-for-duty test categories, including pre-access testing, random testing, for-cause testing, and follow-up testing. This section of the rule also specifies procedures for the conduct of random testing. Random testing was less often part of licensee FFD programs prior to implementation of 10 CFR Part 26. Hence, it is not surprising that it was a major focus of attention for licensees in developing their FFD programs and for inspectors.

With regard to random testing, the rule specifies the following requirements:

- Testing must be unannounced, and imposed in a random manner
- Individuals tested must be immediately eligible for another test
- Tests must be administered on a nominal weekly frequency
- Tests must be conducted at various times of the day
- Testing must be conducted at a rate equal to at least 100 percent of the workforce.

Inspection reports noted strengths associated with the random testing process at 12 separate sites. These strengths included: good mechanisms for ensuring random selection, such as randomized computer programs; a random selection program that consistently ensures that testing is conducted on all shifts, including weekends, holidays, and backshifts; specific means of ensuring that randomly selected personnel were properly tested, such as establishing time limits between the time of test notification and employee reporting; and licensee inclusion of employees in the FFD program.

Of problems associated with random testing, half were related to inadequate coverage of off-normal periods (backshift, weekend, and holiday random testing). Other problems identified in random testing included failure to adequately test employees with infrequent access and testing at an annual rate of less than 100 percent of the workforce.

Relative to the discussion of random testing, there was little discussion associated with the other testing categories. One inspection report described a licensee's program initiative concerning for-cause testing; this licensee is currently upgrading its for-cause testing abilities by teaming with a local hospital. There were also two concerns noted in relation to other types of testing. One inspection report noted problems with a licensee's pre-access testing procedures, while a separate inspection report found a problem with a licensee's follow-up testing requirements.

2.4.4.2 Collection Procedures and On-site Testing/Facilities

Section 26.24(b) of the rule requires that licensees conform to the guidelines in Appendix A of the rule when testing for drugs and alcohol. The inspection reports noted a number of strengths and problems in this area with regard to collection procedures and on-site testing.

In terms of program strengths, inspection reports noted the general quality and professionalism of the facilities at three sites, the provision of on-site testing at two sites, and the design of the facility at one site.

Problems pertaining to collection procedures and on-site testing and facilities included collection equipment or materials that were inadequate to ensure specimen integrity; inappropriate packaging of blind specimens; and cases in which personnel or procedures contributed to a less than adequate test collection environment.

2.4.4.3 Security

The guidelines for testing outlined in Section 26.24(b) and described in Appendix A also require that the testing process be secure. Strengths concerning security were reported in nine inspection reports. These strengths included the use of canine searches for drugs, practices of security personnel in supporting the FFD program, good processes in place for the verification of individuals, and the general security of the collection facility.

Security issues noted were inadequate physical security of the testing facility and inadequate administrative controls.

2.4.4.4 Additional Drugs and Lower Cutoff Levels

Section 26.24(b) of the rule allows for licensees to implement programs that test for lower cutoff levels and/or additional drugs. Licensee policies governing testing for additional drugs beyond the NRC drug panel or using lower cutoff levels in the semi-annual program performance reports were submitted by each licensee. These reports cover the reporting period from January 3 to December 31, 1990, and include 85 reports from 75 nuclear power plant sites and 10 corporate offices.

Of the 85 reporting locations, 39 used levels lower than the 100 ng/ml cutoff required by the NRC in the initial screening tests for marijuana. Of these, 28 used 50 ng/ml for initial screening and 11 used 20 ng/ml. Thirty-nine reporting locations conducted tests for a broader range of drugs than that specified by the NRC. All 39 reporting locations tested for benzodiazepines, 32 tested for barbiturates, 19 tested for methaqualone, 10 tested for methadone, and 9 tested for propoxyphene.

2.4.4.5 Monitoring of Certified Laboratories

Section 26.24(f) requires that licensees use a laboratory certified by the U.S. Department of Health and Human Services in assessing urine samples from their testing program. As of January 24, 1991, licensees had sent a total of 76 laboratory error reports to NRC staff. Of these, 15 were laboratory administrative errors; 27 were laboratory processing errors; and 34 were errors due to the quality or mislabeling of blind specimens. There were five known false positive results as of consequence of these laboratory errors. Three of the false positive results were outcomes of laboratory performance testing and did not directly affect workers in the testing program. The remaining two false positive results--one from a random test and one

from a for-cause test--did affect workers. Both of these cases were eventually resolved in favor of the employee during the appeals process.

2.4.5 Employee Assistance Programs

Section 26.25 of the rule requires that licensees maintain an employee assistance program (EAP) to achieve early intervention and to offer confidential assistance. Employee assistance program services may be provided by utility employees or by contract. Nineteen inspection reports specified the status of EAP programs. At 14 of these sites EAP services were provided exclusively by an external organization, EAP services were provided exclusively by an internal program at 3 sites, and 2 sites provided for both internal and external services.

Nine sites were identified in inspection reports as having strengths in the area of employee assistance programs and policies. These strengths included strong employee awareness and use of the EAP program; the requirement that contractors and vendors provide an EAP program for their employees; innovative programs to gain employee support, such as a recognition program for personnel subject to multiple tests; and the creation of peer support groups to augment the existing EAP.

The inspection reports also identified some problems with licensee EAP programs. In one instance, a licensee policy inappropriately treated employee self-referrals as a positive drug test. In two other cases, the EAP had a punitive image in the eyes of employees. In the remaining two cases, licensees failed to require the EAP to disclose employees who were determined to be a threat to themselves or to others.

2.4.6 Management Actions and Sanctions to Be Imposed

Minimum sanctions for FFD violations are specified Section 26.27 of the rule. These sanctions require that impaired workers be removed from activities that require unescorted access to protected areas. The rule also requires that, following a first confirmed positive test result for illegal drugs, a worker must be immediately suspended from activities that require unescorted access for a minimum of 14 days while an assessment is made and plans for treatment follow-up and future employment are developed. A second confirmed positive test results in suspension from unescorted access for a minimum of 3 years. Sanctions are less specific regarding positive tests for alcohol. Licensees must, however, provide sanctions for confirmed misuse of alcohol and legal drugs that are sufficient to deter abuse.

2.4.6.1 Illegal Drug Sanctions

Twenty-two initial inspection reports provided information on sanctions for illegal drugs. Implementation of sanctions for positive test results for illegal drugs is consistent with the minimum NRC sanctions at 13 of these sites. Five licensees impose more severe sanctions than minimum NRC requirements, but provide the option of reinstatement after the first confirmed positive test result. At the remaining four sites, employees were subject to immediate removal from access for 3 years for the first illegal drug violation. Nineteen initial inspection reports provided information on sanctions for illegal drug violations among contractor personnel.

Contractors were more likely to be discharged on the first positive test for illegal drugs than were licensee employees. Access was denied to contractors based on the first illegal drug violation at 13 of these 19 sites.

2.4.6.2 Alcohol Sanctions

Information regarding sanctions for licensee employees' first alcohol violation was reported for 16 sites. The majority (13) of these FFD programs employed less severe sanctions for alcohol violations than for illegal drug violations. In one of these 13 programs, the first alcohol violation by a licensee employee resulted in a 3-day suspension. Three licensees employed sanctions for first alcohol violations comparable with the minimum sanctions provided for illegal drugs under the rule. As with illegal drugs, contractors were more likely to be denied access due to a first positive test for alcohol than were licensee employees. The first alcohol violation by a contractor resulted in denial of access in 7 of the 11 programs for which the inspection report noted contractor alcohol sanctions.

Data on second and subsequent alcohol violations were included in 15 of the initial inspection reports. For 5 of the 15 sites reporting sanctions for repeated alcohol violations, such sanctions were less severe than for illegal drug use. Four programs provided details on sanctions for repeated alcohol violations for contractor personnel; two of these programs indicated that site access was denied for a second positive test result.

Two inspection reports noted licensee strengths in the area of sanctions. One licensee was commended for applying the same sanction for alcohol as for drugs. Another inspection report cited the licensee practice of affording contractors the same sanctions as licensee employees as a program strength.

2.4.6.3 Management Actions

Three problems relating to management actions in general were noted in inspection reports. In two cases, licensees failed to conduct acceptable suitable inquiries for workers requiring unescorted access. A third problem concerned the perception by employees that a presumptive positive drug screen would result in negative management action.

2.4.7 Appeals

Section 26.28 of the rule requires that licensees establish a procedure for both licensee and contractor employees to appeal a positive alcohol or drug test. Inspection reports noted four problems relating to insufficient training requirements or procedures for the appeals process. In addition, one inspection report noted the failure of a licensee to have a procedure to indicate that a worker may request a re-analysis of a positive specimen. One other licensee did not allow the appeals process to be recorded in any way.

2.4.8 Protection of Information

Section 26.29 of the rule states requirements for the protection of fitness-for-duty information. Inspection reports noted four cases in which FFD programs failed to maintain secure control of computer access and the data stored within the computer. In five additional cases, licensee practices permitted personnel without a need-to-know to have inappropriate access to preliminary or unconfirmed positive test results.

2.4.9 Recordkeeping Requirements

Section 26.71 of the rule requires licensees to keep records of confirmed positive test results, and to collect and compile program performance data every six months. In two cases, inspection reports found that the required FFD program records were incomplete or absent.

2.4.10 Reporting Requirements

Section 26.73 of the rule addresses reporting requirements, and requires licensees to inform the Commission of significant fitness-for-duty events. One site was commended for the quality of its recordkeeping techniques, while four inspection reports identified inadequacies in licensee reporting requirements.

2.4.11 Audits

Section 26.80 of the rule requires licensees to audit their fitness-for-duty programs nominally every 12 months. In addition, licensees retain responsibility for the effectiveness of contractor and vendor programs and the implementation of appropriate corrective action.

Sixteen inspection reports noted the licensee's quality assurance audit program as a strength. The inspection reports noted in particular that these programs were effective in identifying program weaknesses and were performed in a comprehensive, in-depth manner. In terms of problems, two inspection reports noted that licensees had failed to implement an effective FFD audit program.

2.5 Outcomes of the NRC'S Initial FFD Inspection Efforts

Temporary Instruction (TI) #2515/106 requires that each site undergo an initial inspection to evaluate its compliance with the FFD rule. Initial inspections were conducted by NRC regional inspectors to evaluate implementation of licensee fitness-for-duty programs, to provide information needed to assess the effectiveness of the FFD rule, and to determine whether further FFD rulemaking is needed. Initial inspections were sometimes preceded or followed by special reactive inspections when serious problems were identified or when a number of issues remained unresolved. As of March 1, 1991, the NRC had conducted 24 initial inspections and 3 special reactive inspections.

Inspectors were encouraged to provide constructive feedback to licensees. This feedback included discussions of the program strengths as well as the potential problems discussed in Section 2.4. In addition, the feedback included violations, non-cited violations, and unresolved items presented in this section. Violations are more serious infractions of the rule or are minor infractions that were not being identified or adequately addressed by the licensee. Non-cited violations are minor violations of 10 CFR Part 26 that were identified by the licensee and for which the licensee is taking appropriate corrective action. Unresolved items are matters about which more information is required and are resolved subsequent to the inspection; as used in the FFD inspection reports, the term also included a licensee's failure to adhere to generally accepted practices that have not been made legally binding by the Commission, but are expected to be implemented by the licensee. In many cases, the unresolved items involve interpretations of the FFD rule; this is not unusual during the initial implementation of complex regulations.

2.5.1 Violations and Non-Cited Violations

The 24 initial inspection reports and 3 special reactive inspection reports resulted in 14 violations, 13 non-cited violations, and 22 unresolved items. Of the 14 violations, 8 occurred at a single site and resulted from a special inspection. The remaining violations occurred singly, each at one site. Of the 13 non-cited violations, 3 occurred at a single site, while two sites had 2 non-cited violations and the remaining five sites each had 1 non-cited violation. The violations and non-cited violations were distributed across many subject areas of the rule. The following section describes those areas.

2.5.1.1 Written Policy and Procedures

There were two violations and two non-cited violations in the area of policies and procedures. One violation was cited for licensee failure to maintain a permanent record book. The second violation occurred when a licensee's ambiguous procedures governing MRO responsibilities resulted in improper handling of a positive test result. Of the two non-cited violations, one occurred in the area of chain of custody. While processing a simulated blood specimen during the inspection, the on-site testing laboratory technician had temporary custody of the specimen without signing the chain-of-custody form. The second occurred due to licensee failure to maintain a copy of an official policy statement on the use of illegal drugs and the sanctions for such use.

2.5.1.2 Chemical Testing

The violations and non-cited violations in chemical testing fell into the general areas of random and pre-access testing, certified laboratories, and general deficiencies in the specimen collection process.

There were two violations that resulted from licensee failure to include certain groups of workers in the random testing pool. At one site, the licensee failed to include some personnel from their Emergency Operations Facility in the random testing program. At another site, a licensee's random testing program failed to make a tested individual immediately eligible for

another random test. Non-cited violations occurred in three cases where licensees had insufficient random testing during weekends, holidays, and/or backshifts. One of these non-cited violations occurred when the licensee, in an attempt to process a larger number of pre-access tests, failed to conduct random tests for a period of approximately one month. In addition, one site had two violations for inadequate licensee policies regarding pre-access testing. This licensee did not test for alcohol during pre-access testing, and failed to conduct some pre-access drug tests within 60 days prior to the initial granting of unescorted access.

A second area of chemical testing that appeared problematic concerned licensee failure to contract with an HHS-certified laboratory. This failure resulted in one violation. In addition, three non-cited violations occurred due to inadequate licensee evaluation of HHS-certified laboratories. Of the non-cited violations, one occurred because a licensee contracted with a laboratory that was not HHS-certified. The second resulted from a licensee failure to conduct a pre-award audit of the HHS laboratory prior to awarding the laboratory a contract for services. In the final instance, a licensee failed to promptly notify the NRC of a false positive blind performance test and instead waited until their 30-day report to alert the NRC of the incident.

In the remaining area of chemical testing there were two violations. A licensee inappropriately required a blood specimen in addition to urine specimens for some types of tests, and a separate licensee failed to provide behavioral observation for all personnel subject to testing. In addition, there was one non-cited violation for an administrative error that resulted in a worker with a presumptive pre-access positive drug test being granted unescorted access.

2.5.1.3 Supervisor and Escort Training

Three violations resulted from inadequacies in supervisor or escort training. At one site, the licensee did not provide fitness-for-duty training for contractor supervisory personnel. At a second site, the licensee failed to provide procedures for supervisory training. In the third case, the licensee did not administer both initial and refresher training for supervisory personnel. Two non-cited violations also occurred in this area. One non-cited violation occurred when the licensee failed to provide behavioral observation training for several employees who performed supervisory and managerial duties. The second occurred because the licensee failed to train contractor supervisors in their roles and responsibilities in implementing a fitness-for-duty program.

2.5.1.4 Contractors and Vendors

Section 26.23 of the rule outlines requirements for contractor adherence to licensee FFD policies. One violation occurred in this area because several of a licensee's agreements with contractors did not contain the required fitness-for-duty provisions.

2.5.1.5 Management Actions and Sanctions to Be Imposed

One violation and one non-cited violation resulted from licensee failure to conduct suitable inquiries for workers requiring unescorted access. The violation occurred because a licensee

equated the written statement from the individual concerning their history of substance abuse as sufficient suitable inquiry, and were not conducting any further suitable inquiry activities. The non-cited violation occurred when the licensee failed to obtain suitable inquiry information for 33 contractor employees prior to granting them access. The employees had this inappropriate access for nearly two months.

2.5.1.6 Reporting Requirements

One non-cited violation resulted from licensee failure to comply with NRC reporting requirements. In this instance, the licensee failed to promptly report to the NRC that a supervisor had tested positive for alcohol.

2.5.2 Unresolved Items

The 24 initial inspections and 3 special inspections resulted in a total of 22 unresolved items. These unresolved items were identified at 13 of the 24 sites inspected. While this number may appear to be relatively high, such numbers were to be expected given that this effort constituted the first inspection that these fitness-for-duty programs had received. It is expected that as the inspection process progresses, and as inspectors from different regions meet to share information, the number of unresolved items will gradually decline. In addition, it is important to note that, in most cases, licensees took immediate corrective action on the unresolved items.

2.5.2.1 Written Policies and Procedures

Four unresolved items occurred in the area of licensee policies and procedures. These items were all very different in nature. One site had two unresolved items in this area: they did not have a verification procedure for identifying couriers who transferred specimens to the certified laboratory, and their procedure for call-ins inappropriately exempted workers from random testing for drugs. At a second site, the MRO job description did not require the MRO to conduct in-person interviews with individuals who tested positive for drugs. In the fourth unresolved item, the licensee's chain-of-custody forms provided to the MRO did not include the testing laboratory's internal chain-of-custody forms.

2.5.2.2 Chemical Testing

There were three unresolved items in the area of chemical testing. One inspection report noted an inadequate procedure for notifying employees to report to testing. In this case, the licensee permitted supervisors to postpone a test until later in the day if the test posed an inconvenience, but did not limit the amount of time between notification and testing, presenting a potential for abuse. Two other unresolved items concerned a certified laboratory that did not use GC/MS testing for samples that exceeded the cutoff limits and a licensee that had an inappropriate requirement for a blood specimen.

2.5.2.3 Policy Communications and Awareness Training

One unresolved item occurred in this area for a licensee that had insufficient requalification training and procedures. The licensee had incorporated their fitness-for-duty training into their general employee training and believed that this met the requirement for requalification training. However, the inspector's review found that this training did not cover all of the areas required in the rule for refresher training. In addition, three unresolved items resulted from licensees who did not have sufficient records for their training programs.

2.5.2.4 Employee Assistance Program

One unresolved item concerning EAPs resulted from a licensee whose FFD policy treated worker self-referrals to the EAP as a positive drug test. In some cases, the self-referrals were equated to a positive test even when an actual test was not performed. Section 26.25 of the rule requires that EAPs be designed to achieve early intervention and to provide for confidential assistance. This practice is not conducive to achieving early intervention and does not provide for confidential assistance.

2.5.2.5 Appeals

Two unresolved items occurred in the area of appeals. One item resulted from a licensee who failed to provide workers with access to lab records regarding test results. A second unresolved item occurred when a licensee failed to require the EAP to disclose employees who are determined to be a threat to themselves or to others.

2.5.2.6 Protection of Information

Two unresolved items were the result of licensees who provided access of unconfirmed positive test results to personnel who did not have appropriate access to such information. At one licensee site, the supervisor of security received notification of positive drug test results prior to MRO confirmation. At the second site, the licensee's procedures inappropriately required that laboratory test results be sent to the FFD administrator.

2.6 Summary of Implications of the First Year Experience Under 10 CFR Part 26

This section summarizes the implications of the material presented in each of the previous sections of this NUREG/CR, from Section 3 of this NUREG/CR, and from NUREG/CR 5758, Volume 1, for each section of the rule. The purpose of this section is to contribute to the discussion of appropriate changes to the rule, the inspection process, or other NRC activities. The section is ordered according to the major rule elements.

Overall, the results of the first year of rule implementation have been promising. The NRC currently has one of the most extensive, if not the most extensive, fitness-for-duty regulations in the nation. Implementation of the provisions of this regulation has required both the NRC and

the industry to be innovative--using flexibility and common sense to deal with the problems that arise in the implementation of any new program. Given the complexity of implementing the rule, the number of people affected by the rule, and the amount of coordination required both within a utility and between utilities and other organizations (such as laboratories), the problems with this program have been minimal.

The areas of concern discussed in this section refer to (1) new information that indicates some changes in the rule or industry practice may be warranted, (2) issues that have arisen due to the need to clarify the rule, and (3) areas where licensees have experienced some difficulties in meeting the requirements of the rule. In addition to the areas discussed here, minor modifications, such as clarifying or adding definitions for terms used in the rule and minor wording changes, have been suggested.

2.6.1 General Performance Objectives (26.10)

Section 26.10 requires that licensees' fitness-for-duty programs provide reasonable assurance that nuclear power plant personnel will not be impaired as they perform their duties and that these programs aim at achieving drug-free workplaces.

Overall, the experience of the first full year of licensees' FFD program operations indicates that licensees have functioning fitness-for-duty programs devoted to these performance objectives. While there are some differences across the industry in the means and effectiveness of implementing the rule, the program performance reports submitted by licensees and the NRC's initial FFD inspection efforts disclosed no major problems on an industry-wide level in licensees' FFD program performance. In particular, some aspects of random testing, program management, worker welfare, licensee audit programs, and FFD program personnel were found to be strengths in many programs across the industry. Deficiencies of varying significance were found in such programmatic areas as random testing coverage of off-normal periods, training of licensee personnel in various aspects of the program, maintenance of specimen chain-of-custody, and protection of workers' interests.

Licensees performed a total of 278,209 tests for drugs and alcohol during 1990. A total of 2,409 workers or applicants tested positive for drugs and/or alcohol during the year, producing an overall positive rate of .87 percent across all categories of tests. The majority of positive results were obtained in pre-access testing. However, of those workers who had unescorted access to the protected area, 550 had positive results from random tests, for-cause testing produced 214 positives, and follow-up testing accounted for an additional 65 positives.

These and other program data indicate that, relative to other U.S. industries, prevalence of illicit drug and alcohol use may be substantially lower among nuclear power plant workers than among workers in other industrial sectors. Although there are few reliable estimates of the prevalence of drug abuse in the workplace, it appears that industries such as construction, repair services, finance, and wholesale trade are experiencing higher drug and alcohol abuse rates than the commercial nuclear power industry.

2.6.2 Written Policy and Procedures (26.20)

Licensees must establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements set forth in the rule. Section 26.20 enumerates various characteristics that licensees' policies and procedures must have.

While licensee compliance with these requirements appears to be generally acceptable, the initial NRC inspections did note various types of inadequacies in program support procedures. Several of the problems noted by inspectors may be attributable to a need to clarify the rule requirement for an explicit policy statement separate from the implied policies in the procedures. Specific areas lacking in policies or procedures included failure to include a complete policy or procedure to address over-the-counter or prescribed drugs, incomplete procedures to address worker sanctions for FFD violations, and failure of some licensees' procedures to accurately reflect actual FFD program practices. Other problems with current procedures, such as the need to more specifically delineate MRO responsibilities, were also identified.

2.6.3 Policy Communications and Awareness Training (26.21)

Section 26.21 directs licensees to ensure that their workers who are covered by the rule's requirements understand the need for FFD programs and the procedures that are used to implement the rule's requirements.

According to NRC resident inspectors' evaluations of licensee training programs, most required areas of employee awareness training were adequately covered by licensee programs. Eighty-two percent of these training programs were rated as good or excellent by inspectors. In most cases, interviews by inspectors with licensee employees indicated that policies and procedures were well understood. However, areas such as indicators of mental stress, fatigue, and illness; cutoff levels for drugs and alcohol; and the appeal process were found not to be covered by as many as 30 percent of the licensees. In the initial NRC inspections, problems in implementing 10 CFR 26.21 were noted in a relatively few instances. The scheduling, conduct, or policies of FFD requalification training were observed to be insufficient on one occasion. Insufficient requalification training or procedures for that training were also noted in a few instances. At least one licensee was found to be providing FFD training that produced inadequate worker awareness of FFD objectives.

2.6.4 Training of Supervisors and Escorts (26.22)

Managers, supervisors, and escorts must be trained to meet their FFD program responsibilities as required by Section 26.22.

Deficiencies in such training found during the initial NRC inspections indicated that training of supervisors and escorts is an area of program implementation that needs improvement. Since training requirements and the necessity of documenting training are common in the nuclear industry, the relatively large number of difficulties in this area was surprising. Various licensees' behavior observation training, procedures to initiate for-cause testing, and appeals

process training requirements were found to be deficient. Improper scheduling of such training and maintenance of training records were also identified problem areas. Although 87 percent of the supervisory training programs were rated as good or excellent by resident inspectors, the deficiencies noted by these inspectors paralleled those found later by regional inspectors. Up to one-half of licensees did not include subjects related to the recognition of drug use, possession, and sale in their supervisor training programs. Similar problems were noted in the escort training of several licensees. Resident inspectors found that in about half of the escort training programs examined, escorts were not being trained on methods commonly used to hide drugs; techniques for recognizing indications of use, sale, or possession of drugs; and what to do when someone they are escorting appears to be impaired.

2.6.5 Contractors and Vendors (26.23)

Contractor and vendor personnel performing activities within the scope of the rule must be covered either by a licensee FFD program or a similar program reviewed and approved by a licensee.

The implications of Section 26.23 are particularly important in light of the first year's testing results. Contractor personnel, and particularly short-term personnel, had considerably higher positive test rates for both random and pre-access testing. Short-term contractors had nearly twice the percentage of positive random test results as compared to licensee employees (.58 percent and .28 percent, respectively). Likewise, short-term contractors tested positive in 1.40 percent of pre-access tests relative to .89 percent for licensee employees and 1.13 percent among long-term contractors. The fitness-for-duty of short-term contractor personnel, therefore, appears to merit the continuing concern of the NRC and its licensees' FFD programs.

The training of contractor and vendor personnel may also merit additional future attention. Concerns regarding such training arose in at least two regions. In some instances, supervisors for short-term contractors were not receiving training for their FFD responsibilities because of the short duration of the contractors' work to be performed. There were also some problems with the timeliness of the training of long-term contractors' supervisors. The current rule requirement, that supervisors be trained within three months of assignment to supervisory duties, means that training is not required for supervisors of short-term contractors who will be on-site for less than three months.

2.6.6 Chemical Testing (26.24)

In order to deter and detect substance abuse, Section 26.24 requires licensees to implement four types of chemical testing programs: pre-access, random, for-cause, and follow-up. Licensees are required, at a minimum, to test for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol, but may test for other substances with abuse potential. Cutoff levels for both screening testing and confirmatory testing are provided for the required minimum panels. Licensees may conduct initial screening tests on-site. Specimens that are not determined to be negative based on on-site screening must receive additional screening and confirmatory testing in a laboratory certified by the Department of Health and Human Services.

During CY 1990, .87 percent of the total 278,209 tests performed by licensees led to confirmed positive results. By type of testing, this aggregate percentage consisted of pre-access tests being judged positive 1.26 percent of the time, .37 percent of random tests yielding positives, 29.23 percent of tests performed for-cause being determined positive, and follow-up testing resulting in 2.47 percent positive results. While most of these positive results were from tests of workers who never attained access to the protected area, 829 workers with access tested positive during the year. Of the various classes of personnel tested, short-term contract employees had substantially higher positive test rates for both random and pre-access testing than did licensee employees and long-term contractor workers.

Marijuana accounted for almost half of all positive test results during the year. Cocaine and alcohol accounted for most of the rest of the positive results, with 29.0 percent and 18.6 percent of total positives, respectively. Opiates, amphetamines, and phencyclidine caused less than 6.0 percent of the positives. By worker classification, 19 positive test results involved licensed operators, 26 involved licensee supervisors, and 13 involved contractor supervisors. The types of drugs resulting in confirmed positive test results for the operators were different from those resulting in positive tests for the supervisors. Sixty-eight percent of licensed operators' positive results were caused by use of illegal drugs, while 62 percent of supervisors' positive results were for alcohol.

As discussed above, marijuana was the drug most often detected by all testing means during 1990, with the 1,153 positives for marijuana accounting for almost half of the year's total confirmed positive test results for the five illegal drugs plus alcohol in the NRC panel. Cocaine and alcohol, with 706 and 452 confirmed positives respectively, accounted for 29.0 percent and 18.6 percent of those positive results. The 45 positives for opiates, 69 positives for amphetamines, and 8 phencyclidine positives made up the remaining less than 6 percent of the year's total confirmed positives. As many as 39 sites tested for drugs beyond those specified in the NRC's drug panel. The results of these tests included 13 confirmed positives for barbiturates and 15 for benzodiazepines.

These results for the commercial nuclear power industry can be compared with the data on the prevalence of drug use in American society as a whole, discussed in Section 3.2.1 below, and employers' and workers' reactions to drug abuse in the workplace, as discussed in Section 3.2.2 below. The best available evidence of drug use in American society suggests that the prevalence of illegal drug and alcohol abuse in this country is a continuing problem that warrants further action to counteract it. A survey conducted in 1988 for the National Institute on Drug Abuse estimated, for example, that 14.5 million Americans, or approximately 7 percent of the U.S. population over 12 years of age, use illicit drugs (Kopstein and Gfroerer, 1990). According to this survey, 8.2 percent of full-time employed people had used an illicit drug during the past month, 6.8 percent had used marijuana, 5.7 percent had used cocaine during the past year, and as many as 6.4 percent of such employees were heavy users of alcohol. Predictably, surveys discussed in Section 3.2.2 below report that the reaction of employers to the perceived increase in drug use in the U.S. to be one of mounting concern. Workers, too, recognize the increasing seriousness of the impacts of drug abuse on the workplace. In one survey, for example, a majority of unionized public and private sector employees expressed support for

drug testing in the workplace, although that support was primarily for for-cause testing and did not extend to random testing.

Use of lower cutoff levels than those required by the NRC and testing for drugs in addition to those in the Commission's panel were common. Many licensees used lower cutoff levels for on-site screening for marijuana than were required by the rule. Of those sites reporting data, locations that used lower cutoff levels ultimately had substantially higher percentages of confirmed positive test results. Only a few licensees used lower cutoff levels for cocaine and opiate testing. Thirty-nine sites reported testing for a broader panel of drugs than the rule requires, with barbiturates and benzodiazepines being the drugs most frequently added to the testing panels. Though these two additional drugs accounted for only a small percentage of total confirmed positives during 1990, tests for barbiturates and benzodiazepines resulted in higher percentages (2.0 percent and 2.9 percent of the total number of confirmed positives, respectively) than did phencyclidine, one of the drugs in the NRC panel. Because both these drugs can cause significant impairment, they appear to merit consideration for addition to the Commission's required drug panel.

Trends of positive test results in the first and second six-month periods showed decreasing positive results in the second six months as compared to the first six months. For the second six months of 1990, the overall positive rate for all testing was .78 percent as compared to .95 percent during the first half of the year. Testing results indicate that the occurrence of outages had a major effect on positive rates. Those 62 sites that had one or more outages during the year had a mean positive test result rate of .91 percent as compared to a rate of .47 percent for those 13 sites that had no outages.

Patterns of positive test rates varied by region, with Region IV having the lowest overall rate of positive results and Region III the highest. The data also indicate that there was a positive relationship between population density in areas surrounding nuclear power plants and positive test rates at those plants. As population density increased, so too did the positive rates. This relationship was particularly great for positive results for cocaine use.

The initial NRC inspections disclosed various program weaknesses of several licensees in complying with chemical testing requirements. Test specimen collection materials and procedures were found to be inadequate to ensure specimen integrity at a number of licensees. The training and experience of at least one licensee's FFD staff was judged to be too limited. Incomplete FFD personnel requirements and related procedures were noted in seven circumstances. These types of programmatic weaknesses indicate the continuing need for some licensees to upgrade the administration of their testing processes.

Licensees' first full year of chemical testing pursuant to this section produced a variety of procedural or testing process difficulties that merit attention in the coming year. At some plants, for example, NRC inspectors found inadequate random testing coverage during off-normal periods (backshifts, weekends, and holidays). Some plants were found to be failing to adequately test those with infrequent access or to include specified workers in the random testing pool. There appears to be a need to better define the concept of "random" as applied to testing nuclear power plant employees and the degree of flexibility that licensees should

have in applying that concept. There also appeared to be a need to clarify what frequency of follow-up testing is required or appropriate as various licensees implement in varying ways the rule's requirement of "follow-up testing on an unannounced basis."

Complying with proper chain-of-custody procedures also proved to be a problem for some licensees. Failure to acquire required signatures to maintain chain-of-custody or to adequately keep track of specimens after they were taken from a plant were examples of such problems. Inspection reports and inspectors' statements generally indicated that, due to a lack of guidelines, licensees are unclear as to what the definition of a proper chain-of-custody is and how custody of specimens should be maintained in practice.

There also were several other problem areas connected with chemical testing. Among the more notable of these were questions raised about Medical Review Officer performance. The results of the initial inspections raise questions as to whether MRO evaluations are sufficiently consistent. Some NRC inspectors questioned whether certain MROs are properly determining positives confirmed through use of the 6-MAM test as negative due to consumption of poppy seeds by the tested employee. In some instances, deficiencies in specimen collection materials and procedures at on-site testing facilities were noted at some plants. There were also problems with physical and administrative security of specimen collection or on-site testing facilities.

2.6.7 Preventing Subversion of Testing (26.24 and Appendix A, 2.3)

Section 26.24 and Appendix A, section 2.3 are aimed at ensuring that persons responsible for administering the drug and alcohol testing possess high honesty and integrity and that the integrity of such persons is not compromised.

The NRC's initial FFD inspection efforts detected no problems that relate directly to this section.

Subversion prevention does, however, remain a continuing concern. The recent literature on the subject reviewed in Section 3.4 below indicates that the most common subversion techniques continue to be providing a surrogate specimen, diluting the specimen with water, and adding adulterants to the specimen intended to produce false-negative test results. An herbal tea and a soft drink, both commercially available, are adulterants that have been identified. The principal tests for detecting subversion attempts are tests of urine temperature, specific gravity, pH, creatinine concentration, and visual inspection of the specimen. Measures of urine temperature, pH, and specific gravity are particularly useful because these actions can be taken immediately at the collection site. Measuring creatinine concentration and specific gravity may be somewhat less effective because these tests cannot easily be conducted immediately at the collection site after the specimen is supplied but must await work done at a laboratory.

Measuring the temperature of a specimen appears to be one of the most effective means of detecting a substitute specimen. The effectiveness of using temperature to detect subversion depends upon the accepted temperature range that is being used and the technique that is used to measure temperature. NIDA has recommended a range of from 90.5° to 99.8° F. as

the normal temperature range. More restricted ranges--from 96.4° to 100.4°, for example--have also been recommended (Warner, 1989). Relatively narrow temperature ranges can, in fact, be used if special collection containers are configured to include a chemical thermometer in the collection cup. At least one such device is currently commercially available.

2.6.8 Employee Assistance Programs (EAP) (26.25)

Section 26.25 requires licensees to maintain an employee assistance program that offers assessment, short-term counseling, referral services, and treatment monitoring to employees with problems that could adversely affect the performance of activities within the protected area.

Some licensees have had mixed success in complying with the letter and spirit of this section. On the positive side, EAP specialists at three sites were noted as program personnel strengths in the initial NRC inspection reports. On the negative side, some licensees' employees were reported to harbor distrust of self-referral to EAPs because their use of the EAP would not be kept confidential. The EAPs of at least two licensees had acquired a punitive program image. And at one licensee, use of the EAP was considered to be equivalent to a first positive test result, an obvious obstacle to the useful functioning of that licensee's EAP.

2.6.9 Management Actions and Sanctions to Be Imposed (26.27)

Pursuant to Section 26.27, licensees are to perform suitable inquiries to determine whether persons seeking unescorted access to a protected area have ever been associated with drug or alcohol use such that their suitability for assignment to such duties should be questioned. The section also directs licensees to impose sanctions of varying severity depending on whether workers are found to be impaired on the job or to have been involved in the use, sale, or possession of illegal drugs. This section also prescribes sanctions for confirmed misuse of alcohol and valid prescription and over-the-counter drugs.

The initial inspection reports indicated that there is substantial variance between licensees as to the sanctions they impose for illegal drug use and misuse of alcohol. While some licensees impose the minimum sanctions required by the rule, others are employing sanctions somewhat more severe than those minimums. At least one licensee takes action before a positive on-site screening test has been confirmed in a laboratory. Among contractor personnel, the inspection reports indicated that these workers are subject to more severe penalties for illegal drug violations than those generally applicable to licensee personnel. Similar variations among licensees and between licensee employees and contractor workers were also found for sanctions imposed for confirmed misuse of alcohol. A majority of sites mentioned in the inspection reports employed less severe sanctions for alcohol violations than for illegal drug violations. This difference in sanctions for alcohol and illegal drug violations may be one factor in the increased number of confirmed positives for alcohol during the second half of the year compared to the decreased number of confirmed positives for most of the illegal drugs.

2.6.10 Appeals (26.28)

Section 26.28 requires that licensee and contractor or vendor employees have access to a procedure to appeal a positive drug or alcohol determination.

Licensees' appeals processes were found to have various kinds of deficiencies. At various sites, the initial inspections found deficiencies in training personnel about the appeals process. Licensees not giving workers effective access to their lab records regarding test results was also found at a number of sites. In various regions, there were continuing questions as to the period of time after a confirmed positive within which employees have to lodge an appeal, where and to what extent employees' records are to be made available, whether appealing employees are to be given copies of their records, and whether people whose positive tests come in pre-employment situations are to have recourse to the appeals processes required by this section.

In two cases where false positives were identified, reports indicated that, while the appeals process eventually absolved the employees, the process was difficult to implement and required great persistence on the part of the worker. One licensee revised the policy to include more automatic checks on the accuracy of the testing as part of the appeals process.

2.6.11 Protection of Information (26.29)

Section 26.29 requires licensees to protect the confidentiality of personal information about employees collected pursuant to the rule and prohibits the disclosure of such information by licensees, contractors, or vendors except in certain enumerated circumstances.

In at least seven instances noted in the initial inspections, licensee practices permitted access to preliminary or unconfirmed positive test results to personnel without a need to know such information. There were indications that some clarifications are needed regarding the protection of information.

2.6.12 Inspections (26.70)

Section 26.70 allows NRC representatives to inspect licensees' FFD programs and to acquire FFD records from licensees, contractors, and vendors.

As of March 1, 1991, NRC regional inspectors had conducted 24 initial inspections and 3 reactive inspections of licensee fitness-for-duty programs. These inspections were conducted to evaluate implementation of the programs, to provide information needed to assess the effectiveness of the FFD rule, and to determine whether future FFD rulemaking is needed. Inspectors conducted selective examinations to determine whether licensee FFD programs meet regulatory requirements and objectives.

The reports from these inspections mentioned both program strengths and problems. Thirteen separate program areas were mentioned as strengths. Among these, the areas most frequently mentioned were random testing, program management, workers' individual interests, and

licensee audit programs. The inspectors also reported that FFD program personnel were program assets at a majority of the 24 inspected sites. The FFD problems detected by these inspections were classified as either program weaknesses, unresolved items, non-cited violations, or violations. Of the problems identified, 22 were noted as unresolved items, 13 as non-cited violations, and 14 as violations. The FFD programmatic areas with the most identified problems were random testing, training, and protection of workers' individual interests.

2.6.13 Recordkeeping Requirements (26.71)

Section 26.71 requires licensees, contractors, and vendors to retain various kinds of FFD-related records, as well as report FFD program performance data to the Commission every six months.

Problems related to FFD recordkeeping were identified by the inspectors in only two instances. Experience with using the standard form for the reporting of program performance data has, however, indicated room for improvement in that form. The Commission staff is currently working in collaboration with NUMARC to make those improvements so that data that are more useful to both the Commission and the industry will be collected.

2.6.14 Reporting Requirements (26.73)

Licensees must report significant fitness-for-duty events, including the sale, use, or possession of illegal drugs within the protected area and FFD violations by reactor operators and supervisors. During 1990 there were six reports of alcohol or drugs found in the protected area, 19 reports of FFD violations by licensed operators, and 39 reports of FFD violations by supervisors having access to the protected area. A more detailed discussion of these reports is provided in NUREG/CR 5857, Volume 1, Section 3.2.

2.6.15 Audits (26.80)

Section 26.80 requires licensees to audit their fitness-for-duty programs and those of their contractors and vendors nominally every 12 months.

Licensee audit programs was one of the areas most frequently mentioned as a strong element of overall FFD programs by the regional inspectors during 1990.

3 DRUG TESTING ISSUES: UPDATE

To support the development of the fitness-for-duty rule (10 CFR Part 26), the NRC published two reports that reviewed scientific and technical issues associated with the implementation of fitness-for-duty programs, NUREG/CR-5227, Fitness for Duty in the Nuclear Power Industry: A Review of Technical Issues (Barnes et al. 1988), and NUREG/CR-5227 Supplement 1, Fitness for Duty in the Nuclear Power Industry: A Review of Technical Issues (Moore et al., 1989). These reports address drug and alcohol use as a fitness-for-duty concern and describe the testing procedures used to address these concerns. This chapter updates the issues addressed in those two reports.

3.1 Background and Organization

Among the topics addressed in Barnes, et al. (1988) was an evaluation of the extent to which drug use by nuclear power plant workers represents a fitness-for-duty problem (Barnes et al., 1988). The discussion consisted of two principal elements. First, the report examined evidence of drug use prevalence in the American workforce. Second, the report discussed how impairment resulting from drug use can compromise workers' abilities to perform their duties safely and reliably. Based on this evidence, Barnes and her colleagues concluded that illegal drug use should be addressed in licensee fitness-for-duty programs.

In the supplementary review, Moore et al. (1989) examined the prevalence of the use of alcohol and prescription and over-the-counter drugs and their effects on human performance. Results from this evaluation supported the conclusion that alcohol and a number of legal drugs represent fitness-for-duty concerns similar to the concerns represented by illicit drug use. Alternatives to chemical testing (urinalysis to test for illicit drugs and breath testing for alcohol) were examined as a possible means to address these concerns. No suitable alternatives to the deterrence provided by random chemical testing were found. Thus, random urinalysis for illicit drugs and random breath testing for alcohol were found to be important components of an effective fitness-for-duty program (Barnes et al., 1988; Moore et al., 1989).

The need for urinalysis and breath testing in fitness-for-duty programs is addressed in the general performance objectives of the fitness-for-duty rule. Section 26.10(a) of the rule requires fitness-for-duty programs to follow two general performance objectives:

- (1) "Fitness-for-duty programs must provide reasonable assurance that nuclear power plant personnel will perform their tasks in a reliable and trustworthy manner. . . ."
- (2) Fitness-for-duty programs must provide reasonable assurance that personnel "are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause which in any way adversely affects their ability to safely and competently perform their duties."

The scientific and technical information reviewed in Barnes et al. (1988) and Moore et al. (1989) supported these objectives. However, public comments on the proposed NRC fitness-for-duty rule revealed significant opposition to the chemical testing of workers, especially testing in the form of random urinalysis (Bush and Grimes, 1989). Thus, it is important that the NRC continue to examine whether chemical testing of workers (especially by means of random urinalysis) is necessary to achieve the fitness-for-duty performance objectives.

Five conclusions, derived from the previous NRC research reports (Barnes et al., 1988; Moore et al., 1989), guide the research presented in the following sections. These conclusions are as follows:

- (1) Workers' use, misuse, and abuse of illegal drugs, legal drugs, and alcohol represent legitimate fitness-for-duty concerns in the nuclear industry.
- (2) Chemical testing of workers for certain drugs and alcohol is an essential component of an effective fitness-for-duty program.
- (3) Chemical testing of workers for drugs does not fully address fitness concerns; chemical testing must be regarded as but one component in the "broad-brush" approach necessary for an effective fitness-for-duty program.
- (4) It is imperative that workplace drug testing be implemented in a manner that is fair and effective and ensures that workers' rights are protected.
- (5) Testing of workers must include random, unannounced urinalysis for certain drugs and random, unannounced breath testing for alcohol to fully detect and deter drug and alcohol misuse and abuse and its effects in the workplace.

This chapter re-examines these issues in light of recently published information. Section 3.2 examines the need for workplace drug testing programs in the nuclear industry. This section focuses on two topics: the prevalence of drug use (in American society at large and in the nuclear workforce in particular), and the efficacy of workplace drug testing. The information reviewed in Section 3.2 supports the first four statements listed above. That is, information on the prevalence of drug use and the efficacy of drug testing indicates that workplace drug testing is an important component of a workplace fitness-for-duty program, that it is imperative that this testing be but one component in a comprehensive broad-brush program, and that it be conducted in accordance with scientific and administrative safeguards.

Section 3.3 discusses the effectiveness of various random testing programs. Section 3.4 focuses on statement five above; it examines whether random, unannounced urinalysis is essential to ensure an effective testing program. This section updates previously reviewed information on alternatives to random urinalysis. Because evidence summarized in this section supports the conclusion that random urinalysis is essential, the remaining sections focus on issues central to ensuring that random urinalysis (and urinalysis testing on other occasions) is fair and effective.

Sections 3.5, 3.6, and 3.7 examine the major steps involved in the testing process. Section 3.5 discusses the collection of urine specimens, focusing on the issue of subversion of the testing process. Section 3.6 discusses analysis of urine specimens, focusing on the general principles of the two-step analytical process (screening tests followed by confirmation tests) and recent developments in screening technologies. Section 3.7 expands upon this discussion by providing an in-depth discussion of screening practices and issues for specific drugs or classes of drugs. Section 3.8 discusses additional relevant issues such as the qualifications and duties of the Medical Review Officer, maximum time limits on for-cause testing, and the effect of temperature variations on urine specimens.

3.2 The Need for Drug Testing in the Workplace

The literature reviewed by the NRC on the prevalence of illicit drug use in American society and the effects of commonly abused drugs on human behavior and performance clearly indicates that illicit drug use by nuclear power plant workers represents a legitimate fitness-for-duty concern (Barnes et al., 1988; Moore et al., 1989).

At present, there is no clear consensus in the scientific community on the efficacy of drug testing in the workplace. Researchers have presented both positions, advocating and opposing workplace drug testing. These disparate perspectives were also expressed in public response to the NRC rule in which many respondents strongly supported or opposed random urinalysis testing as a means of detecting and deterring drug use (Bush and Grimes, 1989). The NRC continues to examine this important topic to ensure that the technical requirements of the rule reflect sound contemporary scientific evidence. Toward this end, Sections 3.2, 3.3, and 3.4 provide an update on the scientific and technical literature relevant to the efficacy of random urinalysis in nuclear power plant fitness-for-duty programs.

Evaluating the need for drug testing in this section focuses on two issues: drug use prevalence and drug testing efficacy. Section 3.2.1 updates the literature reported in Barnes et al. (1988) on drug use prevalence. Section 3.2.2 examines fitness-for-duty programs in other industries. Section 3.2.3 examines whether current information supports continued use of drug testing in the workplace as a necessary method for addressing workers' use, misuse, and abuse of drugs.

3.2.1 Prevalence of Drug Use

Available estimates of drug use in American society vary substantially. The best available evidence, however, suggests that the prevalence of illegal drug and alcohol abuse warrants continuing action. This section summarizes drug use prevalence in American society, as a whole, and in the nuclear power industry, in particular.

3.2.1.1 Prevalence of Drug Use In American Society

Reliable and complete estimates of the prevalence of drug abuse in the workplace are not currently available (Weiss and Millman, 1989). However, several national studies of drug abuse provide information about illegal drug and alcohol use in the United States.

The National Household Survey on Drug Abuse (NHSDA) was conducted by the National Institute on Drug Abuse (NIDA) in the Fall of 1988 and includes 8,814 respondents 12 years and older. Data were collected in a household survey interview format (Kopstein and Gfroerer, 1990). The 1988 NHSDA survey results indicated that an estimated 14.5 million persons in the United States, or approximately 7 percent of the United States population over 12 years of age, use illicit drugs. Table 3.1 shows the prevalence of illicit drug and alcohol use by drug type and employment status for those 18 years and older. According to these data, among full-time employees, 8.2 percent reported using some type of illicit drug in the past month, 6.8 percent reported using marijuana in the past month, and 5.7 percent reported using cocaine during the past year. Higher rates of illicit drug use are seen for part-time employees, and the rates rise sharply for the unemployed.

Table 3.1 also shows the prevalence of alcohol use. Rates of weekly and heavy alcohol use for full-time employees, part-time employees, and the unemployed are more similar than the reported use rates of illicit drugs. Among full-time employees, 39.9 percent reported weekly use of alcohol, while 6.4 percent reported heavy use. Among part-time employees, 32.9 percent reported weekly use of alcohol, while 5.6 percent reported heavy use. Among the unemployed surveyed, 32.9 percent reported using alcohol weekly, while 7.9 percent reported heavy use of alcohol. Overall, these data show that illicit drug use and heavy alcohol use are prevalent among the American adult population.

Table 3.1 Prevalence of drug and alcohol use by selected drug types and employment status (all ages 18 years or older): 1988

Employment Status and Age Group	Past Month Use of Any Illicit Substance ¹	Past Month Use of Marijuana	Past Year Use of Cocaine	Weekly Use of Alcohol	Heavy ² Use of Alcohol
	Percent of Surveyed Population Sampled				
Full-Time Employed	8.2	6.8	5.7	39.9	6.4
Part-Time Employed	9.4	7.5	4.5	32.9	5.6
Unemployed	18.2	14.8	9.5	32.9	7.9

¹ Includes use of marijuana, hashish, inhalants, hallucinogens, cocaine, heroin, and nonmedical use of stimulants, sedatives, tranquilizers, or analgesics.

² Heavy drinking is defined as having five or more drinks on the same occasion five or more times in the past 30 days.

Source: Andrea Kopstein and Joseph Gfroerer. (1990). Drug Use Patterns and Demographics of Employed Drug Users: Data from the 1988 National Household Survey on Drug Abuse. Washington, DC: National Institute on Drug Abuse.

Table 3.2 shows the prevalence of drug use among full-time employed persons ages 18-40 by selected industries, type of substance, and gender.² All industries show evidence of illicit drug use and heavy alcohol use among the working male population. Current reported use of any recent illicit drug use was highest in the construction industry, repair services, finance, professionals, and wholesale trade. General prevalence rates clustered around 20 percent of the male population reporting illicit drug use in each of these industries. Current reported use of marijuana was highest among males in the construction industry, wholesale trade, repair services, and finance. Approximately 20 percent of male respondents in each of these industries reported using marijuana within the past month. Reported cocaine use was also highest among males in the construction industry and finance. Approximately 19 percent of the male respondents in these two categories reported using cocaine within the past month. Reported heavy alcohol use was highest in the construction industry, followed by retail trade. Reported heavy use of alcohol drops off substantially in other industries.

As a whole, the United States spends several billion dollars annually on drug and alcohol abuse treatment. Table 3.3 shows funding for drug and alcoholism treatment by region. Costs for drug and alcohol treatment are highest in the Northeast, followed by the West Coast, Great Lakes, Southeast, and Midwest. Table 3.4 shows the total financial support provided for drug and alcohol abuse by funding source. The National Drug and Alcoholism Treatment Unit Survey found that the combined public and private funding for drug and alcohol abuse treatment in 1987 exceeded \$3 billion dollars. In 1987, total national costs for drug abuse treatment exceeded \$1.3 billion. Total national costs for alcohol abuse treatment exceeded \$1.7 billion.

As discussed in the following sections, the prevalence of drug and alcohol use continues to represent a central fitness-for-duty concern. Use of these drugs poses job performance, safety, reliability, and economic concerns for American industry as a whole. Although survey data obtained from anonymous self-reports of drug and alcohol use are not available for the nuclear industry, licensee fitness-for-duty program performance data provide some indication of the extent of drug abuse among nuclear power plant workers covered by the scope of the fitness-for-duty rule. Findings from the nuclear power industry are discussed in the following section.

²Note that in Table 3.4 reliable estimates were not available for females in all industries (Kopstein and Gfroerer, 1990).

Table 3.2 Prevalence of drug and alcohol use among full-time employed persons ages 18-40 by selected industries, selected drug type, and gender: 1988

Employment Status and Age Group	Past Month Use of Any Illicit Substance ¹		Past Month Use of Marijuana		Past Year Use of Cocaine		Heavy ² Use of Alcohol	
	Male	Female	Male	Female	Male	Female	Male	Female
Percent of Full-Time Employed								
Construction	21.9	*	20.4	*	19.2	*	17.0	*
Manufacturing	12.3	9.2	11.0	8.3	9.7	4.3	9.4	*
Transportation	12.5	*	11.8	*	9.9	*	4.1	*
Wholesale Trade	19.0	*	19.0	*	8.0	*	3.3	*
Retail Trade	11.7	10.8	9.9	7.7	7.9	10.6	16.6	*
Finance	20.9	*	18.6	*	18.7	*	5.9	*
Repair Services	21.8	*	19.5	*	13.0	9.9	8.9	*
Professional	20.4	7.6	16.6	5.8	9.3	5.6	7.8	*

¹ Includes use of marijuana, hashish, inhalants, hallucinogens, cocaine, heroin, and nonmedical use of stimulants, sedatives, tranquilizers, or analgesics.

² Heavy drinking is defined as having five or more drinks on the same occasion, five or more times in the past 30 days.

*Low precision; no estimate reported.

Source: Andrea Kopstein and Joseph Gfroerer. (1990). Drug Use Patterns and Demographics of Employed Drug Users: Data from the 1988 National Household Survey on Drug Abuse, pp. 1-16, Washington, DC: National Institute on Drug Abuse.

Table 3.3 Funding for drug and alcoholism treatment in 1987 by region
(in thousands of dollars)

Region	Government		Private		Public		Other		Total	
	Drug	Alcohol	Drug	Alcohol	Drug	Alcohol	Drug	Alcohol	Drug	Alcohol
Northeast	218,443	186,301	92,059	210,110	123,119	79,968	10,537	19,186	444,158	495,547
	79,926	110,438	75,163	81,718	10,465	14,979	3,995	8,989	169,509	216,124
Southeast	85,292	127,351	107,373	135,316	21,127	33,100	10,267	12,769	224,058	308,536
	46,453	86,189	74,097	106,028	14,385	14,769	9,302	17,085	144,237	224,071
Midwest	111,883	114,376	197,666	380,000	25,876	29,983	6,160	6,682	341,585	531,041
West Coast										

Derived from the National Drug and Alcoholism Treatment Unit Survey (1987).
U.S. Alcohol, Drug Abuse, and Mental Health Administration, Rockville, MD.

Table 3.4 Total financial support for alcoholism and drug abuse treatment services in 1987 by funding source

Funding Source	Drug Funds	Alcohol Funds	Total Funds
Government (Federal, State, and Local)	\$ 540,848,000	\$ 617,910,000	\$1,158,758,000
Private (Private Third-Party, Client, etc.)	\$ 531,724,000	\$ 855,884,000	\$1,387,607,000
Other Public (Welfare, Medicaid, Food Stamps, etc.)	\$ 195,024,000	\$ 173,524,000	\$ 368,548,000
Other	\$ 40,411,000	\$ 64,752,000	\$ 105,163,000
Total	\$1,308,008,000	\$1,712,069,000	\$3,020,077,000

National Drug and Alcohol Treatment Unit Survey, 1987.

U.S. Alcohol, Drug Abuse, and Mental Health Administration, Rockville, MD.

3.2.1.2 Prevalence of Drug Use in the Nuclear Power Industry

Section 26.71(d) of the rule requires each NRC licensee to submit summary drug testing program data on the type, number, and percentage of workers tested, number and percentage of confirmed positive tests by drug type and worker type, and programmatic lessons learned. These data have been summarized into an annual summary report, NUREG/CR-5758, Vol. 1 (Durbin et al., 1991), and are described below. Compared to data from national surveys, summary data regarding rates of detection in licensee drug testing programs indicate lower estimates of the prevalence of drug and alcohol abuse in the nuclear industry than in other industries. Even recognizing that some substance abusers are not detected, these lower rates may, in part, represent a deterrent effect from the imposition of a testing program. Currently, however, there has been no research performed on the deterrent effect of testing programs.

During the period January 3 to December 31, 1990, licensees reported that they had conducted 278,209 tests for the presence of illegal drugs and alcohol. Of these tests, 2,409 (.87%) were positive. Positive test results varied by category of test and category of worker. The majority of positive test results (1,548) were obtained through pre-access testing. Of tests conducted on workers having access to the protected area, there were 550 positive tests from random testing and 214 positive tests from for-cause testing. Follow-up testing of workers who had previously tested positive resulted in 65 positive tests. For-cause testing resulted in the highest

percentage of positive tests; about 29 percent of for-cause tests were positive. This compares to positive test results of 1.26 percent of pre-access tests and .37 percent of random tests.

Positive test results also varied by category of worker. Overall, short-term contractor personnel had the highest rates of positive tests (1.13%). Licensee and long-term contractor personnel had lower rates of positive test results (.51% and .91%, respectively).

Of all drugs tested, marijuana was responsible for the highest percentage (47.4%) of positive test results, followed by cocaine (29.0%) and alcohol (18.6%).

The licensee fitness-for-duty testing program data indicate that, relative to other industries, the prevalence of illicit drug and alcohol use may be much lower among nuclear power plant personnel. Although overall positive test result rates appear to be very low (in many instances less than 1 percent of the test results are positive for a given testing population), the rates represent a substantial number of nuclear power plant workers with drug or alcohol problems (Durbin et al., 1991).

It is important to note, however, that detection rates may not reflect actual drug use prevalence among nuclear power plant workers. Some workers using illegal drugs or abusing alcohol on the job may escape detection and, therefore, continue using drugs undeterred by a fitness-for-duty program. Thus, these detection rates in all likelihood represent a lower-bound estimate of drug use rates in the nuclear power industry. Survey data from anonymous self-reports of drug and alcohol use from nuclear power industry workers would be needed to provide data comparable to the NIDA Household Survey and other industry surveys on the prevalence of illicit drug use and alcohol use in the workplace.

3.2.2 Employer and Employee Reactions to Drug Abuse and Drug Testing Programs in the Workplace

Employer concern over illicit drug use and alcohol misuse in the workforce population arises mainly over concerns of reduced employee reliability. That is, reductions in productivity and safety result in financial losses and safety concerns. Costs due to employee illicit drug use and alcohol misuse are observed in lost time, increased insurance claims, sick benefits, accidents, theft, and lowered productivity (Regan, 1989).

Results from several surveys underscore the concern expressed by employers regarding drug use in the workplace. One employer survey found that 95 percent of employers responding to the survey had direct experience dealing with an employee drug problem and 98 percent reported that the situation was as bad or worse than it was 5 years ago (Crant and Bateman, 1990). Another survey found that the predominant reasons cited by employers for implementing a drug testing program are incidents of drug use at the company (42%), general concern for employee safety (26%), and response to government regulations (10%) (McCunney, 1989).

Workers also recognize the seriousness of drug abuse in the workplace. A survey of 386 unionized private sector employees and 410 unionized public sector employees was conducted to determine unionized worker attitudes toward drug abuse and workplace drug testing (LeRoy, 1990). The percent of unionized employees in the private and public sectors who accept drug testing in the workplace is presented in Table 3.5. A greater percentage of unionized private sector employees than public sector employees opposed drug testing in the workplace (27.2% compared to 13.8%). Approximately 20 percent of all employees surveyed thought that drug testing in the workplace should never occur. Approximately 78 percent of all private and public sector employees surveyed supported drug testing in the workplace under controlled conditions where the individual's privacy is protected. Two percent of the respondents thought that drug testing in the workplace should occur without restriction.

The survey also found that the presence of a drug testing program in the workplace at the time of the survey did not appear to significantly affect respondents' attitudes toward workplace drug testing. Among unionized public sector respondents without a drug testing program, approximately 15 percent stated that drug testing in the workplace should never occur, 83 percent thought that drug testing in the workplace should occur under controlled conditions where individual privacy is protected, and 2 percent thought that drug testing should occur without restriction. Among unionized public sector employees with drug testing programs in their workplace, 10 percent stated that drug testing should never occur, 87 percent said it should occur under controlled conditions, and 3 percent thought it should occur without restriction (LeRoy, 1990).

Survey respondents were also asked to indicate on a five-point rating scale whether they agreed or disagreed with probable cause testing and random testing. Approximately 62 percent of private sector employees accepted probable cause testing, compared with 77 percent approval by public sector employees.

Table 3.5 Percentage of unionized employees who accept drug testing in the workplace: public and private sectors

Employee Response	Employment Sector		
	Private	Public	All Employees
Drug testing in the workplace should never occur.	27.2	13.8	20.3
Drug testing in the workplace should occur under controlled conditions where the individual's privacy is protected.	70.7	84.3	77.7
Drug testing in the workplace should occur without restrictions.	2.1	2.0	2.0

Source: LeRoy, M.H. (1990). Drug Testing in the Public Sector: Union Member Attitudes. Journal of Collective Negotiations, 19 (3), 165-173.

Fewer employees supported random testing in the workplace. Approximately 14 percent of the private sector employees surveyed agreed or strongly agreed with random testing, compared with 21 percent of the public sector employees. In contrast, 77 percent of the private sector respondents disagreed or strongly disagreed with random drug testing in the workplace, compared with 66 percent of public sector employees (LeRoy, 1990). Thus, overall survey results suggest that the majority of unionized public and private sector employees conditionally support drug testing in the workplace, with the exception of random testing.

A survey of the American Society of Personnel Administrators (ASPA) conducted in 1988 found that personnel administrators view employee drug abuse seriously, but tend to think that the problem is worse in other companies than among their employees (Masters, Ferris, and Ratcliff, 1988). Survey respondents were also asked to rank the relative seriousness of fitness-for-duty concerns; namely, drug abuse, alcoholism, theft, accidents, stress, and mental illness. In comparison with other fitness-for-duty concerns, drug abuse was perceived by only 3.8 percent of the respondents as the number one problem among employees. Alcoholism (23.2%), accidents (18.4%), and theft (8.3%) were more frequently ranked as the number one problem.

3.2.3 Drug Testing Programs in Other Industries

This section provides current information about the types of drug testing programs implemented in a variety of industries.³ Government and military agencies that have implemented drug testing programs are also identified in this section.

In response to the issues of safety, productivity, and health costs raised by drug abuse, many industries in the 1980s adopted drug testing policies. In a 1981 survey by Human Resources Management News, only 3 percent of the companies polled had tested for drugs. Today it is estimated that over 50 percent of companies in the United States have drug testing policies in place (Warner, 1990).

In 1988, a national survey of workplace drug testing programs conducted by the Gallup Organization found that two-thirds of all personnel managers surveyed from large companies (over 500 employees) with drug testing programs had dealt with incidents of drug abuse among their employees in the past year. However, few of those surveyed thought that drug abuse was worse in their companies than in their industry as a whole. The main reason large companies implemented a drug testing program was to improve safety records and reduce accidents (54%). The next most frequently cited reason was to curb illegal drug traffic (10%).

A national survey conducted by the American Management Association (AMA) (1991) found that the number of surveyed firms with drug testing programs rose to 63 percent in January 1991, compared with 51.5 percent in January 1990. This represents a 22 percent increase in a one-year period, and an almost three-fold increase since January 1987. Several factors contributed to this rise in the number of drug testing programs:

³See also NUREG/CR-5227 and NUREG/CR-5227 Supplement 1 for a review of industry programs prior to the fitness-for-duty rule (Barnes et al., 1986; Moore et al., 1989)

- The Department of Transportation implemented regulations that require mandatory random drug testing and other fitness-for-duty measures for the various transportation industries
- The Department of Defense implemented rules which require defense contractors to implement anti-drug programs for employees in sensitive positions
- The Drug-Free Workplace Act of 1988 requires federal government contractors to maintain a drug-free workplace
- Other federal and local initiatives supported NIDA's workplace drug testing guidelines
- Recent court decisions strengthened the employer's right to test
- Insurance carriers provided incentives to reduce liability
- Employers became more aware of drug abuse and its effects in the workplace.

The increase in the presence of drug testing programs has been accompanied by an increase in the use of random testing, which almost doubled in 1990 (a 97% increase over 1989 rates). Pre-employment testing increased by 41 percent during the same period.

The proportion of these tests that were positive declined dramatically from 1989 to 1990. This is attributed largely to explicit warnings of drug testing for job applicants and for current employees who must undergo periodic or random testing. Out of 76,296 employees tested in 1990 by 484 respondent firms, 3,220, or 4.2 percent, were positive. This positive rate is almost half of the rate reported in 1989 (8.1% positive). As noted by the AMA, however, this is not a statistical indication of lower or decreased drug use in the workplace. Rather, it reflects two policy factors. First, a greater number of employees were tested in 1990 for reasons other than suspicion of drug use. In firms testing for suspicion of drug use alone, the 1990 positive test rate was 26.6 percent. In firms testing only after an accident, the positive test rate was 7.7 percent. In firms testing only on a periodic or random basis, the positive test rate was 1.9 percent.

A second policy factor producing a dramatic decline in the positive test rate from 1989 to 1990 may be due to more companies providing education and drug testing information prior to testing as required by Department of Defense and Department of Transportation regulations and advised by NIDA.

One factor that appears to influence the rates of drug use is the increase in companies sponsoring employee drug education and awareness programs. In firms sponsoring such programs, the AMA survey found that the positive test rate was 30 percent lower, dropping from a 5.7 percent positive test rate to a 4.0 percent positive test rate.

The AMA survey findings suggest that the number of drug testing programs is increasing, and that the number of positive test rate results is declining as a result of revised testing policies, practices, and procedures. Declines in positive test results may also be due to deterrent effects, since job applicants and employees are more often routinely informed of drug testing requirements.

Organizations have responded in different ways to illicit drug use and alcohol abuse in the workplace (Staudenmeier, 1989). Workplace drug testing programs are influenced by the nature and scope of the employer's operations, the size of the organization in terms of number of employees, and whether the organization is required by regulation to implement a drug testing program (Bureau of Labor Statistics, 1989).

The presence of drug testing and EAP programs varies substantially by size of establishment (Bureau of Labor Statistics, 1989). As shown in Table 3.6, 1.4 percent of all private nonagricultural establishments in the United States, including communications companies and private utilities,⁴ have a drug testing program and an employee assistance program (EAP) in place.⁵ Among establishments with 100 to 249 employees, 9.4 percent have a drug testing program and an EAP. Among establishments with 1,000 to 4,999 employees, 35.2 percent have a drug testing program and an EAP. Among establishments with 5,000 employees or more, 56.2 percent have a drug testing program and an EAP. The majority of establishments with drug testing programs and EAPs in place test all job applicants. The majority of organizations test employees for cause, while over one-fourth test all employees either periodically or randomly regardless of cause.

The presence of drug testing programs and EAPs also varies by type of industry. Table 3.7 shows the percentage of drug testing programs and EAPs by industry for private non-agricultural establishments (Bureau of Labor Statistics, 1989). Approximately 3 percent of all establishments in the United States have a drug testing program in place, while slightly less than 7 percent have an EAP. A little over 1 percent of all establishments in the United States have both a drug testing program and an EAP. Fewer than 10 percent have a drug testing program or an EAP. At the time of the survey, approximately 4 percent of the establishments were considering adopting a drug testing program and 3 percent were considering adopting an EAP. Over 13 percent of the establishments in the United States have a formal policy on drug use.

⁴"An establishment is an economic unit, such as a factory, mine, or store, which produces goods or services" (Bureau of Labor Statistics, 1989, p. 12).

⁵Consistent with the fitness-for-duty rule requirements, this discussion focuses exclusively on organizations that have adopted a drug testing program as well as an EAP. The discussion does not include organizations that have adopted a drug testing program or an EAP only, organizations considering implementing a drug testing program, or those with a formal drug policy.

Table 3.6 Percentage of organizations with a drug-testing and employee assistance program by size: private non-agricultural organizations, Summer 1988

		Size of Establishment							
	Total	1 to 9 Employees	10 to 49 Employees	50 to 99 Employees	100 to 249 Employees	250 to 499 Employees	500 to 999 Employees	1,000 to 4,999 Employees	5,000 or more Employees
Total Number of Organizations (thousands)	4,542.8	3,140.9	1,083.7	195.6	84.4	23.1	9.5	5.2	0.4
Percent with Both a Drug Testing Program and an EAP	1.4	0.4	2.7	3.8	9.4	20.9	22.7	35.2	56.2

Source: Bureau of Labor Statistics. (1989). Survey of Employer Anti-Drug Programs (Report No. 760). Washington, D.C.

**Table 3.7 Percentage of organizations with a drug-testing or employee assistance program by industry:
private non-agricultural organizations, Summer 1988**

Type of Industry	Total	Mining	Manufacturing			Non-Durable Goods	Transportation	Communications & Public Utilities	Wholesale Trade	Retail Trade	Finance, Insurance & Real Estate	Services
			Construction	Durable Goods								
Organizations												
TOTAL NUMBERS (in thousands)	4,542.8	31.6	458.1	193.9		141.2	153.5	37.5	467.9	1,101.8	403.9	1,553.5
Percentage:												
With a drug-testing program	3.2	21.6	2.3	9.9		9.1	14.9	17.6	5.3	.7	3.2	1.4
With an employee assistance program	6.5	18.8	2.8	10.4		12.8	10.9	30.9	7.8	4.7	9.2	5.5
With both a drug-testing and an employee assistance program	1.4	16.2	.7	4.1		4.8	4.8	11.7	2.3	.4	1.5	.6
With neither a drug-testing nor an employee assistance program	91.7	75.5	95.6	83.9		82.9	79.0	63.2	89.3	95.0	89.1	93.7
Considering implementation of:												
A drug-testing program	3.9	3.1	2.6	10.8		8.9	8.7	9.6	7.0	2.3	2.2	3.0
An employee assistance program	3.2	3.0	.8	8.4		7.5	8.8	5.9	2.9	2.6	2.5	3.0
With a formal policy on drug use	13.1	28.4	9.9	17.6		20.5	29.7	36.3	10.9	12.2	15.3	11.1

Note: The individual categories will sum to more than 100 percent because many establishments had more than one program or policy.
Source: Bureau of Labor Statistics. (1989). Survey of Employee Anti-Drug Programs. (Report No. 760). Washington, D.C.

Within the communications and public utilities industries, the proportion of firms offering drug testing programs and EAPs is much higher than the national average. Over 17 percent of communications and public utilities firms have a drug testing program. Over 30 percent of the establishments in this sector offer an EAP. Approximately 12 percent have a drug testing program and an EAP. However, almost two-thirds of these organizations have no drug testing program or EAP. Currently, 10 percent of the communications and public utilities organizations are considering implementing a drug testing program. Six percent of the organizations in this sector are considering adopting an EAP. Over one-third of the organizations have a formal policy on drug use. Within the sector as a whole, drug testing programs and EAPs have been implemented at a much higher rate than for the national average. However, in comparison with the nuclear power industry, a subset of this population, the percentages of organizations with drug testing programs and EAPs in this sector is much lower. This is likely due to differences in the nature of work, organizational size, and regulatory requirements between nuclear and non-nuclear utilities and communications organizations.

A review of collective bargaining agreements across types of industry indicates that drug and alcohol testing provisions are included in 97 percent of commercial trucking contracts, 67 percent in mass transit (local and interurban transit), 50 percent in primary metals, 44 percent in transportation equipment, and 35 percent in petroleum refining (Bureau of Labor Statistics, 1990). Differences in substance abuse provisions across these industries are due largely to government regulations applicable to each industry. The majority of provisions included both alcohol and drugs; a few collective bargaining agreements addressed only alcohol abuse.

The type of testing employed (e.g., random, for-cause, pre-employment, periodic, or follow-up) varies substantially across programs. A 1987 survey of 250 employers found that among those surveyed (Regan, 1989):

- 45 percent had a formal drug policy
- 25 percent were considering adopting a drug testing policy
- 75 percent tested applicants
- 66 percent test only for-cause
- 58 percent reported positive employee reaction to the testing program.

In general, industry drug testing programs typically incorporate one or more of the following elements (Bureau of Labor Statistics, 1990):

- pre-employment testing
- periodic and random testing
- for-cause testing
- drug abuse policies and awareness
- employee pledges for a drug-free workplace
- employee assistance program (EAP)
- managerial training to address drug-related problems.

In addition to the nuclear power industry, several other regulated industries have been required to implement drug testing programs. For example, the following federal agencies require their regulated industries to provide programs:

- Department of Transportation
- Department of Energy or its contractors
- Department of Defense.

Drug testing programs have also been implemented in many federal agencies. Examples are:

- Administrative Office of the United States Courts
- Federal Bureau of Prisons
- Drug Enforcement Administration
- Federal Bureau of Investigation
- United States Customs Service
- Nuclear Regulatory Commission
- Federal Aviation Administration
- Secret Service Uniformed Division
- Federal Protection and Safety Division of the General Services Administration
- CIA
- NASA
- United States Postal Service.

As previously reported in Barnes et al. (1988) and Moore et al. (1989) the U.S. Department of Defense (DOD) has implemented aggressive drug testing programs throughout the armed services (Barnes et al., 1988; Moore et al., 1989). In 1988, the DOD conducted a pilot study to determine the prevalence of marijuana and/or cocaine use among military applicants (MMWR, 1989). In the pilot study, applicants were not informed in advance about the drug test, and the results were not linked to individual applicants. Forty-two percent of the urine specimens collected were selected at random from a sample of 14,200 specimens; the specimens were obtained from 12 of 70 Military Entrance Processing Stations. The following results for marijuana and cocaine were observed among the uninformed applicants:

- 7.3 percent initial positive rate for marijuana
- 1.8 percent initial positive for cocaine
- 0.7 percent initial positive for both drugs.

No confirmation gas chromatography/mass spectrometry (GC/MS) tests were conducted on the initial screening test positive results. The DOD estimated, however, that, based on data from military drug-screening laboratories, at least 85 percent of the positive screening tests for cocaine and 90 percent of the positive screening tests for marijuana would have been confirmed positive (MMWR, 1989). Using these estimated confirmed positive rates, adjusted results for uninformed applicants are thus:

- 6.6 percent positive rate for marijuana
- 1.5 percent positive rate for cocaine

- 0.6 percent confirmed positive for both drugs (0.7 percent x .0875 average confirmed positive rate for marijuana and cocaine).

After implementing the drug testing program, the frequency of positive test results decreased dramatically. In the second phase of the pilot study, 322,256 applicants were informed that a urine specimen would be collected. All positive specimens from the applicant group were confirmed by GC/MS.⁶ Among the informed applicants tested, the following results were observed:

- 2.4 percent confirmed positive rate for marijuana
- 0.9 percent confirmed positive rate for cocaine
- 0.3 percent confirmed positive rate for marijuana and cocaine.

The dramatic decreases observed in the percentage of positive tests among applicants from the pilot study to the systematic screening program may be due to:

- users abstaining from marijuana and/or cocaine after being notified of a drug test
- some users opting to withdraw from the application process after being notified of the drug testing requirement
- drug testing deterring some users from beginning the application process altogether.

Findings from the military drug testing programs suggest that a strong detection and deterrent effect results from pre-employment screening, the most common form of testing in industry drug testing programs. (Also see Moore et al., 1989, for a discussion of the effectiveness of drug testing in the U.S. military.)

3.2.4 Arguments For and Against Workplace Drug Testing

The increase of testing for drug use in the workplace over the last several years has been accompanied by some continuing controversies regarding the need for such testing. These controversies revolve around various uncertainties. Whether drug use in the workplace is a sufficiently serious problem to require the expenditure of substantial funds and to risk unnecessary damage to innocent workers is one of these continuing questions. The correlation between drug use and job performance and the inability of urinalysis to detect current impairment are others. These and other issues that inform arguments for and against drug testing in the workplace are discussed in this section.

⁶For a discussion of urine tests to screen for the presence of drugs, and to confirm initial test results, see NUREG/CR-5227 (Barnes et al., 1988).

3.2.4.1 Drug Use as a Workplace Concern

Various estimates of the monetary costs of drug and alcohol abuse for American business and industry have been made during the last few years. Estimates of these costs vary from about \$40 billion to about \$200 billion annually. The National Institute on Drug Abuse, for example, has estimated the total financial drain to American companies caused by substance abuse to be approximately \$100 to \$200 billion annually (Warren, 1990). Staudenmeier (1989) has estimated the cost of substance abuse in the workplace due to reduced productivity and lost employment to be \$104.57 billion per year, calculated as lost worker earning power. He attributes over two-thirds of this cost to alcohol abuse and approximately one-third to abuse of other drugs. Many employers, probably acting out of a sense of the financial losses that drug abuse may cause, have implemented drug testing of their employees as at least one response to the perceived problem.

Even in light of such estimates, critics of drug testing in the workplace argue that the actual costs of drug abuse in the workplace are not well known. Horgan (1990), for example, states that statistics on the costs of drug use and the relationship of drug use to work-related accidents are suspect. He argues that, although statistics on the costs of drug abuse abound in the literature, few of the findings are based on well-controlled studies. Horgan also points out that few studies on the subject have appeared in refereed scientific journals, and he cites experts who have challenged the methodology of the few available studies.

One of the underlying problems with arriving at reliable estimates of the financial costs of drug abuse is the still questioned causal relationship between such abuse and job performance. Parish (in Lewy, 1989) summarizes the current state of knowledge of this relationship in the following manner:

The hypothesis that drug usage, either legal or illegal, predicts poor job performance remains essentially untested. Studies of drug usage and job performance are needed.... We enter our war on drugs with less advance intelligence than a high school basketball team has about its next opponent.
(p. 362)

McCunney (1989) echoes this thought when he argues that "accurate data regarding the extent of illness, disability rates, and economic consequences of substance abuse at work are lacking" (p. 592). As a consequence, McCunney states, case studies are used by both advocates and opponents of drug testing to substantiate their claims.

This relative paucity of data describing the relationship between drug use and job performance does not necessarily imply that little is known about risks associated with workers' drug use. Nor does it indicate that drug abuse and its effects in the workplace are not valid safety and productivity issues. Even the most conservative estimates regarding the prevalence and consequences of drug abuse in the United States indicate that a substantial problem exists. Also, studies linking drug use with job performance are but one of various lines of evidence for use in estimating the need for workplace drug testing. Evidence that supports the need for workplace drug testing is available from other types of research.

Such evidence can be obtained from three research approaches that strongly support the conclusion that workers' use of the drugs listed in the NRC rule drug panel is a fitness-for-duty concern. These approaches are: (1) case studies of drugs in the workplace and drug programs; (2) studies of the impairment effects of drugs and alcohol on human behavior and human performance; and (3) studies investigating the relationship between drug and alcohol use and motor vehicle accidents. Evidence from these sources is summarized below.

Case Study Evidence. Case studies provide insights into both the risks associated with workers' use of illicit drugs and the degree to which drug testing might mitigate those risks. It is important to note that data from case studies must be evaluated with caution because they represent anecdotal evidence. Nevertheless, results from a substantial number of case studies suggest that illicit drug use is a concern and that drug testing represents an effective way to address this concern. For example, Cornish (1988) cites two cases that demonstrate this. In the first, the Southern Pacific Railroad reported a 71 percent reduction in accidents and injuries attributable to human error after it implemented drug and alcohol testing. In the second, the Georgia Power Company reported that after it had begun drug testing, the accident rate per 200,000 hours worked at one plant dropped from 5.4 to 0.49. McCunney (1989) also provides case study evidence from the Firestone Company. Estimates from Firestone indicate that drug users increase rates of worker compensation claims fivefold and sick benefits threefold. Indirect costs include liability for negligent hiring and supervision resulting from consumer suits for drug-related accidents involving an employee.

Critics of workplace drug testing have also used case study evidence to demonstrate that the costs of testing may outweigh the benefits (Rosenstock & Cullen, 1987; McCunney, 1989; McBay, 1990; Horgan, 1990). McCunney cites a case that illustrates this. In one company, 500 drug tests were performed; these produced 33 unconfirmed positive results. Of these 33 results, 13 were confirmed positive. Of the 13 confirmed positive, 12 cases were dismissed because of legitimate medical reasons that explained the presence of some drug. Thus, out of a total of 500 tests, one relevant confirmed positive test result occurred (this one was positive for PCP). Each of the 500 screening tests cost \$30, for a total of \$15,000. The 33 confirmation tests costs \$50 each, for a total of \$1,650. Thus, the total cost for identifying one positive PCP case was \$16,650.

This approach to estimating the costs and benefits of drug testing is of limited use. To accurately determine whether or not drug testing costs outweigh the benefits, it is necessary to estimate the benefits that would be gained by reducing the following:

- effects of drugs on work performance by type of drug and dose
- costs associated with poor or incompetent work performance
- costs associated with serious accidents in safety-sensitive environments (e.g., costs of long-term public health, equipment malfunction or breakdown, and so on).

An estimate of costs incurred for any of these reasons might show that the drug testing program described in the example above was cost effective.

Studies of Drug Impairment. Information on the effects of various drugs strongly supports the conclusion that illicit drug use among workers with safety-sensitive positions can be expected to greatly increase safety risks. Results from a survey of research linking drug use to mental and physical impairment were presented in previous NRC fitness-for-duty reports (Barnes et al., 1988; Moore et al., 1989). As discussed in those reports, a substantial body of evidence demonstrates that illicit drugs commonly included in workplace drug testing protocols (i.e., all drugs included in the fitness-for-duty rule drug panel) impair skills, abilities, and other attributes required for workers to perform safely on the job. Recent information obtained since the publication of these reports continues to support this conclusion.

For most illicit drugs included in workplace drug testing programs, there is little controversy about the effects of the drugs on safety-related job performance. Questions about the relationship between safety-significant impairment and use of central nervous system (CNS) stimulants are raised, however, concerning amphetamine or cocaine use. Some of the short-term effects of moderate use of CNS stimulants may well improve performance, because the drugs can heighten energy, attention, and alertness (Barnes et al., 1988). However, impairment associated with high and prolonged doses of stimulants can be dramatic. Stimulants can substantially impair one's cognitive abilities and the social interaction skills required for effective teamwork. Also, withdrawal from CNS stimulants can produce severely impairing fatigue, particularly if such drug use has resulted in substantial sleep deprivation.

Survey results from studies that ask respondents to report on their own drug use also indicate that CNS stimulants can lead to safety-significant impairment. For example, the Cocaine National Hotline reported that of 227 cocaine users, 75 percent admitted to using cocaine on the job and 64 percent of those respondents also admitted that it hindered work performance. About 18 percent of those who admitted using cocaine on the job attributed some work-related accident to their use of cocaine (McCunney, 1989).

Dr. Bryan Finkle, speaking at the 1987 Arnold O. Beckman Conference in Clinical Chemistry, summarized the issue of cocaine use in his response to a question about a study that allegedly demonstrated that cocaine did not cause impairment:

. . . it's hard to make a blanket statement about cocaine. On the other hand, it acts like any other stimulant drug, so that . . . subjects who are sleep-deprived, or bored, in a very few studies show either enhanced performance or the opposite effects of boredom or sleep deprivation for a dose or two. We have known this about amphetamines for years, and there is no reason to think that cocaine would be any different. The issue is, what happens after the third dose or fourth dose or tenth dose or hundredth dose. There is absolutely no question that gross impairment occurs. . . . (Jatlow, Blanke, Finkle, Formey, Gawin, and Jones, 1987, p. 97B)

In summary, the best available information on marijuana, cocaine, opiates, amphetamine, and phencyclidine reviewed in Barnes et al. (1988) and Moore et al. (1989) indicates that these drugs affect human performance in ways that represent a substantial workplace concern. The

same conclusion can be made for alcohol and a number of prescription and over-the-counter drugs, including benzodiazepines and barbiturates (see Moore et al., 1989).

Evidence from Motor Vehicle Accident Research. Available data linking drug use to traffic accidents demonstrates the impairing effects of various drugs on motor vehicle operations. In reviewing commercial motor vehicle fatalities, the National Transportation Safety Board (NTSB, 1990) found that driver impairment from alcohol and drug use was the second most common probable cause of accidents resulting in driver fatalities. The most common probable cause was fatigue, which was a factor in 31 percent of the accidents. Alcohol and drug impairment was a factor in 29 percent of the accidents.

The role of alcohol in motor vehicle accidents has been more extensively studied than that of any other drug. Manno and Manno (1988) reviewed the role of alcohol in motor vehicle accidents in 41 studies that spanned 52 years of research, from 1934 to 1986, and were conducted in the United States, Canada, England, Scotland, Australia, New Zealand, Finland, and Iceland. Results from the studies supported the conclusion that alcohol consumption increases the likelihood of motor vehicle accidents. The importance of this literature can be seen by reviewing numerous studies that examined the percentages of individuals who had blood alcohol contents (BACs) above 0.10 percent and who were involved in fatal accidents. Although there was variation across the studies, the typical findings were:

- in accidents that resulted in fatalities and in which only one vehicle was involved in the accident, approximately 66 percent of drivers had BACs at or above 0.10 percent
- In accidents that resulted in fatalities and in which more than one vehicle was involved, approximately 35 percent of the drivers determined to have been responsible for the accidents had BACs at or above 0.10 percent
- approximately 35 percent of pedestrians killed in motor vehicle accidents had BACs at or above 0.10 percent.

Data linking drug and alcohol use to traffic accidents does not provide direct evidence that alcohol or other psychoactive drugs impair nuclear power plant employees' job performance. Given what is known about the effects of alcohol and other psychoactive drugs of concern, the skill and abilities needed to drive safely, and the skill and abilities needed by many nuclear power plant workers, it is reasonable to infer that drug and alcohol use has an impact on nuclear power plant employee performance.

In summary, a review of scientific literature indicates that a precise correlation between drug use and workplace accident rates has not been established. Nevertheless, research has demonstrated that use of various psychoactive drugs impairs human performance. The large body of data documenting the role of drugs and alcohol in motor vehicle accidents testifies to the potential danger of this impairment.

3.2.4.2 Impacts of Drug Use Beyond Impairment

A number of concerns in addition to on-the-job impairment due to the immediate effects of drug consumption may be very relevant when considering whether drug testing should be a central component of a fitness-for-duty program. While it is true that urinalysis detects only recent drug use and does not detect impairment per se, it is likely that a positive test result indicates indirect decrements in job performance. Some of these indirect effects on job performance are the subject of this section.

The NRC has described one such concern, this being the association of illicit drug use with worker trustworthiness and reliability. As stated by Bush and Grimes (1980):

The NRC is fundamentally concerned with the reliability and trustworthiness of workers within nuclear power plants, and believes that workers who demonstrate a lack of trustworthiness are not fit for duty. By engaging in illegal drug use, a worker demonstrates that he or she does not obey society's laws, which casts doubt onto whether or not he or she can be expected to obey the licensee's rules and the NRC's regulations that are in place to protect public health and safety. (p. 3-7)

Bush and Grimes also noted that off-duty drug use, in addition to causing potential on-duty impairment, can diminish employees' capacity to function due to hangover and withdrawal effects. Bush and Grimes also discussed the implications of employees' use of illicit drugs and their ability to make sound judgments. Given that many nuclear power plant workers perform tasks with obvious safety implications and that illicit drug use can be expected to compromise their ability to perform their duties safely, illicit drug use by itself reflects poor judgment. Clearly, the ability to make sound judgments is an important component of many workers' jobs in the nuclear industry. (The combination of poor judgment and other forms of impairment may also represent an especially critical concern; see Section 3.4.3.1.)

The concerns expressed by the NRC are shared by a number of researchers. In a recent article on industry-based alcohol recovery programs, O'Donnell and Wilson (1989) state:

What is of more relevance practically for industrially-based alcohol programs is the fact that being intoxicated at the place of work is not the only major difficulty for employers. Impaired performance through poor health, deficient concentration, and bad relationships with colleagues is a serious issue. (pp. 1175-1176)

Weiss and Millman (1989) express a similar view:

The fluctuating physical and emotional states associated with withdrawal also interfere with, and may even preclude, the ability to work. Cocaine's short duration of actions is associated with remarkable mood swings, including depression, irritability, and paranoia. Use of certain drugs, particularly cocaine and alcohol, is associated with violence both at home and at work. Drug

seeking behavior, the selling and buying of drugs, and theft can also have a significant detrimental impact on the workplace. (pp. 175-176)

These adverse impacts on overall job performance and employee well-being provide additional support for the need for drug testing as a central component of fitness-for-duty programs.

3.2.4.3 Arguments Against Drug Testing

One concern raised by critics of drug testing is that such testing absorbs funds that could more effectively be spent in other elements of fitness-for-duty programs. Given that a limited amount of funds exist in any fitness-for-duty program, use of a major portion of those funds for drug testing means that other fitness-for-duty program areas, such as employee awareness training and employee assistance programs, may receive less funding than their potential effectiveness as FFD program elements would otherwise merit. This argument about the relative cost effectiveness of drug testing points to the need to include more than drug testing in a fitness-for-duty program rather than building a solid case against such testing. The validity of this concern is recognized in the NRC rule's requirements for a "broad-brush approach" to fitness-for-duty program development and implementation.

Perhaps the strongest arguments against workplace drug testing focus on issues involving workers' rights. In particular, drug testing programs should be concerned with wrongly accusing innocent employees of drug use due to false positives. This concern is accentuated if drug testing is improperly conducted. Rosenstock and Cullen (1987) discussed two scientific and administrative safeguards that are often omitted in private sector drug testing programs--GC/MS confirmation testing and the preservation of confidentiality in the reporting of test results. They point out that decisions are often based upon unconfirmed positive test results, especially in the case of pre-employment testing. Such a practice not only eliminates the essential confirmation testing, but also the essential MRO review of results and consideration of associated information that may provide an acceptable explanation of the results.

The literature on workplace drug testing also includes concerns about invasion of privacy issues. For example, Rosenstock and Cullen state that employers often directly or indirectly obtain information needed to interpret drug results, but that this information is unrelated to decisions regarding the employee's ability to perform his or her job. Often this information includes facts that the employer has an ethical (and perhaps legal) responsibility to keep confidential. For example, information about an employee's prescription drug use and pre-existing medical condition may need to be revealed to evaluate a drug test result. This information is disclosed, for example, when decisions are made to temporarily remove an employee from duty based upon an unconfirmed positive test result. During the confirmation process, especially during the MRO review of the test result, confidential medical information, such as the legitimate use of legal drugs, may be revealed. If the employee has been removed from duty prior to this review, the employee may feel compelled to explain to management (or co-workers) the otherwise confidential reason for the false positive result.

Rosenstock and Cullen also address ethical issues involving employees' "informed consent" and invasion of privacy. They argue that free consent to drug testing is not possible when job

security rests upon giving consent, and that drug testing is invasive. In response to public comments on the proposed FFD rule, the NRC pointed out that such concerns have lower priority in the nuclear industry due to workers' diminished expectations of privacy and the large public health and safety concerns involved:

. . . The NRC believes that, when a person accepts a job which can severely and adversely affect public health and safety, that person must also accept certain responsibilities. One of those responsibilities is providing society with assurance that he or she is always fit-for-duty. Given the trust that society must place in nuclear power plant workers, and the responsibility those workers owe to society, the intrusion of workplace drug testing into the private lives of workers is fully justified. . . . (Bush and Grimes, 1989, p. 14-11)

Bush and Grimes also stated that the important privacy issues are much more valid when no scientific and administrative safeguards have been implemented to protect employees' privacy to the degree possible, as has been done in the NRC rule. Thus, private sector employees in positions with little safety significance may well have valid concerns if they are unexpectedly required to provide a urine specimen under direct visual observation. However, a nuclear power plant worker is responsible for public safety and trust that entails a level of responsibility and diminishment of privacy. Further, the nuclear power plant worker is protected by scientific and administrative safeguards that protect against undue invasions of privacy, such as direct observation of urination when there is no reason to believe that an attempt to subvert the collection process has been made.

3.2.4.4 Summary and Conclusions

In summary, a number of valid concerns have been raised in the literature regarding the need for drug testing in the workplace. These include the questionable evidence of the current extent of the problem, the relationship between drug use/abuse and performance, the costs of testing, and the protection of workers' rights. Such concerns take on added validity when necessary scientific and administrative safeguards are not in place, a compelling safety justification is not apparent, drug use rates are minimal or lacking altogether, or when resources must be pulled from other critical fitness-for-duty program components to support drug testing. Despite these concerns, however, there is ample reason to believe that there are significant safety risks associated with illicit drug use by nuclear power plant employees and that these risks present a fitness-for-duty problem that must be addressed.

Arguments opposing drug testing fail to support the conclusion that drug testing should not be part of licensee fitness-for-duty programs. These arguments clearly show, however, that the NRC rule's many scientific and administrative safeguards designed to protect employees' rights are essential. In the absence of such safeguards, much of the opposition to drug testing in the workplace has considerable validity. Michael Walsh, formerly of NIDA and currently on the White House Council on Drug Abuse, summarized this conclusion well. Walsh stated that the problem of drug abuse is widespread in America, and companies must assume drug use will have a direct or indirect impact on their employees (Walsh, 1989). He also asserted that there

is public consensus that the workplace is an appropriate place to address drug use and abuse. The issue is not whether to test, but how to do so fairly and effectively. This conclusion seems especially applicable to a highly safety-sensitive workplace, such as a nuclear power plant. The remainder of this section is, therefore, devoted to issues pertaining to conducting tests fairly and effectively.

3.3 Effectiveness of Various Random Testing Programs

The optimal random drug testing program is the one that both maximizes detection and deterrence of substance abuse while minimizing monetary and social costs (e.g. employee morale). Many factors are included in determining which type of program will best meet these objectives. One of these factors is the distribution of users in the population to be tested. While it is easy to detect drug use by continuous users, regardless of testing program, it is difficult to detect occasional users who use drugs with short detection windows. Another important factor in determining which type of testing program is most effective is the evaluation of both the detection and deterrence effectiveness of a particular program. Detection effectiveness refers to the probability of detecting drug users in a population. Deterrence effectiveness, on the other hand, refers to the effect a testing program has in decreasing the actual use of drugs.

Statistics provided by Durbin, Murphy, Fleming, and Olson (1991) provide an estimate of the drug user distribution in the nuclear power population. Using this information, a simulation modeling approach can estimate detection effectiveness of various random testing programs. Deterrence effects, however, need to be determined empirically. Appendix C describes in detail the outcome of an analysis of the detection effects of different random testing programs using such a modeling approach and outlines a study that could determine deterrence effects.

Briefly, the study reported in Appendix C analyzed detection effectiveness of nine different testing programs (100% Standard, 100% Tailored, 100% Tailored Two Year Cycle, 25% Standard, 25% Tailored, 50% Standard, 50% Tailored, 150% Standard, 150% Tailored) using three different plausible drug user distributions (Continuous Users, Occasional Users: Long Duration Drugs; Occasional Users: Short Duration Drugs). The results of the modeling effort show the importance of the user distribution in determining the optimal random drug testing program. With a population of users composed of either Continuous Users or Occasional Users of Long Duration Drugs, the 100% Tailored Approach offers the appropriate balance of effectiveness and cost. If, however, the population is composed of Occasional Users of Short Duration Drugs, none of the approaches is particularly effective in detecting users. There may, however, be differences in deterrence effectiveness among these alternatives.

Clearly, a study of deterrence effects would be useful in thoroughly evaluating the effectiveness of the different random testing programs. Such a study could analyze the testing approaches included in the detection modeling study. Subjects would be licensee employees from nuclear plants selected from various regions such that the sample would include plants with key contextual differences (e.g., population density, proximity to an urban area, etc.). Multiple plants from a single licensee could be randomly assigned across testing approaches. Dependent and independent measures might include positive test rate and other information

derived from monthly FFD reports, as well as other indirect measures such as absenteeism rates, FFD violations, etc. Contextual information should also be gathered on each plant. Given this type of information, regression analysis would allow for determination of the deterrence effects that each of the random testing programs is producing.

In summary, further research could be done to determine such factors as the actual drug user distribution in the nuclear power population, detection rates, and the deterrence value of each of the random testing programs of interest. Until these random testing programs have been thoroughly evaluated, it is premature to recommend one testing program over another.

3.4 Alternatives to Urinalysis and Random Testing

The first question that must be addressed regarding testing effectively is an extension of the topic discussed above--is random urinalysis an essential component of drug testing in the workplace? Although the above section addressed this topic to some extent, the focus has been on drug testing in general, rather than on random urinalysis in particular. Thus, Section 3.4 completes the discussion on the need for drug testing. It begins the discussion of procedures that ensure fair and effective testing programs and provides an evaluation of the need for random urinalysis in workplace drug testing programs. This evaluation is a continuation of previous research on alternatives to random urinalysis (Barnes et al., 1988; Moore et al., 1989).

Information reviewed in the previous section indicates that testing employees for drug use is an important component of an effective nuclear industry drug testing program. Barnes et al. (1988) and Moore et al. (1989) reviewed a number of techniques that could be used to perform such testing and concluded that, while there are a number of different methods for conducting workplace drug testing, no suitable alternatives to random, unannounced urinalysis existed at that time. Although random urinalysis is an important component of a workplace drug testing program, it is also controversial. Thus, it is important to continue examining alternatives to random urinalysis to determine if any new, suitable alternatives exist, or if any previously considered alternatives have been substantially improved.

This section provides an update on three possible alternatives to urinalysis. Section 3.4.1 examines performance-based testing. Section 3.4.2 examines two possible alternative specimens for random testing--blood and hair. Though the focus of this section is on alternatives to urinalysis, each of the three alternatives is assessed in a broader context as well. Adequate assessment of these alternatives requires examining the relative strengths and weaknesses of each alternative as compared to both urinalysis in general and, more specifically, urinalysis administered in an unannounced random fashion. Also, where especially relevant, each of the three alternatives is compared with urinalysis administered on other testing occasions. Section 3.4.3 concludes this section with a summary of the findings presented here and a table (Table 3.8) that summarizes the benefits and drawbacks of a number of possible alternatives to random urinalysis. The information in Table 3.8 is drawn both from the findings presented here and from information previously reported in Barnes et al. (1988) and Moore et al. (1989).

3.4.1 Performance-Based Assessment Tests

Performance-based tests are designed to evaluate performance on psychomotor/physical and cognitive ability tasks. These types of measures are currently used by a number of state and federal agencies (Hauth, 1989). Law enforcement agencies, such as the Los Angeles Police Department, use a battery of task performance measures and physiological indicators (most notably eye gaze nystagmus) to assess whether an individual is indeed impaired in situations where the person is already suspected of driving under the influence of alcohol, drugs, or both. The Federal Aviation Administration (FAA), the National Aeronautics Space Administration (NASA) and the U. S. Armed Forces use performance assessment batteries to determine job suitability, for instance, as part of a pilot certification program. Also, computer-administered tests are available that have been designed to measure behavioral and physiological indications of impairment.

In a review of performance-based testing, Hauth et al. (1989) concluded that these measures might be a useful adjunct to urinalysis testing, if they are:

- administered when a worker tests positive for a drug(s) to determine the extent of the substance abuse problem
- used to establish a basis for for-cause referrals
- used to detect impairing conditions caused by additional drugs not included in the panel of drugs addressed in the NRC's rule
- designed to assess the effects of environmental stressors on performance (e.g., heat, noise, and noxious fumes), as well as performance degradations due to psychological fatigue or illness.

Several performance-based assessment batteries were evaluated as alternatives to random urinalysis according to the following criteria by Moore et al. (1989):

- scope
- reliability
- sensitivity
- specificity
- implementation

The most attractive feature of performance-based assessment techniques is that they assess a broader scope of impairment factors than urinalysis and alcohol testing. Thus, a performance assessment could ideally be suited as a referral measure. Results from a performance-based measure may, for example, indicate that an employee is lethargic and inattentive. An investigation by the supervisor might reveal that the employee was overcome by fumes in a confined area and should be treated immediately. A performance-based test might also identify an employee with an impairing condition caused by using a drug not on the panel of drugs tested. Thus, the broad scope of a performance-based referral to verify fitness-for-duty

concerns as an adjunct or as an addition to urinalysis testing is attractive (Kennedy, Turnage, and Osteen, 1989).

In terms of reliability, performance-based approaches reviewed in previous NRC reports demonstrated higher false negative rates and higher false positive rates than confirmed urinalysis screening results (Barnes et al., 1988; Moore et al., 1989). In addition, the establishment of reliable baseline performance levels for performance-based assessment techniques may be confounded by "learning effects" as the subjects familiarize themselves with the tests. This problem can, however, be mitigated by a using (1) a battery of tests instead of one simple test; (2) physiological measurements not susceptible to learning effects, such as eye gaze nystagmus; (3) varying the order in which behavioral tasks are administered; or, possibly (4) developing a battery of parallel tests.

Another potential problem concerning reliability is the variability in performance across subjects after ingesting a standard dose of drugs or alcohol. The Drug Recognition Expert (DRE) program, a program used by law enforcement officials to address driver impairment, attempted to minimize this variability. The DRE program is currently gaining recognition nationwide among law enforcement officials because of its broad scope and demonstrated effectiveness in evaluating drivers suspected of driving under the influence of alcohol and/or other drugs.

While in concept a DRE program could be used to evaluate individuals on a randomly selected basis, currently no studies have been performed on drivers to evaluate the ability of this program to do so. This is due to difficulty in obtaining drivers' consent to the urinalysis and breath analysis tests necessary to confirm the DRE assessment. Until such a study is conducted, there is no way to determine the false negative rate of the DRE program. It is expected that the DRE assessment would demonstrate a higher false negative rate than urinalysis because it can detect only observable degrees of drug-induced impairment. In contrast, urinalysis can detect drug metabolites long after the observable effects of the drug have worn off.

Performance-based tests have also been found to be less sensitive than urinalysis in detecting the presence of drugs. While urinalysis can detect the presence of a drug or drug metabolite in urine at low dose levels long after the immediate effects of the drug have worn off, performance-based assessment techniques rely on observable signs of the drug's effect. Thus, urinalysis has a longer "window" or period of detection of substance use.

The greater sensitivity of urinalysis is important for several reasons. First, very minimal levels of impairment, which only an extremely sensitive performance-based test would detect, might be highly relevant in certain conditions, such as an emergency (see Section 3.7.3.1 for a discussion of effects of low levels of alcohol use). Second, it is important for licensee fitness-for-duty programs to address illicit drug use because of concerns related to illicit drug use and worker reliability and trustworthiness beyond any impairment that may exist at the time of testing (see Section 3.2.3.1).

Another concern with performance-based tests is that they lack the specificity needed to accurately identify the cause of the impairment (e.g., the drug or drugs of concern in the panel

of drugs to be tested). For example, problems of fatigue or illness due to excessive noise, heat, or noxious fumes in the workplace require a much different solution than problems of fatigue or illness due to illegal drug abuse. Although some performance-based assessment techniques, such as the Drug Recognition Expert Program (DRE), accurately identify the cause of impairment among drivers suspected of being impaired, chemical testing consisting of urinalysis and a breath alcohol test is required to confirm behavioral observations or performance-based assessment test results.

Finally, in terms of implementation, there are several costs associated with implementing a performance-based assessment program. Personnel responsible for administering performance-based tests require training to be proficient in identifying substance abuse, stress, fatigue, and physical injury or illness. They should also be trained to administer standard tests and to quickly and accurately recognize an employee's fitness for duty and the cause of any existing performance problems. Further, personnel administering performance-based tests should be certified through written and applied examinations. Finally, with perhaps one or two exceptions, there are no comparable programs in the private sector, government, or military that have addressed these implementation issues in a large-scale random screening program.

At present, a number of performance-based tests, in addition to those reviewed by Barnes et al. (1988) and Moore et al. (1989), are being developed and evaluated. (See, for example, Kennedy, Turnage, and Osteen, 1989; and Kay and Horst, 1988.) Many of these may have strengths that could be applied as effective adjuncts to a random chemical testing program to ensure the fitness of specific groups or classes of workers (e.g., those suspected for-cause, or as part of a procedure to evaluate fitness prior to restoring unescorted access). For reasons outlined here, however, none of these performance-based techniques is an adequate substitute for urinalysis screening of workers.

To summarize, performance-based assessment techniques are not suitable alternatives to urinalysis in a large-scale mass drug screening program and it is unlikely that such assessment techniques will be suitable alternatives until the design, development, and application issues discussed above are addressed. In the meantime, performance-based assessment batteries offer considerable capabilities as an adjunct to licensees' fitness-for-duty programs because they can be used to detect and assess a broader range of worker fitness problems than urinalysis screening alone.

3.4.2 Alternatives to Urine as Specimens for Chemical Tests

As discussed in a previous report, urine is a poor specimen for alcohol testing (Moore et al., 1989). For most other drugs, however, urine is generally considered to be the specimen of choice. Two biological specimens sometimes proposed as alternatives to urine are hair and blood. Evidence supporting or negating the usefulness of hair and blood analysis is summarized in this section.

3.4.2.1 Hair Analysis

There are two potential advantages to using hair rather than urine as a specimen. First, obtaining hair samples may be less intrusive than collecting a urine specimen. Second, hair specimens provide the opportunity to detect drug use that occurred months prior to specimen collection rather than drug use that occurred within only a few weeks, days, or hours prior to specimen collection (Barnes et al., 1988; Moore et al., 1989).

Both of these advantages have potential significance. Given the degree to which some find urinalysis intrusive, an alternative, less intrusive testing technology is attractive. Further, the fact that hair specimens would be obtained in an observed setting would greatly diminish opportunities for subversion at the collection site, a major concern in urinalysis (see Section 3.5). The long detection window associated with hair analysis may greatly increase both detection rates and deterrent effects of drug testing. This latter advantage might be especially pronounced if hair analysis can detect low levels of use of drugs that are quickly eliminated from the body. For example, cocaine metabolites are typically eliminated from the body within about 48 hours. A worker who uses cocaine infrequently, perhaps once or twice a year, is thus at low risk of being detected through a random urinalysis program that tests workers at a rate of 100 percent per year. If hair analysis can detect such cocaine use, however, the period during which infrequent cocaine use could be detected might be extended to several days, weeks, or months, depending upon how frequently the worker's hair is cut. This lengthened detection window greatly increases the probability of detecting such drug use. Further, infrequent drug users may find the increased potential of detection daunting, and the long detection window associated with hair analysis may thus serve as a valuable deterrent.

Recent evidence indicates that a number of potential problems with hair analysis still need to be resolved before it can be used as a suitable alternative to urinalysis or, possibly, even as an adjunct to urinalysis. According to recent arguments and research evidence, hair analysis:

- may not be regarded by workers as less intrusive than urinalysis
- may not provide a better detection window than urinalysis
- lacks the established reliability of urinalysis.

There currently is no consensus in the literature that hair analysis techniques are less intrusive than urinalysis. Hair analysis is based upon the principle that drugs and/or their metabolites present in one's blood are trapped in hair as it grows. Thus, hair analysis requires samples of recently grown hair if it is to detect recent drug use. This involves shaving a small patch of hair (potentially intrusive), rather than simply snipping a few hairs (less or non-intrusive). Willette (1989) argues that these procedures might be regarded as very intrusive by some people and possibly "far more intrusive than urinalysis."

Even when specimens are obtained by shaving, hair analysis may be of only limited use in detecting very recent drug use. For example, Cone (1990) found that it takes seven to eight days from the time of drug use for opiates to appear in hair in detectable quantities (Cone obtained samples by shaving facial hair with a razor). Had the hair been cut with scissors, it would have taken even longer for the drug use to be detectable. These findings indicate that

hair analysis will not detect recent drug use, and that optimizing its ability to detect relatively recent drug use may increase its intrusive nature. Thus, hair analysis appears to be entirely inadequate for for-cause and for follow-up testing.

Another principal problem with hair analysis is that too few studies have been conducted to establish the reliability and validity of this technology. This concern was identified in previous research in support of the NRC rule (Moore et al., 1989) and remains a concern. In 1989, Willette described hair analysis as "in its infancy," and, in 1989, Cone stated:

. . . many . . . questions that have impact on the validity of hair test data . . . remain unanswered. Some individual factors which could limit interpretation are differences in hair growth rate, drug biotransformation rate, drug excretion rate, environmental contamination, hair treatments, and site of hair selection. In addition, many analytical factors become increasingly important to consider due to the unique protein matrix of hair, low drug or metabolite concentration, limited sample availability, and the accuracy and validity of the drug assay employed. (p. 1)

Both NIDA and the Food and Drug Administration (FDA) contend that, because current knowledge of the validity and reliability of hair analysis is low, prospects for it proving to be valid and reliable are not good (Holden, 1987). Holden notes that it has been impossible for anyone to independently validate the procedures currently used to prepare hair for analysis, because the methods are proprietary with patents pending. This lack of information about the reliability of hair analysis raises concerns about false positive and false negative rates intrinsic to hair analysis.

False positives due to hair analysis can appear because of passive exposure and environmental contamination (Cone, 1990). Dr. Michael Walsh, formerly of NIDA and currently on the White House Council on Drug Abuse, believes that environmental contamination of hair represents an unknown factor in results from hair analysis, and David A. Kindell of the Naval Research Laboratory has found that washing hair specimens may not remove all external contaminants (cited by Holden, 1987).

Willette (1989) states that the unknown false negative rate in hair analysis represents as great, if not greater, a concern as the false positive rate:

The major limitation of hair analysis is, what is the false negative rate? We don't have good controlled studies on how much drug must be taken to produce a positive result in hair. One marijuana cigarette probably would not be detected. Maybe one use of cocaine would not be detected. We just do not know. There is probably going to be a high false negative rate. (p. 194)

McBay (1987) described another problem with hair analysis. Although analytical methods suitable for screening tests may be adequate for testing hair, it is difficult or impossible to test hair with analytic techniques acceptable for confirmation. Drugs in the Workplace (1989) and

Willette (1989) note that it is not possible to conduct GC/MS testing on hair specimens. Some of these problems have apparently been overcome, as Cone (1990) has successfully analyzed hair specimens using GC/MS. However, Cone also noted difficulties with the analysis that resulted in reduced sensitivity over the course of a batch process. Although progress is being made in developing reliable confirmation methods, GC/MS analysis of hair specimens is far from perfected and validated at this time. Thus, if a hair specimen tests positive, a urine or blood sample must be obtained to confirm that result. It is likely that such confirmation testing will have a very high false negative rate because of different detection windows associated with these specimens. As discussed above, hair analysis can detect drug use that occurred weeks or months prior to the test, but, unlike urine and blood analysis, it may not detect very recent drug use. Thus, confirmation testing with a blood or urine specimen would result in a positive test result only if the donor used the drugs both sometime prior to several days before the hair sample was taken and within the few hours, days, or weeks prior to the test necessary for a positive urine or blood test.

3.4.2.2 Blood Analysis

Blood analysis has three potential advantages over urinalysis. First, it is theoretically possible to establish a nexus between the test results and impairment. Second, because blood specimens need to be collected directly by a qualified person, there is less opportunity for an unobserved donor to substitute specimens or tamper with a specimen than there is when a donor provides a urine specimen (McBay, 1989). Third, there is some belief that workers may find providing blood specimens to be less intrusive than providing urine specimens.

There are four potential problems associated with blood analysis that may render it an unacceptable alternative to urinalysis:

- (1) Although the magnitude of the correlation between test results and impairment may be higher for blood analysis results than for urinalysis, the nexus that can be drawn remains very limited.
- (2) Blood analysis provides for a relatively short detection window.
- (3) Blood analysis may not, in fact, be regarded by employees as less intrusive than urinalysis.
- (4) There are several risks to the donor that are unique to the collection of blood specimens, arising from the physical invasion of the donor's body.

The literature on urinalysis repeatedly stresses that it is impossible to establish any relationship between the presence of drugs and/or their metabolites in the urine and impairment (McMillan, 1990). Urine test results indicate only recent exposure to detected drugs and tell nothing about the state of the donor at the time the specimen was collected. By contrast, quantitative blood tests do reveal the quantity of the drug or drugs causing central nervous system effects at the time the specimen was collected. For most drugs of abuse however, far too little is known about the dose/effect relationship for any definitive link to be drawn between blood test results and impairment.

Experts generally agree that the current state of knowledge of drug effects does not allow for a clear nexus to be drawn between drug levels present in blood and impairment. Some experts believe that, even in cases of high drug levels, such a nexus cannot be drawn. For example, in a panel discussion of the major drugs of abuse, R. T. Jones states that, even in the case of very heavy marijuana use (sufficient to produce urinary concentrations of THC metabolites as high as 1500 ng/ml), a blood test could not be used to establish impairment (Jatlow et al., 1987). Other experts believe that, in extreme cases, concentrations of drugs in the blood could be used to establish impairment, but that these cases are so rare that they are of little practical value. For example, Richard Hawks states that:

I think if one picks a high enough level (15 ng/ml of THC in blood for instance), there would be general agreement among experts that impairment is probable. This is not a practical presumptive level on which to base legislation, however, since most positives encountered in forensic situations will be lower than this concentration due to the metabolic elimination of THC from the blood and the difficulty in getting a sample after an accident or interdiction. (McBay, 1989; p. 3)

Alcohol is the single exception to this general condition. Sufficient research on the relationship between blood alcohol concentrations and impairment exists for blood alcohol concentrations to be used to provide an acceptable, though not absolutely accurate, measure of impairment (Moore et al., 1989). Blood alcohol concentrations, for example, have been used for years in motor vehicle codes to establish a definition of impairment. More research, however, is required before a similar status is achieved in the knowledge of the pharmacokinetics of other drugs.

Like performance-based testing, blood analysis suffers from a short detection window. For performance-based testing, the duration of observable and detectable behaviors is likely to be shorter than the duration in which drugs or metabolites remain in the urine. For blood analysis, the period in which drugs or metabolites are present in the blood is likely to be shorter than that for urine.

The relative intrusiveness of blood versus urine specimen collection is a matter of opinion which may differ depending upon the particular interest being considered. Cornish (1988) points out that, from a standpoint of physical pain, blood testing is more intrusive and, from a standpoint of dignity and embarrassment, urine testing is more intrusive. Likewise, the U.S. Supreme Court has stated that it considers the procedures for collecting urine samples to create a more extensive imposition on a tested individual's privacy interests than do blood tests (Skinner v. Railway Labor Executives' Association, 1989). A number of drug testing researchers have, on the other hand, expressed serious concerns about the intrusive nature of blood testing. Willette (1989) for example, states that "... blood testing ... [is] far more intrusive than urinalysis". (p. 192)

Blood analysis also has a potential for greater intrusiveness if tests are conducted for substances other than the drugs identified in the drug testing panel. As Cornish (1988) points out:

. . . the potential scope of information the employer can obtain about an employee through blood testing is greater [than the scope of information available through urinalysis] and therefore presents a much greater risk of abuse. Unlike urine, blood specimens reveal many facts about an individual, not the least of which is their genetic structure. . . . No possible search could be considered more intrusive, or more detrimental to autonomy, dignity, and information privacy than involuntary genetic testing of the individual. (p. 49)

Blood testing also presents a greater potential for physical injury to the individual than urine testing. Blood tests create the risk of infection for all donors and prolonged bleeding among hemophiliacs. Further, recent concerns about AIDS may render blood testing highly traumatic for some people.

In summary, while blood testing does offer some advantages over urinalysis, those advantages do not outweigh its disadvantages. Relative ease of subversion prevention is one of blood testing's significant advantages over urinalysis. Another is the fact that blood testing provides a slightly better opportunity to identify the relationship between test results and probable impairment. One of blood testing's disadvantages is that it would probably result in a low detection rate. While most drugs remain in the blood for only a short time, they can be detected in the urine for much longer periods. While blood testing is not so intrusive as to be legally unacceptable, the courts and individual workers may, in fact, consider such testing to be more personally intrusive than urinalysis. Finally, blood testing creates opportunities for physical risks to subjects that are not present in urinalysis.

3.4.3 Alternatives to Urinalysis: Summary and Conclusions

This section has expanded upon and updated information presented in previous NUREG/CRs on alternatives to urinalysis as a means of ensuring the general performance goals of the NRC fitness-for-duty rule. This update reaches the same general conclusions presented in the earlier reports; that is, that no current alternatives provide the reliability of urinalysis. Specificity, sensitivity, and implementation of alternative methods are especially problematic. The general strengths and weakness of these alternative approaches have been reviewed in the previous reports and are summarized in Table 3.8. Three notes of explanation should be made about the information presented there. First, the table reviews both alternatives to urinalysis, which have been discussed here and in the previous reports (Barnes et al., 1988; Moore et al., 1989) and alternatives to testing administered in an unannounced, random manner, which has not been discussed in this section but which was addressed in the previous reports. Second, for performance-based testing, the broad scope of causes for impairment addressed by the testing is listed as a benefit. The ability of the technique to detect fitness concerns other than drug use would, however, require adequate follow-through on the detection of other possible problems. The broad scope of performance-based tests could, therefore, result in cases that are considered false referrals rather than the detection of potential problems. Third, for hair and blood analyses, potential intrusiveness is listed both as a benefit and a drawback because there is no clear consensus on whether these methods are more or less intrusive than urinalysis.

Table 3.8 Alternatives to random testing and urinalysis

Policy	Benefits	Drawbacks
Take no action	Minimal intrusiveness / invasions of privacy	Does not address problems of drugs in the workplace Provides no means to assess FFD programs
Rely upon program elements other than testing (e.g. EAPs, awareness training)	Low intrusiveness / invasion of privacy Total fitness evaluation through EAP Reduces costs of employee absenteeism, health care benefits, etc.	Low detection and deterrence Provides only minimal means of assessing FFD programs
Pre-employment / pre-access urinalysis	Detects drug use in job applicants prior to hiring	Testing is known to applicant, allows user to avoid detection Does not directly address detection or deterrence of drug use in workplace
Post-accident urinalysis	Clearly linked to on-the-job performance Relatively high legal defensibility Some deterrent effect May detect drug use that is not detected in random testing	Relatively low probability of detection Relatively low deterrent effect Does not provide for early detection Depends upon supervisors' willingness to make referrals (providing clear criteria may alleviate this drawback)

Table 3.8 (continued)

Policy	Benefits	Drawbacks
Reasonable suspicion urinalysis	<p>More proactive than post-accident testing</p> <p>Clearly linked to on-the-job performance</p> <p>May detect drug use that is not detected in random testing</p> <p>25% to 30% of tests prove to be positive (in the nuclear power industry)</p>	<p>Relatively low probability of detection</p> <p>Relatively low deterrent effects</p> <p>Does not provide for early detection. Impairment that is relatively minor can seriously degrade job performance but not be readily detectable</p> <p>Depends upon supervisors' willingness to make referrals and abilities to detect problems</p>
Performance-based testing with general fitness/impairment tests (e.g., DRE testing)	<p>Clearly linked to on-the-job performance</p> <p>May detect problems other than drug use</p>	<p>Limited detection capabilities</p> <p>Limited detection window</p> <p>Unknown deterrent effects</p> <p>Very limited ability to detect cause of impairment</p> <p>Forensic acceptability open to question</p>

Table 3.8 (continued)

Policy	Benefits	Drawbacks
Performance-based testing based upon individual base line scores	<p>Clearly linked to on-the-job performance</p> <p>May detect problems other than drug use</p> <p>May be more sensitive than general fitness / impairment tests</p>	<p>Limited detection capabilities</p> <p>Limited detection window</p> <p>Unknown deterrent effects</p> <p>Very limited ability to detect cause of impairment</p> <p>Forensic acceptability open to question</p> <p>May be more expensive or difficult to implement than performance-based testing with general fitness / impairment tests</p>
Medical screening	Total FFD evaluation	<p>Possible limited detection capabilities</p> <p>Limited detection window</p> <p>High costs</p> <p>Unknown deterrent effects</p>

Table 3.8 (continued)

Policy	Benefits	Drawbacks
Blood analysis	<p>May be less intrusive than urinalysis</p> <p>May establish better link between test results and on-the-job impairment</p> <p>Minimizes subversion problems</p>	<p>May be more intrusive than urinalysis</p> <p>Does not establish strong link between test results and on-the-job impairment</p> <p>Requires medical personnel</p> <p>May be very traumatic to some individuals</p> <p>Entails low-probability but very high-consequence risks such as uncontrollable bleeding of hemophiliacs and transmission of hepatitis and AIDS</p> <p>Relatively small detection window</p>
Hair analysis	<p>May be less intrusive than urinalysis</p> <p>Large detection window</p>	<p>May be more intrusive than urinalysis</p> <p>Does not detect very recent use</p> <p>Reliability and validity of technology highly questionable, probably not scientifically or forensically acceptable, especially confirmatory testing</p>

3.5 Subversion of the Urine Collection Process

As discussed in previous NRC reports, preventing subversion of the drug testing process is an important component of an effective workplace drug testing program (Barnes et al., 1988; Moore et al., 1989). Subversion may take place during the collection process, during on-site pre-screening, while specimens are processed for shipment to testing facilities, while they are being shipped, or after specimens are received at laboratories. The testing process can also be subverted by the alteration or distortion of testing documentation. Thus, it is important that techniques for preventing subversion are employed throughout the collection, analysis, and reporting processes. According to Warner (1989), preventing subversion during the collection process is especially important, because this point in the process provides the greatest opportunity to alter, modify, or substitute the specimen. In this context, subversion is a larger concern in urinalysis than in breath alcohol testing and in the collection of blood for testing, because the urine donor has much greater opportunity to subvert the process than does the breath or blood donor. This section, therefore, focuses on subversion issues that are the most likely to be of concern in licensees' fitness-for-duty programs--subversion during the urine collection process.

Although subversion of the testing process was addressed in previous NRC reports (Barnes et al., 1988; Moore et al., 1989), it is a topic that requires ongoing evaluation. Clark (1990) supports this need by stating that "people . . . find creative ways to get around urine screening and . . . the technology of evading drug tests will parallel the technology of detection" (p. 515).

3.5.1 Subversion: General Considerations

The problem of subversion prevention is compounded by the continuing need to minimize the intrusive nature of urine collection. Clark (1990) notes that some of the existing sophisticated techniques for preventing urine testing subversion among career drug users in treatment centers are not routinely employed in workplace drug programs because of their intrusive and offensive nature. Some of these techniques may effectively detect subversion attempts, but they clearly entail an invasion of privacy and can be interpreted as a complete disregard for human dignity.

Two measures that can be taken to counter subversion illustrate the difficulty of minimizing the personally intrusive nature of the testing process while achieving effective subversion prevention. The two measures are using pat-down searches to detect the presence of surrogate specimens and severely minimizing the time between notification of testing and the actual testing. While potentially effective as countermeasures, both may be perceived as too invasive by most nuclear power plant workers. While pat-down searches are a routine part of gaining access to protected areas, similar searches may seem more objectionable when used as part of the testing process. Similarly, having to be tested almost immediately after notification may be an effective means of, for example, keeping the persons to be tested from obtaining access to surrogate urine samples. Many employees may, however, consider such treatment to be unnecessary and demeaning.

These and other somewhat invasive procedures may well be necessary to detect that a determined drug user is providing a substitute specimen, because a relatively unsophisticated slight-of-hand is all that is necessary to fool a casual observer. According to their own admissions, drug users have successfully provided bogus specimens while under direct observation when observation protocols that were not extremely rigorous were being followed (Person & Ehrenkranz, 1988).

However, many workers, including the majority who adhere to the NRC rule or licensee policy with regard to drug use, would undoubtedly find the use of rigorous subversion detection techniques highly objectionable. The use of techniques that unduly intrude upon privacy could well undermine worker support for the drug testing program and undermine the effectiveness of the entire FFD program. Further, it is possible that the courts may rule that such practices constitute an unnecessary invasion of privacy. Perhaps, most importantly, the determined drug user may still be able to subvert the process even when rigorous collection procedures are being followed by using more extreme subversion techniques.

Given that illicit drug use itself is a high risk behavior, it is likely that users will take risks when trying to beat the system as well. If reasonably effective measures are used to prevent subversion, it can be anticipated that even drug users who are sophisticated in subversion will sooner or later take too great a risk and will be detected.

As currently written, the NRC rule appears to take an appropriate approach toward prevention of subversion. The rule requires licensees to make reasonable efforts to prevent subversion, but the measures taken are to be balanced against the need to minimize the potentially invasive and offensive nature of the process. As stated by Clark (1990), "Rational drug testing programs attempt to balance the need for accuracy of the process with the need to preserve the rights and dignity of the people tested" (p. 515). In an attempt to continue to minimize successful subversion of the collection and testing process, drug testing programs should continue to search for techniques that can successfully detect subversion without unduly increasing the intrusive or offensive nature of the testing program. The most effective ways to achieve this balance are through security of the testing site (e.g., blueing agents in the toilet water to prevent dilution of specimens) and by conducting tests on specimens that can detect attempted subversion.

3.5.2 Common Subversion Techniques

Common subversion techniques include (1) providing a surrogate sample, i.e., substituting a clean urine specimen rather than actually urinating in the collection container; (2) diluting the specimen, either by adding water to it or by consuming large quantities of fluids prior to specimen collection; and (3) adding adulterants to the specimen that are intended to produce false negative test results. The MRO Manual for federal drug testing programs identified one extreme subversion method. With sufficient advanced warning of an imminent test, a donor voids his or her bladder and uses a catheter to refill it with "clean urine."

New subversion techniques continue to be developed and, as noted by Moore et al. (1989), a drug abuser intent upon subverting urinalysis programs does not want for resources.

Information on how to beat the system is available in sources such as Hoffman's book, Steal This Urine Test (Hoffman and Silvers, 1987), and this information base is continuously updated. For example, a 1990 issue of the San Francisco Bay Guardian informed readers of a booklet on recommended subversion techniques (Clark, 1990). The laboratory that sells the booklet also sells "powdered urine" and adulterants that can be added to specimens to (allegedly) produce false negative test results for THC. The company even offers "wholesale" rates on bulk purchases of some of its products. No studies evaluating these products have been identified at this time.

A review of recent literature identifies adulterants that can be added to urine samples to produce false negative test results, including Golden Seal Tea, a commercially available herbal tea (Clark, 1990). Moore et al. (1989) provides a more extensive list of adulterations. There have also been reports of substances that can be used as substitutes for urine that will pass pH and specific gravity tests, most notably the soft drink; Diet Mountain Dew. However, it appears that a visual inspection of the specimen would typically detect such substitutions, and that the substitution of clean urine specimens remains a more significant concern than the use of non-urine substitutes. It seems likely that a sophisticated drug user, aware of common substitutes (e.g., Diet Mountain Dew), would also be able to obtain and provide a clean urine specimen.

3.5.3 Tests for Detecting Subversion

The principal tests for detecting subversion attempts have been described by Moore and his colleagues (1989). These include tests of urine temperature, specific gravity, pH, and creatinine concentration. Measures of urine temperature and pH are especially useful because these measures can be taken immediately at the collection site. Thus, if the specimen is out of bounds with regards to any of these measures, a second specimen can immediately be collected under direct observation. Thus, the tests provide an especially effective means of detecting drug users who, knowing that they are at risk of failing the test, attempt to subvert the process at the collection site. Also, the fact that donors witness these tests on the specimens they provide may have a deterrent value. Measuring creatinine concentration and specific gravity is more complicated; these tests are generally performed in a laboratory rather than at the collection site. The fact that these tests are not conducted immediately gives a drug user using subversion techniques an edge. If a drug user attempts to subvert the process through a technique that can be detected through measures of creatinine content or specific gravity, immediate use of these measures may detect the subversion and a second specimen can be collected under direct observation. The wary drug user may, however, expect to be required to provide another specimen under observation and may be prepared for the test with a more sophisticated subversion technique, such as self-catherization or temporary abstinence from drug use.

Warner (1989) examined the effectiveness of several common adulterants on RIA, EMIT, and the Abbott TDx Fluorescence polarization immunoassay and found that, depending upon the assay used and the drug(s) for which tests are conducted, several popular adulterants can cause both false-negative and false-positive results. She also found that there are simple and

reasonably effective methods of detecting these adulterants, such as temperature, pH, relative density, residue checks, and shake and sniff tests.

3.5.3.1 Tests for Specimen Temperature

One of the most effective methods of detecting a specimen substitute is by measuring the temperature of the specimen. The importance of temperature measurement is born out by recent experience in the nuclear power industry. Evidence obtained from the NRC staff indicates that there have recently been three separate incidents in which the heating of surrogate specimens has been discovered to be part of attempts to subvert the testing process (personal communication with Loren Bush, Aug. 13, 1991).

Two closely related issues that affect the usefulness of temperature measures are (1) the accepted temperature range and (2) the technique used to measure temperature. The broader the acceptable temperature range, the easier it will be for the user to provide a bogus specimen that falls within that range. Thus, measurement techniques that provide very accurate measures of urine temperature will allow for narrow temperature ranges to be used, making it more difficult to subvert the process through specimen substitution. Temperature measures can also be used to detect certain adulterants, provided that the measure assesses peak urinary temperature. Ehrenkranz reported in a New York Times article that certain adulterants, such as oxidizing agents (e.g., bleach), will raise urine temperatures (Cheslow, 1987). This rise in temperature is detectable by a thermometer that measures urine temperature at the time of voiding and then "holds" the reading of the peak temperature. A temperature reading taken a few minutes after voiding, however, would probably not detect this change, as the specimen temperature would quickly fall back into the normal temperature range.

Theoretically, a very narrow range of acceptable temperatures can be used, because freshly voided urine is a direct measure of deep-core body temperature. Urine temperature is, in fact, used clinically as an alternative to oral or rectal temperatures and, as a measure of deep-core temperature, it is in fact more constant than oral temperature.⁷ However, the width of the acceptable temperature range is clearly a function of how the urine temperature is measured. For example, if a specimen is provided in an uninsulated cup and several minutes pass between urination and temperature measurement, a relatively lower boundary must be used. Measuring the temperature with a liquid crystal thermometer attached to the outside of the collection cup will also require using a relatively low boundary as the cup will provide insulation between the urine and the thermometer.

The NIDA guidelines recommend a range of 90.5° to 99.8° F. as the normal temperature range (NIDA, 1988). Such a broad range may be appropriate if relatively imprecise or inaccurate measuring techniques are used and it is desirable to avoid false-positive subversion test results. However, it appears that, if precise techniques are used to measure urine temperature, a much narrower range could be used. Warner (1989) suggests using a much

⁷Oral temperature fluctuates more as a function of circadian rhythms and changes in peripheral temperature than does the deep-core body temperature.

more restricted range, from 96.4° to 100.4° F. Person and Ehrenkranz (1988) conducted experiments in which previously voided urine was decanted into aspirin bottles and eye-drop containers and then held in either the armpits or groins of subjects for 15 minutes. The urine was then poured into containers with FDA-approved urine thermometers attached. In all cases, the stored urine did not reach 96.0° F., the minimum temperature register on the thermometers used in the study.

Using special collection containers configured to include a chemical thermometer in the collection cup would allow for an immediate and accurate measure of peak urine temperature. Such containers would allow relatively narrow temperature ranges to be used in the specimen verification process and would increase the likelihood of detecting adulterants that raise urine temperatures. One commercially available device has a built-in disposable urinary thermometer that measures the urine temperature within 45 seconds of voiding and then holds a reading of the peak urine temperature. The thermometer is hidden inside the container where the donor cannot see it without breaking a seal on the container. The collection container is insulated so that it is difficult for a donor to heat the urine (cooling of the urine is an irrelevant issue, as the thermometer locks onto the peak urine temperature). Such a design may also make it more difficult to add adulterants to the urine, although it may also make it relatively easy to shake the container to thoroughly mix any added adulterants.

3.5.3.2 Visual Inspection

As noted in 10 CFR Part 26, it is useful for collection site personnel to visually inspect each specimen. These inspections can detect dilution from toilet water (which should contain a blue dye), any undissolved solid adulterants, any unusual properties in the specimen that result if certain adulterants are used, and the substitution of clean urine samples if the samples are more than a few days old. Although visual observation can detect obvious signs of adulteration, the efficacy of visual inspection as a means of detecting less obvious signs of subversion is questionable. Visual inspection is not always an accurate indication of tampering in less obvious cases because normal urine will range from very light yellow to dark amber or even slightly pink, and from clear to turbid depending on concentration and the relative health of the donor. A woman's menstrual cycle can change her urine color and a kidney or bladder infection can alter the clarity of a specimen. A diet high in fresh fruit consumption can cause a urine sample to be cloudy as can heavy exercise or even a major infectious process. To ensure that these visual inspections are effective, the urine should be collected in a clear container, or transferred to a clear shipping container, and the collection site personnel should be trained to know what to look for in the specimen.

Warner notes that sodium chloride (table salt) is a relatively effective adulterant, but that the quantity of salt needed to produce a false negative test result will probably leave a visible residue. Another common adulterant, bleach, can be detected, at least for the first few minutes subsequent to its addition to a sample, because it causes fizzing. If soap is added to a specimen, vigorously shaking the specimen will produce bubbles that will be more copious and longer lasting than the bubbles from normal urine; these bubbles will refract light in the rainbow pattern typical of soap bubbles (Warner, 1989). The urine may also have a cloudy appearance

(Mikklesen and Ash, 1988). Substituted clean urine specimens may be identified as suspect by particulate matter that will settle in the bottom of the cup. Urine contains a reasonably high concentration of minerals that will condense over time into visible particles. This process may also give the urine a cloudy appearance.

Warner noted that transferring the specimen from a collection container to a shipping container will make it easier to see undissolved solid adulterants and to smell certain adulterants such as alcohols and bleach. Warner also recommended using a collection cup that is relatively small. If the required amount of specimen nearly fills the container, it will be difficult to stir the urine to thoroughly dissolve adulterants. An added collection site safeguard might be to use a glass container (rather than plastic) so that if a subject attempts to stir in adulterants, the site inspector would be more likely to hear the stirring motions.

3.5.3.3 Chemical Tests

Along with temperature and visual inspection, measures of urine pH, specific gravity, and creatinine content can be used to detect possible tampering. Measures of pH can detect adulteration by basic and acidic substances such as vinegar, liquid drain cleaner, and baking soda. Measures of specific gravity can detect dilution and adulteration with salt (Warner, 1989; Mikklesen and Ash, 1988). Bleach may also be detected through such tests (Warner, 1989). Low creatinine concentrations indicate that the urine has been diluted (either subsequent to voiding or via the donor drinking large quantities of fluids). Moore et al. (1989) recommended that specimens having a specific gravity below 1.003 or a creatinine concentration below 0.2 g/l be considered suspect.

On-site measurement of the pH level or the specific gravity of specimens are both a more effective means of detection of adulteration than is visual inspections. Specific gravity is a measurement of the ratio of dissolved solids to water of urine, blood, plasma, or any like mixture. Time of day, hydration, health versus disease processes, and even diet can change specific gravity throughout the day. Normal urine specific gravity is considered to be between 1.010 to 1.030. The upper or lower normal limits can be the same as those of certain abnormalities making this measurement imprecise as an indication of overall health (Kolmer, 1944). Specific gravity can, however, give a fairly accurate indication whether a sample has been adulterated with the most common adulterants such as table salt, bleach, or detergents. These substances will quickly and unmistakably change the specific gravity of the fluid. Advantages of measuring specific gravity are: (1) specific gravity correlates well with creatinine, (2) the test is inexpensive, and (3) the test requires minimum time or personnel training.

The pH of a fluid is the ratio between its relative acidity and alkalinity (base). It is an arbitrary range from 1-14 with 1 being highly acid and 14 highly alkaline. Normal urine has a pH from 7.3 to 7.5 and averages 7.35; it is therefore slightly alkaline. Many body changes can alter urine pH but the altered ranges do not significantly vary from the normal. Measuring the pH of a collected urine sample is a quick, inexpensive test to help ensure that the specimen has not been adulterated. Most items that would be used to adulterate a sample would change the urine pH. A simple test strip can be used to note the sample pH.

Creatinine is the anhydride of creatine. Creatine is a normal alkaline constituent of urine and blood. It is a product of endogenous protein muscle metabolism and is unaffected by diet (Miller & Keane, 1972). High concentrations of creatinine can occur in at least 14 diseases/abnormalities that include a simple urinary tract infection or unusual, strenuous exercise (Kolmer, 1944). The measurement of creatinine is sufficiently complex that it is best left to the certified laboratory and trained technicians. Test strips for creatinine measurement are not readily available. Using the measurement of creatinine as an on-site determinant of urine sample adulteration is neither cost effective nor justifiable based upon the test for specific gravity. Measuring creatinine requires more sophisticated equipment and highly trained personnel. The creatinine test results give neither more information nor more accurate tampering evidence than a measurement of specific gravity.

The simplest means of measuring pH and specific gravity would be by use of a "dip stick", a paper pad on which chemically reactive reagents have been impregnated. These pads change color in response to the urine's parameters.

Unfortunately, at this time, no U.S. manufacturer markets a pad that checks only pH and specific gravity. Test market research of over 200 large hospitals (including Veteran's Hospitals and NIDA- certified laboratories) showed a special test strip dedicated to pH and specific gravity would not be marketable. Hospitals and DHHS/NIDA-certified laboratories are accustomed to routinely checking a urine sample for multiple factors. A laboratory may not want to stock, store, or handle this specialized strip because requests for testing only for pH and specific gravity are rare.

There is, however, an inexpensive way to measure specific gravity without a test strip. Using a device that floats in the sample, specific gravity can be read on a scale much as reading a thermometer. The device is not disposable and must be rinsed between tests. Although simple, potential inaccuracy due to cross-contamination between specimens renders it less than ideal.

The determination of pH can also be accomplished easily and inexpensively. There is a device into which a drop or two of urine is placed. The hand-held apparatus is then placed in front of a light where the pH is read like the scale of a thermometer. As with the device to measure specific gravity, this equipment is non-disposable and is susceptible to the perception that cross-contamination of samples may cause inaccurate results.

In summary, there are a number of techniques that can be used to subvert the urine collection and analysis process, but countermeasures exist for all of the identified techniques. The countermeasures provide evidence of subversion, which can then be used to initiate the collection of a specimen under direct observation. The major subversion techniques, the specific (EMIT) drug assays that they effect, and the countermeasures that can be used to guard against these subversion techniques are summarized in Table 3.9.

3.6 Analysis of Urine Specimens

The FFD rule requires that confirmed positive urinalysis results be determined through a three-step process. First, the licensees send all specimens to an HHS laboratory for screening tests. Second, presumptive positive tests from the HHS-certified laboratory screening testing are tested by GC/MS analysis as a confirmation test. Finally, samples deemed positive in the confirmation testing and alternative explanations provided by the person testing positive are reviewed by the MRO. Each of the three steps in this process serve important functions, and all are necessary to achieve reliable urinalysis results.

The rule also provides licensees with the option to use on-site testing as a preliminary screening test. When on-site testing is used, those specimens found to be "presumptive positive" in the on-site analysis and a sample of specimens initially testing as negative are sent to an HHS laboratory for screening and confirmation testing.

The previous literature reviews performed in support of the NRC rule have examined many technical issues associated with the analysis of urine specimens for drugs (Barnes et al., 1988; Moore et al., 1989). However, since those reviews were conducted, new developments in urinalysis screening technology have occurred. One issue that has emerged concerns the actions that can or should be taken on the basis of unconfirmed positive test results from on-site pre-screening. This section updates information on screening technologies (Section 3.6.1) and discusses the issue of on-site testing in more detail than the previous NUREG/CRs (Section 3.6.2).

Table 3.9 Subversion methods and their detection

Subversion Method	EMIT Assay Affected		Detection/Prevention Method
Sample substitution	All		Security of collection site Peak specimen temperature, pH, and specific gravity Non-analytic inspection (appearance--color, carbonation) Limiting time between notification and testing
Sample dilution	All		Security of collection site Creatinine content Specific gravity Non-analytic inspection (color)
Hydration -- drinking large quantities of fluids to dilute urine	All		Creatinine content Providing minimal advance notice of testing
Vinegar	Marijuana		pH
Salt	Amphetamines Barbiturates Cocaine	Opiates Benzodiazepines PCP	Specific gravity Non-analytic inspection (visible residue)
Oxidizing agents (bleach)	Amphetamines Barbiturates Cocaine	Opiates Marijuana	Peak specimen temperature Non-analytic inspection (odor)
Some liquid drain cleaners	Amphetamines Barbiturates Cocaine	Opiates Marijuana	Peak specimen temperature pH
Golden-Seal Tea	Marijuana		Non-analytic inspection (color)
Some soaps	Barbiturates Benzodiazepine	Marijuana PCP	Non-analytic inspection (cloudy appearance, bubbling properties)
Some eyedrops	Benzodiazepines Marijuana		Positive control assay
Bicarbonate	Opiates		pH

The format and bulk of the information in this table is based upon a table produced by Franklin Diagnostics, Inc., P.O. Box 246, Morristown, NJ 07963-0246.

Additional information in this table comes from:

Manno, J. E., (1986). Specimen collection and handling. In Hawks, R. L., and Chiang, C. N. (Eds.), Urine testing for drugs of abuse (Research Monograph 73, pp. 24-29). Washington DC: National Institute on Drug Abuse, Department of Health and Human Services.

Mikkelsen, S. L., and Ash, K. O. (1988). Adulterants causing false negatives in illicit drug testing. Clinical Chemistry, 34(11), 2333-2336.

Peterson, K. W. (1987). Employee drug screening: Issues to be resolved in implementing a program. Clinical Chemistry, 33(11), 54B-60B.

3.6.1 Overview of Urinalysis Screening Technologies

In recent years, urinalysis screening products have undergone considerable refinement and many new products have entered the marketplace. Evaluating these developments requires a clear understanding of the specific objectives of urinalysis screening (discussed in Section 3.6.1.1) as well as an understanding of the capabilities of different methodologies of testing (discussed in Section 3.6.1.2).

3.6.1.1 Purpose of Urinalysis Screening Tests

There is strong consensus in the scientific community about the specific purpose of each of the three steps in drug urinalysis--screening testing, confirmation testing, and reviewing of results by an MRO. However, some of the common terminology used to describe these steps and the results of the analyses of each step carry implications that are contrary to that consensus and that can lead to confusion about the purposes of the different steps. Specifically, the terms "presumptive positive" (used to describe positive screening test results) and "confirmation testing" imply that positive screening test results are probably true positives and need only to be confirmed to remove doubt. This implication is, however, invalid for many drugs.

The purpose of screening tests is to reliably identify specimens that are free of the drugs or drug metabolites for which the tests are conducted. That is, the purpose of screening tests is to reliably identify negative specimens. These negative specimens are then removed from the process (for the sake of cost and efficiency) and the remaining specimens receive confirmation testing to identify positive specimens. Finally, these positive test results identified through confirmation testing are reviewed by the MRO to ensure that no acceptable alternative explanation exists for the GC/MS confirmed positive result. When the urinalysis process is conducted in this manner, false positive screening test results are of trivial concern, as all such results should be determined to be negative in the confirmation testing and MRO review. The only concern with false positive screening test results is the increased cost of confirmation testing of those specimens. However, false negative screening test results are a major concern, because those positive specimens that have been screened as negative will be removed from the testing process and drug use will go undetected.

The principal purpose of screening tests, then, is to identify negative specimens as opposed to confirmation testing, which identifies (rather than confirming what is already virtually certain) positive specimens. Attempting to achieve different goals with the different steps in the process, such as attempting to minimize false positive screening test results at the expense of potentially increasing false negative results, may undermine the effectiveness of a testing program. Hawks and Chiang (1986) explains the purpose of screening tests as follows:

The principle of screening by immunoassay, a highly sensitive technique, is to minimize the possibility of false negatives. By selecting highly sensitive techniques for broad classes of drugs, however, absolute specificity is lessened such that some false-positive results may be produced from cross-reacting substances having a similar chemical structure present in the specimen. For this reason, positive results from the screening procedure should be considered

only presumptive; they must be confirmed by a second and distinctly different analytical technique. (Hawks and Chiang, 1986, p. 36)

The scientific community strongly supports the need for confirmation testing. The view expressed by Finkle (1987) on this point reflects the consensus found in the scientific literature: "Whether to confirm or not should no longer be tolerated as a debatable point. Rather, this is an absolute requirement as an integral part of a complete test" (p. 13B).

Further support for this point is found in official statements from two prominent scientific communities. The policy statement from the Toxicology Section of the American Academy of Forensic Sciences states:

Confirmation of results is essential in forensic toxicology. Positive results or toxicological screening tests, regardless of the method used, and positive toxicological analysis results obtained by immunoassay methods should either be adequately confirmed before the results are used for forensic purposes, or be clearly designated as unconfirmed results. Analysis methods used for attempted confirmation of presumptive results must be appropriately sensitive and specific or unequivocally selective for the analyte(s) in question, and must be based upon different chemical or physical principles than the initial analysis method(s). (Finkle, 1987, p. 13B)

The official consensus statement issued by the National Institute on Drug Abuse (NIDA) states that screening tests should be regarded only as a tool for identifying negative specimens:

On-site screening can reliably identify negative specimens provided appropriate safeguards are built into the procedure. These safeguards include . . . [f]orwarding under chain of custody all "presumptive positive" specimens to a certified laboratory for testing by their screening and confirmation test procedures. (U.S. Department of Health and Human Services, 1990, p. 18)

As suggested in these statements, the potential for false positive screening test results is not caused by deficiencies in a given technology, but is an inherent characteristic of the technology. Effective screening relies upon the assay being "highly sensitive . . . for broad classes of drugs," rather than on being highly specific to individual drugs, and there is a tradeoff between these two factors (Hawks and Chiang, 1986). Making an assay more specific may reduce its sensitivity. Thus, as discussed below, attempting to minimize screening test false positive rates may increase false negative rates in at least two ways. This relationship of false positive rates and false negative rates applies to changes that might be made both in the analytic technology and in its implementation.

The first potential disadvantage of making a screening test more specific is that doing so may reduce the capability of the assay to detect some drugs which it is desirable to detect. This tradeoff between sensitivity and specificity in assay technology can be seen in a recent development in amphetamine screening technologies. This development entails a change from using polyclonal antibodies in the assay, which have very low specificity, to more specific

monoclonal antibodies. The use of polyclonal antibodies can cause false positives due to the presence of a number of relatively commonly used licit drugs in the urine, including ephedrine and methylephedrine (found in many over-the-counter cold and cough medicines) and at least one substance found in some penicillin tablets (Usagawa, Nishimura, Uda, and Nakahara, 1989). Monoclonal antibodies can be expected to diminish, but not eliminate, false positive test results from sources such as these (Usagawa et al., 1989; Cody, 1990; Ruangyuttikran and Moody, 1988). The drawback of the more specific antibodies is that their use might diminish the sensitivity of the assay for methamphetamine, for which licensees are required to test, and for designer drugs that are analogs to amphetamine. Though licensees are not required to test for these analog drugs at this time, these drugs have properties similar to amphetamine, have a high potential for abuse, and should be considered as drugs for which testing may in the future be necessary or appropriate (Cody, 1990).

Ruangyuttikran and Moody (1988) found that the high-specificity RIA confirmation tests improved the detection rates of both amphetamine and methamphetamine. These researchers also state, however, that both the more specific EMIT and RIA confirmation tests decrease the detectability of some amphetamine analogs (the reduced detectability was significant but relatively minor). Cody found that the "high specificity" Abuscreen reagents do significantly reduce false positives due to licit drug use, but that they also reduce the ability of the assay to detect 3,4-methylenedioxy-amphetamine.

The cost associated with the loss of sensitivity in the amphetamine assays depends upon whether or not licensees are conducting confirmation tests for the analogs and the degree to which the analogs represent a fitness-for-duty concern. It is certainly possible that the benefits of increased specificity are worth the costs of decreased sensitivity in this case. However, this case demonstrates that increased specificity of an assay is not necessarily an improvement in the technology, per se. The potential problem described here -- that increasing the specificity of an assay for a particular drug reduces the sensitivity for other drugs -- is a significant issue in any case where the assay is used to screen for several drugs within a general class. Thus, this concern is especially relevant to assays used to detect amphetamines, opiates, barbiturates, and benzodiazepines.

The potential disadvantages of increased specificity are not limited to assays designed to detect broad classes of drugs. There can be disadvantages to increased specificity in cases where the assay is used to detect an individual drug as well. These disadvantages can be manifested through changes in the implementation of the technology as well as through changes in the technology itself. That is, implementing the technology in a manner to minimize false positive screening test results may increase false negative test results. The decisions that licensees make with regard to cutoff levels used in marijuana testing provide an example.

As explained by Moore et al. (1989), the lower limits of acceptable cutoff levels for marijuana testing may be driven by the limits of GC/MS analysis rather than by the screening test technologies. The screening assays used to detect marijuana metabolites in urine have relatively low specificity and detect a number of marijuana metabolites in addition to THC, which is the single metabolite detected in the GC/MS procedure. For this reason, the cutoff level used in the GC/MS test is generally set much lower than the cutoff level used in the screening

test. Moore et al. recommended that the confirmation cutoff level for marijuana testing not be lowered beyond 10 ng/ml, in order to ensure that positive GC/MS test results are reported with confidence:

The 10 ng/ml confirmation cutoff is sufficiently high that GC/MS positive results can be reported with confidence. As this level is only one-half the proposed screening level of 20 ng/ml, it is anticipated that some unconfirmed positives will occur if the 20 ng/ml screening cutoff level and the 10 ng/ml confirmation cutoff level are used. Occasional unconfirmed positives may also occur with the 50 ng/ml screening cutoff level; however, as the ratio of these cutoff levels is 5:1, it is expected that this will occur only infrequently. (Moore et al., 1989, p. 6-5)

Some specimens that contain sufficient quantities of marijuana metabolites to test positive at a screening cutoff level of 20 ng/ml will not have 10 ng/ml of THC in them and will not be confirmed positive. However, some specimens that have concentrations of metabolites at or slightly above 20 ng/ml may, in fact, have 10 ng/ml of THC in them and thus be confirmed positive. Thus, the use of a 20 ng/ml screening cutoff level and a 10 ng/ml confirmation cutoff level represents a conservative practice that is consistent with the goals of the NRC rule in that both false negative and false positive test results are minimized. The GC/MS level is sufficiently high to prevent false positive results, and the screening level is sufficiently low to ensure that there is a very high probability that any specimen containing sufficient THC to be deemed positive in the confirmation test will be sent to the laboratory for confirmation testing. This practice is acceptable, however, only if the original intended purposes of screening and confirmation testing are preserved; that is, if the purpose of the screening test is to minimize false negative test results, and the purpose of confirmatory testing is to identify positive specimens. The disadvantage of using this relatively low cutoff level is that the licensee will have to pay for some confirmation tests that do not detect drug use. However, if the purpose of the screening test is taken to be the minimizing of false positives, as it must be if actions are to be taken based upon unconfirmed positive screening test results, then this practice would be unacceptable, as it would result in a relatively high (screening test) false positive rate.

These cases of amphetamine and marijuana testing indicate why, in part, the scientific literature on drug testing consistently states that screening tests should be used exclusively to minimize false negative results. The practice of using an immunoassay test to screen and then confirm presumptive positive results provides a cost-effective means of ensuring both low false negative and low false positive rates. While some improvements in the screening technology may lower false positive screening test rates without negative consequences, other "improvements," either in the technology or in its implementation, may lower false positive rates at the expense of raising false negative rates.

Thus, optimizing the ability of the screening test to eliminate false negative results and relying upon GC/MS testing to ensure against false positive test results appear to be essential. Further, taking actions based upon unconfirmed positive screening test results appears to be in conflict with this approach, because such practices will encourage attempts to optimize the ability of the screening test to minimize false positive test results at the expense of it minimizing

false negative test results. Of course, a review of all true positive test results by an MRO is also essential (see Barnes et al., 1988; Moore et al., 1989).

3.6.1.2 Urinalysis Screening Methodologies

Workplace drug screening should be performed using an immunoassay that meets the requirements of the Food and Drug Administration (FDA) for commercial distribution. There are four basic types of immunoassay available that meet these requirements:

- Enzyme immunoassay (EIA), which uses a protein enzyme to produce a chemical reaction
- Radioimmunoassay (RIA), which uses a radioactive labeled drug
- Fluorescence polarization immunoassay (FPIA) processes
- Antigen-antibody agglutination (AGAB) processes.

Utilities and testing laboratories have access to a significant number and variety of suppliers, test kits, and testing processes. Therefore, the number of drug screening options available to a licensee or testing laboratory is quite large. A test must, however, meet four factors to be acceptable:

- Sensitivity--the ability to reliably detect low concentrations
- Specificity--the ability to identify a single chemical component in a mixture of chemicals and biological materials
- Adaptability to automation
- Cost.

Two immunoassays, radioimmunoassay (RIAs) and enzyme immunoassay (EIAs), are the most common and most widely accepted approaches to conducting workplace urinalysis screening and pre-screening. Both of these immunoassays are based on the principle of competition between labeled and unlabeled antigens (drug or drug metabolites) for binding sites on a specific antibody. The two technologies differ in how the antigens are labeled. In RIAs, the antigens are labeled with a radioactive marker. In EIAs, an enzyme is used as the marker (Hawks and Chiang, 1986).

In reviews of these technologies, Barnes et al. (1988) and Moore et al. (1989) found that both technologies are perfectly adequate for workplace urinalysis screening programs, and that laboratory confirmation testing using gas chromatography/mass spectrometry is essential regardless of which technology is used.

These basic immunoassays can be used in combination with "confirmation kits" to reduce the number of false positives for amphetamine caused by an over-the-counter amphetamine or reactions with other substances. Two types of "confirmation kits" are available, polyclonal and monoclonal kits. The difference between the two is that the polyclonal kit does not reduce the number of false positives as much as the monoclonal. This is because the polyclonal does not prevent interaction with other substances, such as methylphenidrine and ephedrine. The monoclonal kit does not react with these substances and results in fewer false positives than the polyclonal kit. The monoclonal antibodies may, however, also reduce the ability of the assay to detect amphetamine analogs (designer drugs) that have high abuse potential.

The possible combinations of immunoassays, confirmation kits, and instruments are quite large, making it difficult to assess the "best" alternative. Further, some apparent advantages of one approach over another may be of limited value. For example, as discussed in Section 3.6.2, the sensitivity of immunoassays for detecting marijuana metabolites has reached the level where the limitations of GC/MS confirmation testing are becoming the limiting factor for how low a cutoff level is practical for screening tests. Thus, a revolutionary new screening technology that could support cutoff levels substantially lower than the current technologies would have relatively little added value.

No single technological approach is apt to be best in all settings, as there will likely be tradeoffs between technologies. One such tradeoff, discussed in more detail in Section 3.6.2, is between the sensitivity and the specificity of the technology used. Improvements in specificity often entail losses in sensitivity. Numerous other tradeoffs exist as well. For example, technology "A" may be more sensitive to drug "X" than technology "B", but may be more vulnerable to false negative results for all (or most) drugs as a consequence of adulteration of specimens. Thus, if a licensee believes that abuse of drug X is especially pronounced in its region, and that adulteration of specimens and other process subversion techniques are a minor concern, then the licensee may choose to use technology A. By contrast, another licensee may be located in a region where the prevalence of drug X is low but has reason to believe that drug-using workers are attempting to subvert the testing process by adulterating specimens. This licensee should probably choose technology B.

Due to complexities such as these, some experts believe that attempting to determine the best technology for screening is a futile effort. For example, in response to a question addressed towards that end, Dr. Bryan Finkle (1987) states:

. . . it's neither appropriate nor necessary for us to compare companies and advocate or defend their commercial products one way or the other. What is more important, in terms of specific approaches, is their sensitivity and specificity, which are not all the same. It depends upon the particular drug analytes involved, under what circumstances, and how sensitive and specific a method is needed for a particular drug.

This discussion should not be interpreted to mean that licensees and laboratories should merely select an FDA-approved kit at random. The technological approaches do have significantly different strengths and weaknesses that should be evaluated critically in light of

licensee needs. There is a large body of literature that can be used to inform such decisions. Urinalysis technology has improved, and continues to do so, and licensees should carefully consider the equipment and techniques that best meet their operational settings.

3.6.2 On-Site Screening and Taking Actions Based Upon Unconfirmed Positive Screening Test Results

The federal workplace drug testing program and drug testing programs in commercial enterprises governed by federal bodies (e.g., the Department of Transportation and the NRC) are required to follow the three-stage process discussed earlier. Screening tests are desirable because their use greatly decreases the cost of drug testing. Screening tests eliminate the need for the more expensive GC/MS testing for about 97 percent of all specimens. Because screening tests are not totally reliable, however, screened positive test results must be confirmed with GC/MS testing. Further, because GC/MS testing often cannot distinguish illicit drug use from licit use of medications, a final MRO evaluation of the test results is critical. There are, however, reasons to believe that it may be advantageous to modify this approach by taking at least some actions based upon unconfirmed positive screening test results.

The laudable objective of protecting workers' individual rights by using the three-stage testing process is not without potential costs. Specifically, taking no action until a confirmation test is evaluated by the MRO may create an avoidable risk to public health and safety in that a worker who may be impaired by drugs, as indicated by the screening test, is not immediately removed from safety-sensitive duties. Thus, while taking action based upon a presumptive positive screening test may infringe upon individual rights, taking no action may threaten the public's health and safety. This conflict suggests the need to consider whether it may be possible and advantageous to take some course of action based upon presumptive positive screening tests. For example, a worker might be removed from safety-sensitive work or denied unescorted access pending the results of a confirmation test and MRO evaluation of the test results.

Balancing individual rights against public safety in this context entails considerations of both the consequences and probability of risks involved. Four factors can be evaluated in making a judgment about taking action to temporarily remove a worker from safety-sensitive duties based upon screening test results:

1. What is the magnitude of the potential consequences to the public if no action is taken?
2. What are the probabilities of the potential consequences to the public occurring if no action is taken?
3. What is the magnitude of the potential consequences to the individual if action is taken?
4. What are the probabilities or the potential consequences to the individual if action is taken?

In addition to balancing public health and safety against individual workers' rights, a second set of issues must be considered when evaluating whether actions should be taken based upon unconfirmed screening test results. These issues involve questions of how taking actions and

not taking actions impact the effectiveness of the fitness-for-duty program. This section examines these issues. Section 3.6.2.1 discusses the public health and safety implications of not taking action based upon presumptive positive test results, Section 3.6.2.2 discusses how taking such actions may affect workers' rights, and Section 3.6.2.3 discusses the implications of taking actions may have on the effectiveness of a fitness-for-duty program. Section 3.6.2.4 summarizes the main points of this discussion.

3.6.2.1 Public Health and Safety

If no action is taken based upon an unconfirmed positive test result, the magnitude of the worst case potential consequence to the public is high. The worker who has tested positive on a screening test may be impaired on duty as a result of drug use and thus be unable to perform safety-sensitive duties in a trustworthy and reliable manner. This impairment could, in turn, lead to an accident with grave consequences to public health and safety. The consequences of an accident in a nuclear power plant are sufficiently substantial to justify taking very serious steps to avoid such accidents. In fact, in at least one case where the potential consequences of on-duty impairment were much less significant, a Federal District Court ruled that the consequences were severe enough to justify taking actions based upon a positive screening test result. In that case, which involved a school bus driver who was removed from duty on the basis of a positive screening drug test, the court stated:

Recognizing the public's vital interest in the safety of school children, the necessity for a hearing before termination need not preclude temporary reassignment or even suspension, pending confirmation of a positive EMIT test and a hearing. Such reassignment or suspension is not precluded provided that the hearing is held and the issue resolved promptly, and, if plaintiff survives the confirmation test and the hearing, [he or] she is fairly compensated for any loss incurred on account of the reassignment or suspension. (Jones v. McKenzie, 1986, p. 1507)

The public's interest in ensuring that a nuclear power plant is safe is no doubt at least as, and probably more, pronounced than its interest in ensuring the safety of children riding on a school bus. In fact, an opinion expressed in a Supreme Court case dealing with a different issue than workplace drug testing suggests that the consequences of a disastrous accident in a nuclear power plant might be so grave that this factor alone could be used in setting standards of balancing individual and public rights. In a dissenting opinion in the case, a justice cited the secured areas of a nuclear power plant as a prime example of a setting where liberties with individual rights could be taken due to overriding concerns about public rights. The justice stated that worker impairment in such a setting might "produce such catastrophic social harm that no risk whatever is tolerable." (National Treasury Employees Union v. Von Raab, 1989, p. 1400)

The standard of "no risk whatever," however laudable, is somewhat meaningless for two reasons. First, minimizing risks associated with the human factor within systems as complex as nuclear power plants is itself extremely complex, and many actions that remove risks in one way may add risks in another. This problem may well be a factor to be considered in this case,

and is discussed further in Section 3.6.2.3. The second and more basic problem with the "no risk whatever" standard is that it is simply unattainable. Regardless of what actions are taken to promote the safety of nuclear power plants (perhaps short of decommissioning all plants), some additional actions could be taken to further minimize the risk of accidents that pose a threat to public health and safety. Thus, the principle of removal of all risk is an unattainable and imperfect goal.

Current practices in nuclear power plants suggest that allowing a potentially impaired worker to remain on duty is not regarded as a totally unacceptable risk. There are a number of measures that could be taken by licensees to increase the probability that workers who use illicit drugs are removed from duty as soon as possible. For example, with a testing rate of 100 percent of the workforce per year, it is likely that some workers who abuse drugs will remain undetected for considerable lengths of time before they are tested on an occasion when they have detectable quantities of drugs/metabolites in their urine above the cutoff level. The decision to test at any rate less than 100 percent every two days is based upon an implicit recognition that the risk of allowing workers who use illicit drugs to remain on duty must be balanced against the financial cost and personal impact of testing.

In a case involving toxic waste standards (benzene), the Supreme Court acknowledged the limitations of the unrealistic "risk-free" standard. On rendering their opinion the justices stated:

. . . the Secretary must make a finding that the workplaces in question are not safe. But "safe" is not equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm. (100 S. Ct. 287, cited in Tietenberg, 1988, p. 450)

In a concurring opinion, Justice Powell went further:

. . . the statute also requires the agency to determine that the economic effects of its standard bear a reasonable relationship to the expected benefits. (100 S. Ct. 287, cited in Tietenberg, 1988, p. 451)

The principles currently guiding NRC requirements regarding licensee testing practices and stated by the Supreme Court (albeit in a different context) appear the only logical choices available. Fitness-for-duty programs cannot eliminate all risk of impairment, and the value of incrementally increasing safety must be balanced against the cost of doing so. Although there may well be many unknowns in assessing the costs and benefits of specific aspects of fitness-for-duty policies, it is not impossible to ensure that the costs "bear a reasonable relationship to the expected benefits." The costs to be considered, however, are not exclusively monetary costs. In the case of taking action based upon an unconfirmed screening test result, the infringement of individual rights should be considered among the costs.

Although behavioral observation is not adequate to detect impairment in all cases, it adds to the likelihood of removal of obviously impaired individuals. Perhaps the most basic factor that lowers the risk to the public is the fact that the screening tests are not totally reliable. Because of this lack of reliability, a positive screening test for a broad family of drugs may, in fact,

contain no metabolites whatever of the specific drug of interest within that family. In this case, the test provides no more indication of a possible fitness concern than does a screening test that is determined to be negative because there are no indications of any drug use whatsoever. Even if the test result is a true positive, it does not establish that impairment exists or will exist between the time of the screening test analysis and the confirmation test analysis and review. Urinalysis tests for drugs detect only recent drug use, they do not detect impairment. While the presence of a true positive test result may well indicate an increased probability of future on-duty impairment, it does not automatically establish that such impairment will occur. Given that the individual in question will be on duty for only a short period of time between the screening test in the HHS-certified laboratory and the confirmation test, the probability of on-duty impairment being prevented by removing the worker from duty may be relatively low. There is also a real, but difficult to quantify, concern that an individual who disobeys society's laws by using illicit substances will be less reliable in following strict procedures in emergency conditions or in responding appropriately to unforeseen emergency circumstances.

Even if on-duty impairment does exist between the screening test and the time of the confirmation test and its review, there should be additional measures in place to ensure that this impairment does not lead to disastrous consequences. One such measure is the licensee's behavioral observation program. In some cases, an effective behavioral observation effort may detect the impairment and the worker will be removed from duty based upon individualized articulable evidence of a fitness-for-duty concern. Licensees' routine examination of their employees' finished work, at least on a sample basis, is another measure that may detect the results of impaired job performance. Random screening should not be relied upon to remove impaired workers. The primary purposes of random testing are to deter illicit drug use and to detect it before it leads to on-duty impairment. Behavioral observation should probably be regarded as the primary method of detecting significant physical impairment.

In summary, when evaluating the cost of not taking actions based upon presumptive positive screening test results, it appears that the magnitude of potential harm to the public is very high, but the probability of such harm appears to be relatively low. The high magnitude of the potential harm certainly warrants consideration, but does not appear to be in and of itself sufficient justification for taking action based upon presumptive positive test results.

3.6.2.2 Worker Rights

If a worker is to be temporarily removed from duty based upon the results of an unconfirmed positive test result, the potential consequences could be very severe, and the probability of the worker suffering severe consequences is moderately high. This is true even if only the most minimal actions necessary to minimize risk are taken along with reasonable precautions to protect innocent workers from harm. Specifically, it is assumed here that the worker would simply be removed from safety-sensitive duties or denied unescorted access pending confirmation results and that reasonable efforts would be made to protect the worker's reputation. Clearly the worker would suffer more grave consequences if less sensitive actions were taken (e.g., suspension of the worker without pay and allowing there to be wide knowledge of the reason for his or her absence).

A worker temporarily removed from duty or denied access due to an unconfirmed positive screening test may suffer unjustified, yet substantially negative consequences. One such consequence could be that the worker's reputation among co-workers (including peers, superiors, and subordinates) might be harmed if information on the drug test is disclosed to (or inferred by) others. Legal precedents on slander (oral defamation) and libel (written defamation) demonstrate that allegations of illegal drug use, whether explicit or implicit, can cause severe damage to a person's reputation. Such allegations are considered legally defamatory for two reasons. First, the allegations indicate illegal behavior. Second, the allegations are derogatory statements about the person's personal habits and characteristics.

The courts have consistently recognized that both allegations of illegal acts, in general, and illegal drug use, in particular, can constitute serious acts of libel and slander. According to Pember:

Probably the category of words responsible more than any other for the greatest number of libel suits pertains to crime and criminal acts. Any imputation that a man or woman has done something illegal--from murder to jaywalking--is libelous. (Pember, 1984, p. 114)

Pember also discusses how derogatory statements about a person's personal habits and characteristics can be defamatory:

Much of a person's reputation is concerned with his personal habits. Is he honest, ethical and kind? . . . does she use dope? Does he smoke pot? . . . She drinks too much, she is a drunkard, she is always potted or smashed, she is an alcoholic, she is a member of Alcoholics Anonymous, she is on the juice, she was arrested for drunken driving, all of these charges are libelous. The same is true of statements regarding the use of drugs and marijuana. (Pember, 1984, p. 116)

Risk of defamation does not necessarily end when, subsequent to the confirmation test, the worker is returned to normal duties. Some may believe that the positive screening test was correct and that the negative report on the confirmation test was in error (e.g., "He probably dodged a bullet by having just enough dope in his urine to fail the screening test but not enough to fail the confirmation test," or "I bet he got off on the poppy seed defense").

In addition to concerns of defamation, taking any action against a worker as a result of unconfirmed positive test results entails closely related risks of invasion of privacy. Taking any action based upon presumptive positive test results creates opportunities for confidential medical information to be disclosed. The grounds upon which an MRO may deem a positive test as negative often concerns confidential medical information. The test result may, for example, be caused by the worker's prescribed use of licit medication. Regardless of whether or not the actions taken on the basis of the presumptive positive test actually damaged the worker's reputation, either the worker may believe that such damage occurred (or is likely to occur) and feel inclined to justify why the presumptive positive test occurred. In so doing, confidential medical information, such as information about the worker's medical history or the

worker's use of medications, may be revealed. Placing the worker in a position where he or she feels obligated to choose between a tarnished reputation or the publicizing of confidential information is problematic.

It is difficult to keep the reason for a worker's change in routine confidential for the time necessary for a specimen to undergo GC/MS confirmation testing. At a minimum, the supervisor who releases the worker for drug testing will know, or certainly be able to easily infer, what has occurred. Further, it is likely that a change such as removal from duty or denial of access will be conspicuous. Even if co-workers do not assume that the change is due to a drug test result, they are likely to notice that something is going on and believe that the worker in question did something to warrant the apparent sanctions/discipline. Given that the change in the worker's routine will last for several days, there will be considerable time for speculation to circulate through the company "rumor mill" before a negative result of a confirmation test or the MRO evaluation restores the normal routine.

Finally, requiring an innocent worker to wait for a week or 10 days for a confirmation test result may be extremely stressful to the worker. The consequences of a test result that is inaccurately positive not being overturned through the GC/MS confirmation test and the MRO review can be extremely severe. Also, even if the worker's reputation is not significantly damaged, upon returning to duty the worker has no way of knowing whether management and co-workers have disregarded the preliminary results. Thus, the worker may be subject to continued stress and may feel shunned or distrusted by co-workers or managers.

The probability of at least some if not all of such negative consequences occurring is high. In assessing the probabilities of such consequences occurring, two factors must be considered. First, what is the probability that a positive screening test will be caused either by ingestion of a legitimate substance or by a technical error in the testing process? Second, if a screening test is in fact falsely positive, what are the probabilities of those negative consequences occurring?

The limited available data indicate that, for the five drug types in the NRC panel considered collectively, only a relatively low rate of presumptive positive results from on-site screening will ultimately be declared positive by MROs. A survey of 10 licensee on-site testing programs revealed that only 30.1 percent of all of those licensees' on-site presumptive positive test results during 1990 were ultimately confirmed positive both by GC/MS confirmatory testing and, subsequently, by an MRO. The results for testing for particular drugs varied widely, however. Presumptive positives for cocaine were ultimately declared positive by an MRO 89.7 percent of the time. At 62.9 percent, presumptive positives for THC were the next most likely to be declared positive by an MRO. The results for amphetamines, PCP, and opiates were 5.1 percent, 3.5 percent, and 2.0 percent, respectively. (See Appendix B for a detailed discussion of this survey.) These data would suggest that, if employment actions are taken based only upon presumptive positive test results, a high percentage of such actions would ultimately be found to be unjustified for all drugs other than cocaine. And even in the case of cocaine, it is questionable whether having roughly 90 percent of presumptive positives being declared positive by MROs would support taking action based upon the presumptive positive tests for that drug.

The data from the survey discussed above may not appear to be consistent with the far lower false positive test rates advertised by some assay vendors. However, these findings are probably representative of how the available screening technologies can be expected to perform in the real world. Quite simply, the "false positive" rate for a screening technology is not a valid measure of the probability that a given positive screening test result will be false. Assessing this probability requires consideration of both the accuracy of the testing technology and the prevalence of use of the drug in question in the tested population.⁸ A simple example illustrates how considering only the false positive rate of the technology grossly distorts this probability assessment. Consider the case where the technology has historically demonstrated a false positive rate of one in 10,000 and one person out of every 10,000 in the tested population frequently uses the drug.⁹ Under this scenario, one would expect the screening testing to lead to two positive test results for every 10,000 tests. One of these results would be the one in 10,000 false screening positive and the other would be the detected drug user. Thus, the probability of an unconfirmed screening test result being positive is not 0.0001 (one in 10,000) but 0.5 (one in two); half of the unconfirmed positive screening tests would be false positives.

Because the prevalence of drug use in the nuclear industry workforce appears to be low, the screening technology would have to be extraordinarily reliable for the probability of false positive test results to be acceptably low. Consider, for example, a hypothetical situation in which the risk of taking employment action based on unconfirmed positive test results is considered acceptable only if there is at least 90 percent certainty that the screening test results will be confirmed. One way of judging the feasibility of actually achieving that goal is to consider the first-year fitness-for-duty performance data regarding testing for PCP. In the case of PCP, the first-year fitness-for-duty performance data indicate that there were, among all licensees, eight confirmed positive tests for PCP out of a total of 278,209 tests. Given these first-year results, the false positive rate for the screening technology would have to be only one false positive in approximately 309,000 screening tests to achieve the 90 percent goal. That this goal is not achievable in the case of testing for PCP is borne out by data from the survey of 10 licensee on-site testing programs described in Appendix B. That survey found that only 3 of 83 presumptive positives for PCP were confirmed by GC/MS testing. These results clearly indicate that the 90 percent standard could not be achieved, at least for PCP testing.

The effect of drug use rates on the probability of a presumptive positive screening test result being false also has implications on how this probability will change through time. If fitness-for-duty programs are effective at reducing drug use rates, the probability of individual positive

⁸ The probability of a false positive rate is also a function of the prevalence of possible causes of false positive results relative to the prevalence of the (target) drug use. For example, the presence of the legal drug dextromethorphan in urine can lead to false positive PCP test results. If many workers use dextromethorphan and few use PCP, a very high false positive rate for PCP can be expected.

⁹ This scenario is somewhat over-simplified for clarity of the example because there is a high probability that the one person in 10,000 who uses the drug would not be detected. Thus, it would be more accurate to describe this scenario by specifying that the drug use in the population was such that it would be expected that one person would be tested who had sufficient quantities of the drug/metabolites in his or her urine to be detected.

screening results being false will increase. Ultimately, if all use of a given drug is stopped, then all positive screening test results will be false. Thus, hopefully, the percentages of positive screening test results that are false will increase over time (due to lower prevalence rates) rather than decrease (due to improved technology).

In summary, taking action based upon unconfirmed positive screening tests could cause serious damage to a worker's reputation. There is a high probability that some workers who do not use drugs would be subjected to such risks, and a probability that damage to some workers would occur in such cases.

3.6.2.3 Effects of Taking Actions Based on Unconfirmed Positive Screening Test Results on Fitness-for-Duty Programs

There are two ways in which taking actions based upon unconfirmed positive screening test results could undermine the effectiveness of licensees' fitness-for-duty programs. First, because the probability of false positive test results is high for many drugs, licensees who take action based on unconfirmed positive test results may feel compelled to minimize false positive screening test results so that only workers with true positives are subjected to the risks. Second, taking actions based on unconfirmed positive screening tests may send messages to workers that undermine the effectiveness of the program.

In the interest of protecting workers' individual rights, it appears appropriate to attempt to minimize false positive screening test results if actions are to be taken based on positive screening test results. However, such a practice is antithetical to the basic purpose of screening tests if it also results in a higher false negative rate. Many of the practices that could be taken to minimize false positive screening test results will, in fact, increase the false negative rate (e.g., using highly specific analytic methods and the highest screening cutoff level permissible). Thus, it appears likely that, if licensees take actions based on unconfirmed screening test results, they will be encouraged to also take actions that raise the false negative rate. It should be noted that every false negative test result means that a drug-using worker has escaped detection and will continue to pose a potential threat to public health and safety until he or she either leaves the workforce or is identified as a drug user through some other means (e.g., behavioral observation or a subsequent random test). In contrast, the risk associated with not taking action based on a presumptive positive result only entails allowing possible drug users remaining on duty for a few days between the time of the screening test and the completion of the testing process.

Taking actions based on unconfirmed positive screening tests may send two very inappropriate messages to workers. First, workers who do not use illicit drugs may believe that they will suffer as a result of the program when they see that workers who do not use illicit drugs are periodically removed from duty. This message is undesirable because it may undermine worker support for the program. Second, if actions are taken that raise false negative rates, workers who use illicit drugs and are not detected may receive the message that they are immune to detection. Such a message is obviously inconsistent with the objective of deterring drug use. In addition, both messages will work to undermine the credibility of the program on

the part of all workers. Thus, a policy of taking actions based upon unconfirmed positives may send the wrong messages to both those workers who do not use illicit drugs and those who do.

3.6.2.4 Summary

Although the potential negative consequences to the public of taking no action based upon an unconfirmed positive screening test result are substantial, the probability of significant consequences may be relatively low for a number of reasons. The current scientific approach to drug urinalysis is based on the principle that screening tests be used to identify negative specimens, and that highly specific confirmatory tests are necessary to determine true positive results pending MRO confirmation. Attempts to modify this approach either in the screening technology or its implementation may produce detection rates that are less than optimal. Taking actions based upon presumptive positive screening tests may lower an already relatively low probability of severe harm to public health and safety. However, this policy may require actions that raise false negative rates, which may reduce both detection rates and deterrence. In addition to legal and ethical issues associated with workers' individual rights, any perceived harm to innocent workers could undermine worker support for a fitness-for-duty program.

3.7 Testing for Specific Drugs

In addition to general issues concerning the fairness and effectiveness of workplace drug-testing programs, there are a number of issues that are unique to specific drugs or classes of drugs. This section examines those issues for drugs included in the NRC rule drug panel and examines other types of drugs that might be considered for inclusion in the panel. This discussion also updates information presented in previous NRC reports (Barnes et al., 1988; Moore et al., 1989) and expands upon the more general discussions presented earlier in this report. Section 3.7.1 discusses the drugs for which urinalysis testing is required by Section 2.1A of Appendix A of 10CFR Part 26 (excluding alcohol). Section 3.7.2 discusses additional drugs for which testing is not currently required under the rule, but which may be advantageous for licensees to include in their drug testing panels. Section 3.7.3 presents new evidence for alcohol testing procedures and findings.

Before examining recent data regarding the specific drugs in the NRC drug panel, it would be useful to revisit the basic rationale for testing for any particular drug. A drug should be included in a licensee's testing panel if (1) it represents a potential fitness-for-duty concern--that is, its use may cause on-the-job impairment and/or indicates lack of reliability and trustworthiness; and (2) there is evidence that the drug is used by nuclear power plant workers. While a reliable testing technology for any particular drug obviously must be available before that drug is put in the testing panel, the existence of such a technology should not be used as a reason for testing. Instead, existence of a reliable testing technology should be considered an enabling rather than a driving factor in determining whether to include a particular drug in a testing panel. It is inappropriate to test for a drug simply because an inexpensive test exists. Jatlow et al. (1987) found that some industries plan their drug testing panels around available testing technologies and end up testing for whatever the commercial laboratories offer. This practice may result in testing for additional drugs without a good rationale. For this reason the NRC

should be skeptical when considering the drugs being tested in other industries as a basis for adding drugs to the panel.

3.7.1 Drugs for Which Testing Is Required

The NRC fitness-for-duty rule requires licensees to conduct testing for all of the drugs included in the HHS federal drug testing guidelines--marijuana, cocaine, opiates, amphetamines, and phencyclidine (PCP). Licensee experience indicates that all of these drugs are, or have been, used by nuclear power plant workers covered by the rule (Durbin et al., 1991). The rationale for testing for these drugs has been discussed in previous reports. This section provides new supporting evidence for testing.

3.7.1.1 Marijuana

A summary of licensee data on fitness-for-duty program performance indicates that marijuana is a major concern (Durbin et al., 1991). Confirmed positive test results for marijuana accounted for 47.4 percent of all confirmed positive test results (1,153 out of a total of 2,433). This number exceeded all other drugs by a wide margin (cocaine, the second most often detected drug, accounted for 29 percent of the test results). In part, the high percentage of marijuana positives may be attributed to the relatively long detection period for this drug. Nevertheless, these findings clearly show that marijuana is a major drug of use among those few nuclear power plant workers who use illicit drugs (Durbin et al., 1991).

Because of this preponderance of marijuana positive test results, it may be advantageous for the NRC to lower the cutoff levels for marijuana. The current HHS guidelines and NRC rule cutoff levels are 100 ng/ml for screening and 15 ng/ml for confirmation. Moore et al. concluded in 1989 that the then current technology could support cutoff levels of 50 ng/ml for screening tests and 10 ng/ml for confirmation testing. They also found that the technology might be capable of supporting lower levels if adequate scientific and administrative safeguards are used.

Based on fitness-for-duty program performance data, it appears that lowering marijuana cutoff levels may result in much higher rates of detection. Initial data from licensee semi-annual fitness-for-duty performance reports showed that licensees using lower cutoff levels for marijuana tests had higher detection rates. Detection rates at the different cutoff levels were .31 percent at 100 ng/ml compared to a rate of .45 percent at 50 ng/ml and .70 percent at 20 ng/ml (Durbin et al., 1991). Thus, licensees with the lowest cutoff levels (20 ng/ml) reported detection rates over two times higher than licensees using the 100 ng/ml cutoff level.

A recent NIDA consensus report recommended that marijuana screening cutoff levels be lowered to 50 ng/ml, while the confirmation cutoff level remain at 15 ng/ml (U.S. Department of Health and Human Services, 1990). That report, however, recommended that the cutoff levels should not be changed until "a careful laboratory evaluation of the recommended changes has been completed" (p. 27).

3.7.1.2 Cocaine

Licensee data also indicated that cocaine use is a concern in the nuclear power industry. Cocaine accounted for 29 percent of all confirmed positive drug tests (706 out of a total of 2,433). Given that cocaine can be detected only for a short period of time subsequent to its use, this figure may underestimate the actual use rate. Detection rates varied by region, with cocaine being the most frequently detected drug in Region 1, accounting for 38 percent of the positive test results (as compared to 37 percent for marijuana). These figures suggest that taking actions to improve the detection and deterrence of cocaine use among nuclear power plant workers should be a high priority.

Although less so than for marijuana, using lower cutoff levels may increase detection of cocaine use. Such a change would add a few hours to the length of time during which cocaine is detectable. A recent NIDA consensus report has recommended lowering cutoff levels for cocaine to 200 ng/ml for screening tests and 100 ng/ml for confirmation tests (HHS, 1990). The report also recommended, however, that the cutoff levels should not be changed until "a careful laboratory evaluation of the recommended changes has been completed" (p. 27).

There is also useful new information regarding follow-up testing for cocaine use. Previous research had indicated that all detectable traces of benzoylecgonine, the metabolite of cocaine detected in urine tests, are eliminated within 72 hours of cocaine use. Thus, any positive follow-up test occurring more than 72 hours after the initiation of treatment would indicate continuing cocaine use. More recent research by Burke, Ravi, Dhopes, Vandergrift, Maany, and McLellan (1989) questions the validity of this 72-hour period, however. In an experiment using 35 abstaining cocaine users, these researchers found that at a 300 ng/ml cutoff level, 11 (31.4%) of the subjects had detectable quantities of cocaine in their urine 120 hours or longer after admission to a drug-free treatment facility. Furthermore, eight of the subjects had their last positive test on a day following a negative test. Since follow-up test results are valid only if it can be established that positive results are not attributable to drug use that occurred prior to treatment, this research has serious implications regarding the validity of follow-up testing for cocaine. In light of these findings, the researchers caution that clinical judgment should definitely be used in interpreting what appears to be a positive follow-up test occurring more than 72 hours after initiation of treatment.

3.7.1.3 Opiates

Opiates accounted for 1.8 percent of all confirmed positive test results (45 out of a total of 2,433). Opiate use, although a small percentage of the total positive tests, nevertheless represents a continuing cause of concern for the nuclear power industry.

As discussed in previous reports, a critical issue associated with testing workers for opiate use is the potential for poppy seeds, a legitimate food, to prompt a true positive test result for opiates. The small quantity of morphine and codeine in poppy seeds can produce such a result, and current analytical techniques cannot distinguish between licit and illicit sources of morphine or codeine in the urine. Analytical techniques can, however, sometimes determine

that a positive test result is attributable to heroin rather than poppy seeds (or other form of opiate consumption).

One analytical technique used during GC/MS testing to detect illicit or unacceptable opiate use involves testing specimens for the presence of 6-O monoacetyl morphine (6-MAM). 6-MAM is a substance that is metabolized to morphine in the liver. According to Foltz, Fentiman, and Foltz (1980), the major pharmacological effects of heroin are due to MAM and morphine and, because of this, the presence of MAM can be considered presumptive evidence of heroin use. There are two principle limitations of testing for MAM. First, this technique has a limited scope in that it can provide reliable evidence only of recent heroin use and cannot detect the use of other opiates, such as morphine and codeine (Moore et al., 1989).

The second limitation in testing for 6-MAM is that it appears in detectable quantities for a very short period of time. Cone and Welch (1989) found that 6-MAM was detectable for only about 8 hours subsequent to heroin use, while morphine was detectable for 18 to 24 hours. This narrow window of detectability is likely to result in a number of cases in which employees will test positive for morphine, but negative for 6-MAM.

A second method for determining opiate use is for the Medical Review Officer to uncover additional evidence of substance abuse, such as needle marks during interviews. However, while the HHS guidelines (and the NRC rule) stipulate that clinical evidence of substance abuse, such as needle marks, can be used to determine whether the positive test results are attributable to substance abuse, the guidelines do not require the MRO to interview the worker in person. The problems associated with analytical techniques for determining opiate use suggest that the MRO should be required to conduct physical examinations of workers who have had confirmed opiate test results before deeming such results negative. This does not mean, however, that finding clinical evidence of substance abuse should be a necessary prerequisite for a positive finding of opiate use.

3.7.1.4 Amphetamines

Even though there were relatively few confirmed positive test results for amphetamine and methamphetamine, these positives indicate that these drugs still represent a concern in the nuclear power industry. Amphetamine accounted for 2.8 percent of all confirmed positive drug tests (69 out of a total of 2,433).

The NIDA consensus report recognized an important concern associated with urine testing--the procedure used to confirm positive amphetamine and methamphetamine urine tests should be able to resolve the d- and l-isomers¹⁰ of these drugs (HHS, 1990).

In both amphetamine and methamphetamine, different isomers of the drugs (d- and l-isomers) exist and, as a result, these isomers have very different pharmacological properties (Foltz et al.,

¹⁰ Isomers are substances that contain the same elements in the same proportions as another but have different arrangements of the elements and different properties.

1980). In the case of amphetamines, the d-isomer is four to ten times as potent as the l-isomer with respect to central nervous system (CNS) effects. The d-isomer of methamphetamine also has stronger CNS effects than the l-isomer. Using a procedure that can distinguish between the two isomers is essential, Foltz states, because at least in the case of methamphetamine, the relatively benign l-isomer is present in certain legal drugs, such as over-the-counter antihistamines. The authors also discuss GC/MS techniques that can be used to distinguish these isomers.

Though neither the HHS guidelines nor the NRC rule currently contain a requirement for distinguishing between d-isomers and l-isomers in testing for amphetamine and methamphetamine, the need for this provision in forensic toxicology has been recognized for at least a decade. Suitable methods of accomplishing this goal have also been available for years.

Because of these potential detection problems, additional action to ensure against false positive amphetamine and methamphetamine test results may be desirable. Three possible courses of action are as follows:

- Ensure that the HHS procedures for certifying a laboratory verifies that the laboratory uses a procedure that distinguishes between l- and d- isomers of amphetamine and methamphetamine.
- Use only those laboratories that use a technique to distinguish between the l- and d- isomers of amphetamine and methamphetamine.
- Require that blind proficiency testing of laboratories includes the analysis of specimens that are negative for d-amphetamine (methamphetamine) but positive for l-amphetamine (methamphetamine).

3.7.1.5 Phencyclidine (PCP)

Data from licensee fitness-for-duty program performance reports show a low confirmed positive rate for PCP tests (8 positive test results in/from a total of 2,433). Walsh (quoted in Weiss and Millman, 1989) states that PCP is a good example of a drug that represents a regional concern:

PCP seems to be a major problem in Washington, Baltimore, and Los Angeles, and nowhere else in the country is it as big a problem. We certainly recommend that if you are setting up a new office in Washington you'd better test for PCP because it seems to be the drug choice among young people there. In Peoria you couldn't justify the expense of a PCP assay. (p. 181)

Although Walsh was referring to testing programs in industries that may not have as high a safety sensitivity as the nuclear power industry, it does make sense to examine the incidence of PCP in different regions. The eight positive PCP tests found in the first-year data occurred at six separate sites in three of the five NRC regions. Currently there is not enough data to determine whether PCP occurs more often in particular regions or cities. Given this absence of

data, and the extremely impairing effects of PCP (see NUREG/CR 5227), even the low rates of PCP use found during the first year of testing justify the cost of testing for the drug.

3.7.2 Additional Drugs to Be Considered

The following sections present updated information on barbiturates, benzodiazepines, and methadone as drugs of potential fitness-for-duty concern.

3.7.2.1 Barbiturates and Benzodiazepines

Moore et al. (1989) examined the legal drugs that may constitute a fitness-for-duty concern and concluded that, in addition to the illegal drugs included in Section 2.1(a) of Appendix A to 10CFR Part 26, barbiturates and benzodiazepines were likely candidates for inclusion in the NRC drug testing panel. Barnes et al. (1988) reported that drugs in these classes are widely used, misused, and abused in American society. These drugs can cause significant impairment, and suitable technologies exist for their detection. Information that has become available since the latest NRC review (Moore et al., 1989) indicates that these drugs remain prime candidates for inclusion in the NRC drug panel.

A number of experts on drug testing in the workplace strongly support the inclusion of these drugs in testing programs. Finkle, for example, states that it would be "perfectly appropriate" to include benzodiazepines in a workplace testing program, at least in the context of for-cause testing, because some of the benzodiazepines are, without question, drugs that are open to self-medication, present the potential for serious misuse and abuse, and have serious consequences in the workplace (Jatlow et al., 1987).

Jones identified an additional reason for including benzodiazepines in the testing panel. There is evidence that some people are using benzodiazepines, often with a valid prescription, to cover up a drinking problem (Jatlow et al., 1987). Chlordiazepoxide and diazepam (two types of benzodiazepines) can be used to cover the smell of alcohol on one's breath. The extent to which workers engage in this practice is unknown, but it is clearly important to detect such behavior.

Data gathered from licensee programs indicate that these drugs pose problems in the nuclear workplace. Durbin et al. (1991) reported that, for the 39 nuclear sites that tested for a broader panel of drugs than required under the NRC rule, all 39 tested for benzodiazepines and 32 tested for barbiturates. For the 39 sites that tested for benzodiazepines and/or barbiturates, these drugs accounted for 2.9 percent and 2 percent of the confirmed positive tests, respectively. These percentages are comparable to opiates, which accounted for 1.8 percent of the confirmed positive test results, and are substantially higher than PCP, which accounted for 0.2 percent of confirmed positive test results.

The NIDA consensus report provided mixed recommendations regarding testing for barbiturates and benzodiazepines (United States Dept. of HHS, 1990). The report did state that these drugs should be considered for inclusion in testing protocols when they can be justified as special problems in particular workplace environments. NIDA, however, does not include

barbiturates and benzodiazepines in the HHS guidelines at this time. Hence, uniform cutoff levels and quality control measures for these drugs have not been established.

3.7.2.2 Methadone

Another legal drug that may warrant inclusion in the testing panel is methadone. Methadone is an orally administered synthetic narcotic commonly used as a treatment for heroin addiction. Methadone works to block the effects of heroin and prevents the effects of withdrawal. It is not in itself, however, a cure for addiction (GAO, 1990). Methadone is most often administered through methadone maintenance clinics, which offer limited doses of methadone at reduced prices as a part of a treatment program for heroin.

Data gathered from licensee programs in the first year (and reported in Durbin et al., 1991) provide inconclusive evidence as to the prevalence of methadone use by employees covered by the rule. At the 10 sites that tested for methadone, there were no confirmed positive test results out of the 48,268 tests administered. Because of the low number of licensees testing for this drug, the incidence of positive tests that would occur if all licensees tested for methadone cannot accurately be predicted.

There has been little evidence linking methadone use to fitness-for-duty problems. While methadone has been known to produce side effects, there is little evidence that methadone causes a decrement in performance when administered under stable dosage and appropriate supervision (Bourne, 1975). Kreek (1983) has studied side effects from methadone in the early phases of methadone treatment when doses of methadone are initiated, gradually increased, and then stabilized. Constipation, sleep problems, and sexual difficulties appeared to be the most common and significant side effects, and all of these effects were reduced at lower doses of methadone. While most of these side effects would not cause impairment, they could hamper a worker's productivity depending upon the nature of the job.

Independent of the direct effects of methadone in the workplace, there are a number of other concerns with the use of methadone that support testing for this drug. One major concern with methadone use is that it is often used as a substitute for heroin rather than as a treatment. Cannella (1987) states:

... methadone also is a drug that can be abused. More importantly, it's used by addicts who are out of control and use methadone until they can get their supply of other drugs lined up again. (p. 64)

In support of this theory, Bourne (1975) found a large correlation between the dropout rate at methadone clinics and the availability and purity of heroin on the street. One factor that appears to influence the misuse of methadone is the care in which a methadone clinic screens its patients. Bourne (1975) states:

When a (methadone) program has an "open door" admission policy the less well-motivated patients tend to use treatment as a haven when heroin is scarce and to leave when it becomes available again. (p. 6)

A second concern with methadone is that although methadone alleviates the effects of withdrawal from heroin, the recidivism rate remains relatively high. Goldstein (cited in Bourne, 1975) found that after six months in a methadone treatment program, 30 percent of patients tested positive for heroin, and after a year in the program, positive rates continued at 5 to 10 percent. Research has not produced an explanation for these recidivism rates. Bourne (1975) states:

Theoretically, there should be no reason for a patient who is "blockaded" to take heroin . . . however, the theoretical notion that methadone will eliminate the desire for heroin does not seem to hold up in actuality. (p. 11)

The first two concerns with methadone use support testing for this drug because both drug substitution and recidivism imply that an employee may, in the future, be using illegal drugs. This represents both a trustworthiness and a fitness-for-duty concern.

A third concern is the use of methadone as a primary drug of addiction. While the incidence of this has been disputed, many maintenance programs in New York have found that 15 percent of their patients seeking treatment are primarily addicted to methadone (Bourne, 1975). Sapira (cited in Chambers and Brill, 1973) studied methadone addicts and found that these addicts had many problems similar to addicts of other types of drugs. In addition, persons who completed methadone treatment programs were two to three times more likely to return to methadone than the general narcotic addict population.

This third concern may not directly support testing for methadone because this drug does not in and of itself produce impairment. Because methadone addiction may be indicative of other problems that the employee may be experiencing, however, licensees should be made aware of such methadone use.

While methadone is a legal drug that does not appear to be a potential cause of direct on-the-job impairment, its use by employees assigned to the protected area may nonetheless present fitness-for-duty concerns. These concerns may justify tracking methadone use. There are a number of options for accomplishing these objectives. These include adding methadone to the current testing panel, incorporating methadone into existing EAP programs, or requiring methadone users to report their use to licensee management. Through these means, the fitness-for-duty implications of methadone use may be controlled.

3.7.3 Alcohol

Licensee experience indicates that workers' use of alcohol represents a significant fitness-for-duty concern. Alcohol was the third most frequent drug detected by licensees (after marijuana and cocaine), accounting for 18.6 percent of all confirmed positive test results (452 out of a total of 2,433). This section provides updated information on alcohol as a fitness-for-duty concern.

3.7.3.1 Blood Alcohol Concentration Cutoff Levels and Abstinence Periods

Modell and Mountz (1990) summarize evidence from a study of drug testing in the workplace sponsored by the FAA. They recommend that the 0.04 percent blood alcohol content (BAC) cutoff level be lowered to 0.01 percent and that the 8-hour pre-duty alcohol abstinence period used by the FAA be extended to 24 hours. Modell and Mountz maintain that these changes are necessary because of the degree of impairment that is possible at BACs below 0.04 percent. They also state that these changes are necessary to ensure against impairment caused by alcohol-induced hangovers. This finding is generally consistent with previously reported findings (Moore et al., 1989). It should be noted that their information summary did not address concerns about how intrusive a workplace policy using a BAC cutoff level of below 0.04 percent would be on workers' private lives. It also failed to discuss the current limitations in testing technology that might affect the feasibility of such a policy.

Alcohol Impairment in Emergency Conditions. Even low levels of impairment may be of special significance in unusual conditions, such as an emergency. This point is made repeatedly both in studies examining impairment at low BACs and in studies examining alcohol tolerance. Research has repeatedly shown that after consuming alcohol, people can perform well on simple experimental tasks or routine and well-practiced tasks but do not necessarily respond well to unusual, unpredictable, or complex circumstances. Emery (1986), for example, stresses that alcohol impairment is especially pronounced in emergency situations:

It is important to remember that although experienced drinkers can learn to compensate for the effect of alcohol on their ordinary behavior and can continue to perform routine tasks effectively at relatively high blood alcohol concentration, they cannot "learn" for the emergency situations. In any task which requires judgment, reasoning, memory, or quick reaction, their response will be impaired by alcohol and present a possible safety hazard. (p. 22)

Yesavage and Leirer (1986) similarly conclude that:

Alcohol also reduces the ability to perform non-routine acts and even greater effects when subjects are required to respond with . . . an alternative, nontypical response . . . this suggests that in emergency (i.e., non-routine) conditions the effects of alcohol may be most pronounced. (p. 1549)

Emergency conditions are likely to maximize the safety significance of even minor impairment. Thus, although BACs below 0.04 percent may be associated with only minor impairment under normal operating conditions, such low-level impairment may be significant in unusual conditions. In such unusual or emergency conditions, workers must be free from any cognitive or psychomotor impairment.

Significance of the Impairment of Judgment. Even low levels of impairment from alcohol consumption may represent a safety concern. Goldstein (1983) demonstrates the effects of increasing alcohol consumption on judgment and driving skills. In that study, bus drivers who had won driver safety awards were asked to judge how narrow a gap between fixed objects

they could successfully navigate a bus. They were then asked to actually navigate a bus between those objects. As BACs increased, the drivers required more distance between the objects, but judged that they needed less. Results from this study demonstrate that low levels of alcohol consumption can impair routine well-learned skills, while causing people to overrate their abilities in these areas. The combination of actual versus perceived abilities may pose a greater risk than either factor alone.

Alcohol in Combination With Other Factors. As discussed in Moore et al. (1989), alcohol is commonly used by poly-drug users. In combination with certain drugs, it is possible that even very small quantities of alcohol could have very pronounced impairing effects. Alcohol can also exacerbate other forms of impairment, such as fatigue or emotional stress. For example, alcohol is one of a number of factors that can cause perceptual conflicts.¹¹ Reason and Branch (1975) and Bittner and Guignard (1985) identify a number sources of perceptual conflict that can be expected to have cumulative impairment effects. These include fatigue, disordered sleep, illness, alcohol hangovers, and motion sickness. In combination with alcohol, impairment from any of these sources is exacerbated. Thus, in combination with any of these factors, even minimal alcohol-induced impairment may be associated with significant overall impairment.

Low BACs as an Indicator of Hangovers. One of Modell and Mountz's (1990) principle concerns with the 0.04 percent cutoff level is that low BACs are indicative of possible hangovers. There are two ways in which a worker could report for duty with small quantities of alcohol in his or her system. First, the worker may have recently consumed small quantities of alcohol, which represents a trustworthiness concern, if the worker consumed the alcohol during the pre-duty abstinence period. Second, he or she may have consumed relatively large quantities of alcohol prior to the abstinence period, which raises the concern that the worker may be suffering hangover effects associated with the consumption of large quantities of alcohol.

Hangover effects of alcohol are real and do cause significant impairment. In studies reviewed by Yesavage and Leirer (1986), impairment due to the effects of hangovers occurred on complex experimental tasks, but not on relatively simple tasks. The tasks in which hangover effects were identified included reaction time in making choices, letter-to-number coding tasks, a variety of cognitive tasks, and driving tasks. The studies in which no hangover effects were found differed from these studies in that the subjects consumed slightly lower amounts of alcohol and less time had elapsed between drinking and completing the tests. Also, those tests for impairment involved simpler tasks, such as simple perception and attitude control, tracking, and visual reaction time. Laurell and Tornos (1983) have described other studies in which hangovers degraded subjects' abilities to perform complex tasks (e.g., decrements of driving performance in complex situations, which placed heavy demands on subjects' vigilance, reaction speed, and motor coordination) (in Starmer, 1989).

¹¹ Perceptual conflict disorders occur when the information received through the senses does not match the expected patterns of input in the brain.

After reviewing the studies of hangover effects, Yesavage and Leirer (1986) hypothesized that hangover-induced impairment may be most strongly associated with relatively complex tasks. They tested this hypothesis with pilots in flight simulations. In the experimental condition, pilots consumed alcohol to achieve a BAC above 0.10 percent (0.101 to 0.121 percent) and were tested in a flight simulator 14 hours later (the pilots had abstained from alcohol consumption for a minimum of 48 hours prior to the experiment). The pilots' performance revealed that alcohol resulted in impaired performance, and that hangover effects were greater for some of the pilots than for others.

It is important to note that in studies reviewed by Yesavage and Leirer (1986) and Laurell and Tornos (1989), the subjects typically underestimated the degree to which they were impaired. It is also noteworthy that hangover effects from alcohol (acute direct effects) may be synergistic with other impairing factors. For example, the impairing effects of hangovers may exacerbate motion sickness (Bittner and Guignard, 1985).

The need to address hangovers in workplace alcohol programs is beginning to be recognized in the scientific literature. In an evaluation of the FAA rule on alcohol use for pilots, Modell and Mountz (1990) recommend modifying the FAA rule to prohibit pilots from flying for 24 hours after a drinking session in which five or more drinks were consumed.

BACs Through Time. Perhaps the strongest argument for measuring relatively low BAC levels is that such test results might indicate policy violations. For example, suppose an employee tested during the last few hours of a shift has a BAC of .03 percent. Because BACs rise shortly after drinking and then fall over time, it is possible that the employee either had a BAC above the 0.04 percent cutoff level earlier in the shift or had consumed alcohol while on duty. This suggests that even low BACs (lower than .04%) should trigger some type of response by the employer.

As indicated in Moore et al. (1989), there is a large body of literature available on the kinetics of alcohol. Given this knowledge, it is possible to calculate what the BAC levels would have been at different times prior to the test. Information continues to be published on this subject. Those interested in detailed information on this topic may wish to consult two publications that have become available since the publication of Moore et al. (1989). These publications include a comprehensive two-volume publication on the kinetics of alcohol produced by the Chemical Rubber Company (Batt, 1989), and a discussion of the use of calculated BACs in legal proceedings written by Field and Basteyns (1988).

A second reason for measuring low BAC levels is because such levels may produce on-the-job impairment. Modell and Mountz (1990) studied the effects of low BACs in pilot performance and found BAC levels between 0.03 and 0.05 percent to be associated with impairment, short-term memory, and various aviation tasks such as aircraft descent and complex coordination. The authors concluded their study by recommending a 0.01 percent BAC cutoff level for workers engaged in safety-sensitive jobs. Thus cutoff level is problematic, however, since current testing technology is unable to reliably test for BACs at such a low level.

Although research evidence indicates that low-level BACs may result in job performance decrements, current testing technology does not support using cutoff levels lower than .03 percent. The NRC rule requires that alcohol testing be conducted with the most valid and reliable technology available. Recently, the National Highway Traffic Safety Administration (NHTSA) approved evidential-grade breath testers. To qualify as a valid evidential grade breath testing device (EBT), the device must, on average, read blank for alcohol-free specimens or no higher than 0.01 BAC percent. Further, individual readings for blank specimens can be as high as 0.02 BAC percent (National Highway Traffic Safety Administration, 1977). These standards suggest that the best available breath testing technology cannot be expected to reliably test BACs at levels below 0.02 percent BAC. Certainly, some EBTs may perform beyond this minimum standard, but certification standards do not require that they do so. Thus, using approved EBTs does not guarantee reliable testing technology when considering test results at or below 0.02 percent.

Back calculations of blood alcohol levels have been found to be of limited accuracy. Alcohol elimination rates during the last few hours that alcohol is in the system may be highly variable (Field and Basteyns, 1988). Therefore, the accuracy of low-level BAC measurements is limited. Thus, it does not seem reasonable for licensees to take any action based upon a measured BAC of 0.01 percent. Instead, such a measure should be considered a negative test result. Furthermore, for all of the reasons discussed in Moore et al. (1989), it does not appear advisable to use a cutoff level below 0.04 percent BAC in a workplace alcohol testing program. However, it may be appropriate to take some action based upon BAC results of 0.02 and 0.03 percent in certain cases.

BACs of 0.03 and 0.02 percent may be especially relevant in for-cause testing situations. In such cases, the circumstances that led to the test already provide some evidence of a problem. The measured BAC provides additional indications of a possible problem. This is especially true if the test occurs late in the worker's shift. Calculations could be performed to demonstrate that there is a very high probability that the worker either had a BAC above the cutoff level while on duty or consumed alcohol while on duty. As pointed out by Field and Basteyns (1988), however, there are a number of factors that affect the accuracy of such calculations and calculated BACs should always be discussed in terms of probabilities. Thus, no hard and fast rules for interpreting such calculations can be made. In extreme cases, such as a for-cause test occurring in the tenth hour of a worker's shift that indicates a BAC of 0.03 percent, such calculations would provide a very strong indication (and very solid evidence) of a policy violation.

3.7.3.2 Quality Assurance In Blood Analysis for Alcohol Concentration

Moore et al. (1989) discusses a number of issues regarding quality assurance in both breath and blood analyses for alcohol concentration. This section addresses several additional concerns in blood alcohol analysis.

Blind Proficiency Testing. Although 10 CFR Part 26 provides for laboratory proficiency testing with regard to the analysis of urine specimens, no laboratory proficiency testing of blood specimens for alcohol is required at this time. The common practice used to ensure quality in

forensic blood alcohol testing is through open proficiency testing programs--the laboratory is aware that test specimens used to measure the laboratory's analytical proficiency are being analyzed. As stated in the NIDA consensus report on workplace drug testing (HHS, 1990), blind proficiency testing is the preferred method of quality control in drug testing. In this situation, the laboratory is unaware that it is analyzing specimens that will be used to assess analytical proficiency. The NIDA consensus report states that blind proficiency testing is the "ultimate method for demonstrating the competency of a laboratory, since it tests the entire laboratory operation as applied to routine specimens" (p. 36). In fact, the consensus report indicates that:

In order to assess the true proficiency of a laboratory, the PT [proficiency testing] challenge must be blind to the laboratory. Only then will a PT challenge be received, stored, accessioned, processed and reported as a routine specimen. (HHS, 1990, p. 34)

The consensus report also notes that blind proficiency testing can be difficult and expensive. These problems may be more pronounced in the case of blood testing for alcohol than they are for urinalysis for illicit drugs. Specifically, a test specimen must be similar to routine specimens in appearance and attributes. Thus, in the case of blood testing, the specimen must be human blood, and the exact concentration of the specimen must be known. It must also be firmly established that the specimen has not been altered in any way (i.e., the specimen must not be subject to tampering, it must contain proper concentrations of preservatives and anticoagulants, and it must be stored properly prior to transportation to the laboratory). To address these issues of specimen quality for urine testing, NIDA's report suggests that a sample of specimens be evaluated before they are used in blind proficiency tests. This recommendation also includes analyzing specimens by a minimum of three certified laboratories before they are sent to client laboratories. Further, the consensus report recommends that vendors of the proficiency testing samples maintain supporting documentation of the specimens by re-assay throughout the shelf life of the specimens.

Although no ideal source of quality control materials for blind proficiency testing of blood specimens has been identified at this time, it should be possible for licensees to obtain adequate materials for such proficiency testing. There are a number of organizations that produce quality control materials for blood analysis that are typically prepared for open proficiency testing programs. It should be possible to obtain specimens for blind proficiency testing from one of these organizations. In addition to preparing true positives and perfectly "clean" negative samples, some organizations that provide such specimens prepare specimens that do not contain ethyl alcohol, but do contain substances that may be confused with alcohol if poor analytical procedures are used. Depending upon several factors, such as cost and availability of such specimens, licensees may wish to consider purchasing specimens that contain no alcohol, but which contain substances that might be mistaken for alcohol.

Materials for conducting open proficiency testing of blood analysis for alcohol can be obtained from a number of sources (see Field, 1988, for a detailed discussion). The College of American Pathologists (CAP) is recognized as having a high-quality, open proficiency testing program for blood alcohol analysis. This organization has substantial experience in developing

and handling quality control materials. Although the specimens that CAP normally prepares are intended for open proficiency testing, they could be used for blind proficiency testing as well.

Laboratory Certifications and Accreditation. An important scientific safeguard delineated in the HHS guidelines and the NRC rule requires that only NIDA-certified laboratories conduct confirmation tests. Unfortunately, NIDA does not certify laboratories for forensic testing of blood for alcohol, nor does any other authoritative body. The CAP has a rigorous accreditation program for laboratories conducting clinical blood alcohol analysis. The CAP also offers a program for evaluating and accrediting forensic urinalysis laboratories. Because the analytical issues are the same in forensic and clinical analysis, using CAP-accredited laboratories parallels at least a portion of the intent of the HHS requirement. It is important to note, however, that forensic analysis entails procedures beyond those required in clinical analysis. For example, laboratory security and proper execution of chain-of-custody procedures are critical in forensic analysis, while these issues are only minor concerns in clinical analysis.

Licensees can, however, verify that a laboratory follows sound analytic procedures for blood analysis and is aware of and fully capable of following sound forensic procedures. This can be accomplished by selecting a CAP-certified laboratory for clinical blood alcohol analysis that has also been certified or accredited, either by NIDA or by the CAP for forensic urinalysis. Since the NIDA certification program is the standard for workplace drug testing programs, use of a laboratory which is CAP-certified for clinical blood alcohol analysis and NIDA-certified for forensic urinalysis would provide the highest available degree of assurance of quality.

3.7.3.3 Saliva Alcohol Testing Devices

There is some evidence that saliva alcohol testing devices are an accurate means of screening individuals for alcohol ingestion. Dubowski (1986, 1991), and McColl et al., (1979) have expressed confidence in the basic science and techniques of this system and believe that it has future promise. Jones (1981) found that the saliva alcohol and blood alcohol concentration correlation was remarkably constant and believes that tests for saliva alcohol may be appropriate in medico-legal work. He states, "... it is evident that blood alcohol concentration can be reliably estimated from analysis of a saliva specimen and an application may be found in clinical or medico-legal work" (p. 565).

Before the currently used saliva collection and testing techniques were created, it was difficult and time consuming to collect saliva specimens, and testing required highly trained technicians. Saliva had to be collected for 8 to 10 hours, then a complex series of oxidation reduction tests were performed. Now, it is quick, relatively inexpensive, and requires only moderate training of the tester (Dubowski, 1986, Jones, 1979).

Dubowski (1986, p. 32) states that determining BACs from saliva specimens "... lends itself well to screening tests, is readily accessible by noninvasive collection procedures, parallels the plasma alcohol concentration reasonably, and can now be measured relatively simply and rapidly by enzymatic oxidation methods." Saliva alcohol tests correlate extremely high, at least as initial, screening devices. Dubowski (1986) equates saliva alcohol BAC determination to be equal in accuracy to results of breathalyzers, blood, plasma, and serum tests. He also stated

that, to his knowledge, saliva alcohol testing devices have not yet been accepted for evidentiary purposes in courts of law (K. M. Dubowski, July 16, 1991 personal communication).

There are two methods available for saliva alcohol screening. One device incorporates a swab to collect saliva from the mouth and reads the alcohol concentration using electronics. This equipment is comparable in price and user training requirements to a breathalyzer. Another method for determining BAC from saliva is the "test strip." This technique employs a paper pad impregnated with a chemical sensitive to alcohol. Once wetted with saliva, detectable alcohol will cause a color change to the strip which can be compared to a color chart for BAC determination.

The test method that employs a swab and machine for BAC determination (i.e., the Enzymatics QED-150) although comparably accurate to a breathalyzer, offers no advantage over the breathalyzer. The method that uses a test strip has the advantages of portability, less cost, and ease of use. This device, however, has the disadvantage of inaccuracy. One government agency study found the test strip gave false negatives as high as 55 percent of the time and a false positive rate up to 53 percent under normal conditions (Frank and Flores, 1986). Dubowski stated that "the era of "touch and tell" has not quite arrived for strip tests for saliva-alcohol analysis, but it is near" (p. 32).

At this time, there have been no court proceedings in which saliva alcohol device results have been accepted as evidence.

3.8 Additional Relevant Issues

3.8.1 Medical Review Officer Duties and Qualifications

The Medical Review Officer has the ultimate responsibility for evaluating drug test results, and thus plays a central role in assuring both the accuracy and fairness of workplace drug testing programs. The NRC fitness-for-duty rule and other sources have specified numerous MRO duties and qualifications. In actual practice, however, MRO responsibilities appear to be even more extensive and, because of this, it is important to consider the qualifications necessary for the MRO to successfully perform these tasks. Currently, there is no accreditation requirements for MROs; however, the National Institute on Drug Abuse (NIDA) is considering implementing such an accreditation system ("NIDA begins," 1991).

3.8.1.1 Medical Review Officer Duties

The NRC rule states that the role of the MRO is to review and interpret positive test results obtained through the licensees' testing program. The NIDA consensus report is more specific on the MRO role in stating that the primary role of the MRO is to assess and determine whether an alternative medical explanation can account for positive drug test results. While both statements are relatively straightforward, implicit in these statements are a number of duties. The MRO not only plays advisory and oversight roles, but also has administrative responsibilities in documenting all activities and may be required to testify in court. As part of

these duties, the MRO must review the fairness and credibility of test results, and must provide for the privacy and confidentiality of employees' personal history during the course of reviewing drug test results.

What is often more difficult than the number of duties is the nature of the duties performed by the MRO. Clark (1990) notes that many MROs operate on unfamiliar and uncomfortable ground. For many physicians, the very act of playing a forensic role may be a new and difficult experience. Some physicians may have reservations about whether it is appropriate for physicians to serve in the forensic (as opposed to clinical) role of an MRO. Ethical concerns of a physician may be especially pronounced if the physician perceives that the program focuses on the control of substance abuse through punitive sanctions rather than on treatment and rehabilitation. In addition, many physicians may not be familiar with specific forensic issues, such as chain-of-custody procedures.

3.8.1.2 Medical Review Officer Qualifications

The NRC fitness-for-duty rule requires that a Medical Review Officer be:

A licensed physician ... who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

The NIDA consensus report also stresses the importance of technical qualifications, and concludes that "clearly, an MRO must be a licensed doctor of medicine or osteopathy" (p. 29).

In addition to the technical qualifications required for the MRO, there are a number of additional skills that are needed to perform the various duties required in this position. These include:

- The investigative skills necessary to gather all applicable information and evaluate the validity and reliability of this information
- The skills necessary to analyze and evaluate a positive test result in light of other information
- The personal skills necessary to interview employees on an individual basis and gather the information necessary to make a decision
- General knowledge of the standard treatment for medical problems to enable the evaluation of given reasons for drug use, knowledge of the range of treatment services available, and appropriate referral to EAPs for evaluation
- Proficiency in managing and auditing, and willingness to attend to detail
- Assertiveness in reporting positive test results to licensee management

While the above skills and characteristics are important, many are difficult if not impossible to accurately measure when selecting an MRO. In addition, the necessary autonomy of the MRO position makes it difficult for the NRC to accurately monitor the performance of MROs once they are selected.

Currently, there are some sources of specific training in MRO duties available to practitioners (e.g., FFA, American College of Occupational Medicine). In addition, instructional materials are available to MROs, such as the NIDA and DOT MRO manuals. However, these cannot substitute for actual practice. In fact, in a survey of MROs (see Section 3.8.2 for more on this survey), most MROs felt clinical experience is a desired MRO qualification. Also mentioned by MROs in the survey were the advantages of regular communication among MROs across the country.

3.8.2 Medical Review Officers in the Nuclear Industry

A Battelle survey of licensee MROs shows that many of the issues raised in this discussion of MRO duties and qualifications have been recognized in licensee fitness-for-duty programs. Licensee MROs also have concerns about and have begun addressing many of the other issues raised in this report that are relevant to their duties. They have, for example, been working to resolve many of the issues associated with the review of alcohol test results discussed in this report.

To further evaluate the role of the MRO, Battelle conducted telephone interviews with nine non-randomly selected licensee MROs. Most of the utilities were contacted through the FFD manager, who then referred the interviewer to the MRO. A 15-20 minute telephone interview was conducted with each MRO or medical director. All interviewees were assured anonymity. The MROs were asked about:

- adequacy of the qualifications required of MROs
- actions and policies regarding alcohol testing
- on-site drug pre-screening.

Each interviewee was also asked to provide CY 1990 data on the number of presumptive positive drug tests by drug, the number of positive drug tests confirmed by GC/MS at the HHS-certified lab, and the number of drug tests confirmed by the MRO. Results from these interviews are summarized briefly below.

In general, the interviewees did not see the need for additional qualifications for MROs. Clinical experience was considered to be the most important qualification. Annual training at counterpart meetings for MROs was the only change that the interviewees recommended. Such training would allow the MROs to establish and maintain contact with each other and enable them to share current knowledge. Not one interviewee, including at least one of the interviewees who is a toxicologist, saw the need for MROs to be toxicologists as some groups have recommended. In fact, many thought that a toxicologist would be unqualified to perform most of the MRO duties. Some commented that each HHS lab has a toxicologist on staff with

whom the MRO can consult if needed. Table 3.10 further describes the interviewees' opinions about MRO qualifications.

Currently, MROs are not required to review all positive alcohol test results. However, it is known that MROs often do review alcohol test results. In this survey, two issues were investigated. First, should MROs review all positive alcohol test results and, second, should MROs extrapolate back in time for alcohol test positives? Table 3.11 outlines interview information obtained about alcohol testing policies and procedures. All interviewees (except one) believed that the MRO should review all alcohol positives. One MRO stated that lab personnel were capable of the review. Also, the MROs interviewed typically review positives below .04 in some formal or informal capacity. They often extrapolate back, as well. However, several mentioned that this is done informally, which allows the MRO the flexibility to intervene early to get help for the person (rather than waiting for random testing to detect an alcohol positive above .04). These results indicate that the MRO plays an integral role in early detection of alcohol problems; however, no interviewee wanted an official policy. Several commented that an official policy might hinder their ability to be flexible and to intervene early.

Table 3.10 Recommended Medical Review Officer (MRO) qualifications

PLANT	RECOMMENDATIONS
1	Licensed practitioner in specialty directly related to substance abuse. Does not recommend two-day MRO course.
2	Utility - Complete MRO certification of American College of Occupational Medicine (ACOM) Union - Qualified toxicologist
3	Some involvement in toxicology or drug testing; toxicologists are not recommended as MROs.
4	No changes but experience with patients or people with addiction problems would be useful.
5	Clinical experience is necessary and good; toxicology not necessary.
6	Practicing physician with MRO training.
7	Ongoing MRO training; unnecessary for MRO to be toxicologist. MRO should keep in contact with toxicologists regularly.
8	Clinical experience and dealing with substance abusers.
9	Clinical experience very important. MROs need ongoing training--e.g., like ACOM annual training. Ongoing contact with other MROs.

Table 3.11 Alcohol testing policies and procedures

PLANT	SHOULD MRO REVIEW ALL ALCOHOL POSITIVES?	SHOULD MRO REVIEW ALL ALCOHOL POSITIVES BELOW .04 TO MAKE RECOMMENDATIONS?	WHAT ACTION DOES MRO TAKE FOR ALCOHOL POSITIVES BELOW .04?
1	YES	NO	MRO called as a courtesy; back extrapolation done on for-cause tests.
2	YES	YES	Zero tolerance (removed from duty or terminated) for any positive alcohol test in for-cause testing.
3	YES	YES	MRO evaluates all alcohol positives (including below .04); below .04 are sent home. For-cause positives not permitted to return to work while drug results are pending.
4	YES	YES	Alcohol positive greater than .04 referred to MRO. Repeated positives between .01 and .04 are referred to MRO.
5	NO*	NO*	MRO consults with lab personnel for positives below .04.
6	YES	NO	Alcohol positives below .04 are informally referred to MRO for counselling or referral (no corporate policy).
7	YES	YES	MRO reviews all positive alcohol results. Medical staff at site counsel people as result is found.
8	YES	YES	Alcohol breathalyzer only reveals results above .04, but if alcohol use is suspected, MRO counsels and refers.
9	YES	YES	MRO reviews all alcohol positives and works with individual and psychologist (EAP). MRO reviews and refers; does not counsel.

*But lab personnel should.

The rule specifies that presumptive positive urine test results be confirmed by the GC/MS method at an HHS-certified lab to ensure against false positive results and then the lab testing results be confirmed by a qualified MRO to ensure that other explanations for positive results are considered. In this survey, we attempted to investigate the relationship between: (1) presumptive positive test results and GC/MS confirmed positives; and (2) GC/MS confirmed positives and MRO confirmed positives. Data regarding the GC/MS positive test drug results and MRO confirmed positive drug test results were received from six of the nine plants. Table 3.12 summarizes the GC/MS confirmed positive drug test results and MRO confirmed positive drug test results. Only three of the six plants conducted in-plant pre-screening (for presumptive positive data), thus, presumptive positive data are not reported in Table 3.12; with only three cases, interpretation is difficult.

A comparison can be made between GC/MS and MRO confirmed positive results by plant, although these differences cannot be statistically evaluated; six plants is an inadequate number to test results statistically. From these results, it is unclear why there is a discrepancy in the number of GC/MS confirmed positives and MRO confirmed positives for cocaine or marijuana (THC). For both of these drugs, there is little reason to suspect legal (or pharmaceutical) use. For plant #2, lower cutoff levels were used for GC/MS than for MRO confirmation; this explains the discrepancy. For positive amphetamines and opiate tests, legal use will often be determined as is demonstrated in these data. However, based upon this study, we have no information on the reasons behind these data. These data were not available nor compiled at the time of the MRO interviews. These results do warrant further investigation into the confirmation process and suggest that FFD managers and MROs be sensitive to this issue.

The results of this survey are summarized below:

- The results of this survey are preliminary and based on a very small sample, thus limiting generalizability; however, these results indicate issues needed further attention and also indicate the benefit of collecting more detailed data than collected in the first year of the NRC rule.
- The MROs interviewed reported that clinical experience is the desired MRO qualification. Toxicology was viewed as useful but not critical to the MRO position since toxicologists are available for consultation through the HHS lab.
- MROs report that they are handling positive alcohol results that are less than .04 in a flexible manner. Most reported that management was viewing any positive alcohol result as an indication of a potential problem without being punitive (if it is less than .04). MROs and testing staff often extrapolate back alcohol test results and inform the employee of this.

Table 3.12 GC/MS positive drug testing results vs. MRO confirmed positive results

	DRUG					
PLANT	RESULT	AMPHETAMINES	COCAINE	OPIATES	PHENCYCLIDINE	THC
1	GC/MS Confirmed MRO Confirmed	30 0	21 21	39 0	0 0	52* 52
2	GC/MS Confirmed MRO Confirmed	2 0	73 73	50 2	1 1	171** 171
4	GC/MS Confirmed MRO Confirmed	1 0	4 3	2 0	0 0	2 1
6	GC/MS Confirmed MRO Confirmed	1 1	5 5	6 0	0 0	6 6
7	GC/MS Confirmed MRO Confirmed	1 1	9 9	27 0	0 0	6 6
8	GC/MS Confirmed MRO Confirmed	0 0	0 0	0 0	0 0	8 8

* Cutoff level was 50 ng/ml.

** Initial screening cutoff level was 20 ng/ml (1/90-10/90); or 50 ng/ml (11/90-12/90).

3.8.3 Workers' Access to Records

Section 26.29 of the NRC rule states that workers should have access to their own drug test records, but does not state that licensees must provide copies or allow workers to make copies of their own records. Experts on drug testing generally advocate that tested individuals should have complete access to information about their own test results. For example, speaking in a panel discussion at the 1987 Arnold O. Beckman Conference in Clinical Chemistry, Dr. Kurt Dubowski and Professor Edward Imwinkelried addressed the need for employees subject to workplace urinalysis programs to have access to their own testing records. Dubowski stated:

If you operate in a system that accepts adversary proceedings and allows access to the courts as necessary to the resolution of disputes or to other recognized means of resolving disputes, such as arbitration hearings, how in the world do you initiate a legitimate challenge if the individual is not informed of the results and thus is not in a position to challenge what may well be an inappropriate or erroneous result? (Dubowski, Blanke, Burtis, Butler, Finkle, Imwinkelried, and McBay, 1987; p. 50B).

Imwinkelried also stated that allowing employees access to their own records is essential to maintaining a viable appeals process, and also stated that he believed it was important in ensuring that the testing process is scientific:

I agree [with Dubowski and] . . . completely apart from any philosophy of the advisory system, we're talking about science. The whole thrust of science is openness, a willingness to submit results to others who may attempt to replicate them, to validate them. It's really antithetical to the scientific tradition for the laboratory to obfuscate here (Dubowski et al., 1987; p. 50B).

3.8.4 Chain-of-Custody

Chain-of-custody refers to the procedures used by licensees to ensure the integrity of urine specimens by tracking their handling and storage throughout the testing process. The NRC rule states specific requirements for use of chain-of-custody procedures. These requirements are becoming increasingly important in ensuring that positive test results are defensible in court. A report on the Army's urinalysis drug testing program (The Einsel Commission, 1983) concluded that poor quality control records make it difficult, if not impossible, to legally document drug tests. Walsh and Yohay (1987) state several other reasons supporting the use of chain-of-custody procedures:

- To guarantee that the specimen analyzed does in fact belong to the person identified on the label
- To ensure that the specimen has not been tampered with in transit
- To identify all persons who handled the specimen

In order to ensure that a program is credible to employees and defensible in court, it is in the best interests of both the NRC and licensees to ensure the proper use of chain-of-custody procedures.

Licensee fitness-for-duty program events involving chain-of-custody have been relatively minor to date. An analysis of 27 fitness-for-duty inspection reports (including 24 initial inspections and 3 special inspections) identified only two chain-of-custody issues. One of these issues resulted in a non-cited violation, while the other was an unresolved item.

One issue that has been raised regarding chain-of-custody is whether the licensee should use chain-of-custody procedures when transferring specimens to the courier for transport to the certified laboratory. The NRC rule is explicit with regard to this question. Appendix A to 10 CFR Part 26 states:

Licensee chain-of-custody forms shall be properly executed by authorized personnel upon receipt of specimens. Handling and transportation of urine and blood specimens from one authorized individual or place to another shall always be accomplished through chain-of-custody procedures.

This requirement applies when licensee personnel transfer specimen packages to couriers for transport to a laboratory. The courier employee who picks up the package must sign the chain-of-custody form to fully maintain proper chain-of-custody. This section should not be read, however, to require each person within a courier company who handles a specimen package to have to sign the chain-of-custody form. Courier companies have their own internal procedures that long experience has shown to be reliable for the purpose of keeping track and maintaining the integrity of parcels delivered to them. It is sufficient, therefore, for the initial courier employee to sign the form when taking possession of the package and for the courier employee who delivers the package to the laboratory to sign the form upon giving up custody. Likewise, when specimen packages are sent by registered mail, U.S. Postal Service personnel should sign the chain-of-custody form both when they take and give up custody of the package.

There are several reasons why chain-of-custody procedures should cover couriers. The first and most central reason is that, by definition, chain-of-custody is meaningless unless it is maintained throughout the entire testing process. Programs that fail to maintain a complete chain-of-custody cannot guarantee the integrity of the specimen and risk losing both credibility with employees who submit for testing and defensibility of specimens if the accuracy of testing is challenged.

A second reason that supports the inclusion of couriers in chain-of-custody procedures is that it acts as a safeguard against tampering. Licensees are currently required to package specimens in tamper-resistant containers. However, individuals intent on subverting the process will most likely continue to find new ways in which to do so and, at some point, this is likely to threaten the integrity of the testing process. In addition, the use of tamper-resistant containers is not a safeguard against those specimens being lost altogether. Chain-of-custody procedures that include the courier would decrease this possibility as well.

3.8.5 Permanent Record Book

Appendix A of the NRC rule currently requires that licensees maintain a "permanent record book" to be used to permanently record identifying data on each specimen collected at a collection site in the sequence that specimens are collected. The Appendix also requires that licensees' specimen collection procedures require that tested individuals be asked to read and sign a statement on either the chain-of-custody form or in the permanent record book certifying that the specimen identified as having been collected is in fact the specimen he or she provided. The Appendix specifies that the permanent record book is to be a permanently bound book. During the first year of fitness-for-duty program operations, these requirements have been questioned. Some licensees have suggested that the information that is to be entered in a permanently bound record book can be better recorded and stored by computer.

The requirement for a permanent record book serves the purposes of both the licensees doing the testing and of those people being tested. Having a permanently bound book maintained at the test site allows collection site personnel to note in their own handwriting all relevant information that identifies specimens as they are collected. It also allows collection site personnel to contemporaneously comment in writing on any other information regarding the test conditions or the people being tested. Having this information in the handwriting of the collection site personnel rather than on a computer printout could prove important if the authenticity of the recorded information is subsequently challenged. It is likely that handwritten information would be more credible in case that information was needed to support the validity of test results in a subsequent adjudicatory proceeding.

Maintaining a permanently bound record book that tested employees can sign also adds a measure of protection for the people being tested. Signatures have long been used as the primary means of showing or declaring assent to something or of attesting to the authenticity of something. In the FFD testing context, the person tested can certify by signature that he or she has, in fact, provided the specimen identified as having been collected from him or her. This requirement protects the people being tested because it greatly reduces the chances that a specimen provided by one person will be incorrectly attributed to another person.

It is not clear whether these protections afforded by the opportunity to enter information in the handwriting of collection site personnel and for people being tested to attest to the authenticity of specimens can be maintained if these records are kept by computer. While computerizing these functions may prove more efficient and cost effective, these benefits may not outweigh the benefits of maintaining a permanently bound record book.

3.8.6 Maximum Time Limits on For-Cause Testing

For-cause testing has proved to be an important component of NRC fitness-for-duty programs. In CY 1990 for-cause testing accounted for 214 positive test results among workers with unescorted access to nuclear power plants. As an element of fitness-for-duty programs, for-cause testing serves as an additional deterrent to taking drugs or alcohol on the job.

In order to ensure that for-cause testing is performed in a manner that is optimally effective and that licensee practices in administering for-cause testing are consistent, the NRC is considering the feasibility and desirability of imposing a maximum limit on the amount of time within which a person must be tested after having been designated for a for-cause test.

The existing rule, while not explicitly clear on a time limit, directs that testing be performed in a timely manner, before drugs are excreted from the body. This is most critical for alcohol, as other drugs can be traced in the body past easily observable physical symptoms. This is consistent with other industries' for-cause testing policies (Hunt, Yost, & Geisendorfer, 1989; Klingelhoef, Kuest, Mitchell, & Turanski, 1989). Section 26.24(a) of the NRC fitness-for-duty rule requires that licensees "(test) for-cause, i.e., as soon as possible following any observed behavior indicating possible substance abuse...." While this requirement may seem clear, there are indications that licensee practices vary substantially.

There are several factors that should be considered in determining a reasonable maximum time limit on for-cause testing. One important determinant is the amount of time that it takes the body to process alcohol. Research shows that it takes one hour for the average person to process one serving of an alcoholic beverage from the body (Klingelhoef et al., 1989). It takes approximately three servings of alcohol to give an average person a BAC of over .04 percent (the level at which an individual is violating the FFD rule). Thus, if a maximum time limit is set at 3 hours or longer, it will be difficult to detect workers who were in violation at the time of identification.

A second and closely related determinant of a maximum time limit is whether the licensee back-calculates BACs to the beginning of a shift. Currently, the fitness-for-duty rule neither requires nor prohibits this activity, and licensee practices vary substantially in this area. If back-calculation is used and the results enforced, the time limit on for-cause testing can be extended. However, such calculations may be more difficult to defend legally.

A third determinant involves the reasonable limitations on licensees in responding to for-cause testing. In some programs, for example, once a supervisor identifies an employee as a candidate for for-cause testing, he/she must take a number of steps, such as obtaining a second opinion from another supervisor. Licensees also have physical limitations, in that many have testing facilities that are not near the protected area, and must transport employees to that location. Also, the availability of collection staff and Medical Review Officers may be limited during backshifts and holidays. It is important for the NRC to consider the nature of these limitations when considering a maximum time requirement.

The processing of alcohol from the body suggests that a maximum time limit ranging between 1 and 3 hours would be most effective at ensuring that alcohol abusers are identified. However, the NRC needs to consider comments on such a proposed requirement with respect to restraints on licensees in conducting the testing. In addition, the NRC needs to determine how back-calculation (see Section 3.7.3.1) fits into the rule and whether or not it should be a standard practice, since the use of back-calculation affects the maximum amount of time necessary to identify an on-the-job alcohol user.

3.8.7 Effect of Temperature on Urine Specimens

Urine samples may be subject to variations in temperature during storage and shipment. There appears to be little information in the literature that specifically addresses the question of how extremes of temperature and of how cyclical changes in temperature may affect urine samples slated for drug testing. However, the increasing use of urine testing for drugs may suggest that more research is desirable.

Although the effects of temperature variation on specimens have not been extensively examined, one effect, the growth of bacteria if the specimen is kept in a warm environment, is a known concern. Specimens left at room temperature for 3-4 days could have enough bacteria growth to seriously hinder testing. Concentrated bacteria in a urine sample can alter the pH of the specimen and/or may yield a false negative due to the limitations of the EMIT assay screen. It is also possible for a sample to be so heavily concentrated with bacteria that a test cannot be performed. Although this is very rare, a specimen with high bacteria content would be viewed with suspicion by a DHHS/NIDA-certified laboratory, and another, fresher sample would be required. Specimens are placed under refrigeration or frozen primarily for the purpose of slowing bacteria growth. The possible effect of cold on urine samples has been of less concern than heat, and aliquots are often frozen for long-term storage.

Some guidelines for maintaining specimens either frozen or under refrigeration are provided in 10 CFR Part 26. These guidelines focus exclusively on maintaining temperature during storage at the licensee facility or at the HHS laboratory, however, and do not provide guidelines for maintaining specimen temperature during shipment. Since temperature variation may be extreme during shipment and could result in specimens left at room temperature for up to 3 days, the overall efficacy of the current guidelines may be questionable.

The current NRC fitness-for-duty rule guidelines for the handling and storage of specimens state that specimens should be transported immediately or refrigerated and kept at 6 degrees centigrade if six or more hours are expected to elapse between collection and transportation. The receiving laboratory must store specimens at a temperature not to exceed 6 degrees centigrade if the specimens will not receive an initial test within 7 days from receipt. Frozen specimens must be placed in secure refrigeration with emergency power equipment available in the event of power failure [10 CFR Part 26, Appendix A, Subpart B, #2.7(c)].

Samples may be transported via couriers, postal services, or private forwarding companies. Samples could be enroute for several days in an unrefrigerated condition. There are no requirements that these specimens be kept at a constant temperature during transit. This means that samples may be subjected to temperature variances.¹² Allowing temperature to vary during shipment of specimens is common practice.

¹² For example, specimens may be shipped in the unheated, uncooled cargo compartment of an aircraft where temperatures could be very high while awaiting take-off and very cold while at high altitude. The trunk of a car or back of a van may become extremely warm for hours while transporting samples in a hot climate.

The current guidelines for refrigeration and frozen storage of specimens appear to be inconsistent. For example, the requirement that emergency power equipment be available may be unnecessarily protective--since a specimen may stay at room temperature for a number of hours without known negative effects. In contrast, the number of days allotted prior to storage, combined with the lack of guidance regarding shipment, may allow the specimen to be subjected to warm temperatures for a sufficient period of time to cause concern regarding bacterial growth. Hence, it may be beneficial to provide guidance regarding a minimum transit time and special packaging for specimens and reconsider the requirement for emergency power.

In addition to reconsidering the guidelines with regard to shipment and storage in light of concerns over bacterial growth, further research to gain a better understanding of the full effects of temperature and temperature changes on specimens would be desirable.

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APPENDIX A

INTERVIEW PROTOCOL FOR PRE-RULE DRUG TESTING SURVEY

DETAILED TABLES AND CASE STUDY DESCRIPTIONS

INTRODUCTION

Appendix A includes materials used to collect information from the Pre-Rule Drug Testing Program Survey. Data collected from this survey are also summarized here.

The first document lists the questions asked of FFD managers during the interviews.

The second part contains five tables summarizing the detailed data collected during the interviews

The last part includes narrative case study descriptions of the nine plants included in this survey.

FITNESS FOR DUTY TELEPHONE SURVEYS
Interviews with FFD Managers/Administrators
(February 1991)

I Pre-Rule Drug Testing

Fitness-for-duty managers and administrators were asked to respond to interviews and provide other information on drug testing performance prior to rule implementation (January 1990). FFD managers or drug testing staff were asked to provide pre-rule data about the type of drugs tested, number of positives, and to compare pre-rule to post-rule testing. Each interviewee was assured anonymity.

A. Pre-rule Drug Testing.

1. What year did your plant (utility) begin conducting drug or alcohol testing?
2. What drugs were included in the testing?
3. What were the cutoff levels for each drug?
4. What type of testing was conducted (e.g. random, pre-access, pre-employment, for-cause)?
5. What clinical testing methods were employed (GC/MS) and at what facility did the testing occur (in-plant pre-screening, HHS lab, American College of Occupational Medicine (ACOM), certified labs, etc.)?
6. What sanctions or actions were taken upon finding a positive drug test?
7. Did your pre-rule drug-testing program also include elements such as training, EAPs, searches, etc.?
8. Please send pre-1990 drug testing data. Send the number of positive drug or alcohol tests, what type of testing (random, pre-access, for-cause, etc.), and type of drug tested for. Any data that you have are appreciated.

B. Post-rule Drug Testing.

1. What drugs does your plant (utility) currently test for (beyond what is required in the rule)?
2. What cutoff levels does your utility use (other than those required by the rule)?
3. Do you conduct in-plant drug pre-screening?

C. Briefly describe the differences between the pre-rule and post-rule drug testing at your plant.

Table A.1 Drug testing cutoff levels: Pre-rule and post-rule

DRUG TESTING CUTOFF LEVELS		
PLANT	PRE-RULE	POST-RULE
1	Amphetamine - 300 ng/ml Barbiturates - 300 ng/ml Benzodiazepines - 300 ng/ml Benzoyllecgonine - 300 ng/ml THC - 50 ng/ml Methadone - 300 ng/ml Opiates - 300 ng/ml Phencyclidine - 75 ng/ml Propoxyphene - 300 ng/ml Alcohol - No requirement Methaqualone - 300 ng/ml	100 ng/ml (THC); NRC cutoff levels
2	Alcohol - 0.5% THC - *20/10 ng/ml Cocaine - 300/150 ng/ml Opiates - 300/300 ng/ml Amphetamine - 300/250 ng/ml PCP - 25/25 ng/ml Barbiturates - 300/250 ng/ml Benzoyllecgonine - 300/250 ng/ml Methaqualone - 300/100 ng/ml	Same - except for THC (e.g., 20 ng/ml)
3	Missing data	NRC cutoff levels
4	NRC cutoff levels for 5 panel THC - 25 ng (other drug cutoff levels unknown)	NRC cutoff levels except THC - 50 ng/ml (initial test)
5	NRC cutoff levels	NRC cutoff levels
6	Morphine - .5 mag/ml Opiates - 1.0 mag/ml Amphetamine - 1.0 mag/ml Methamphetamine - 2.0 mag/ml Phencyclidine - 1.0 mag/ml Propoxyphene - 1.0 mag/ml Barbiturates - 1.0 mag/ml Hydromorphone - 1.0 mag/ml Pentoazoinine - 2.0 mag/ml Phenmetrazine - 1.0 mag/ml Phenothizines - 2.0 mag/ml Quinine - 1.0 mag/ml Methaqualone - 2.0 mag/ml Meperidine - 2.0 mag/ml Cocaine - 2.0 mag/ml THC - 50 ng/ml	NRC cutoff levels
7	NRC cutoff levels	NRC cutoff levels
8	NRC cutoff levels except THC 20 ng/ml	NRC cutoff levels (THC 50 ng/ml)
9	THC - 50 ng/ml Cocaine - 300 ng/ml Opiates - 300 ng/ml Amphetamine - 1000 ng/ml	THC 50 ng/ml

*20/10 When two numbers are listed with a slash, the first represents the initial screening test cutoff levels (in nanograms per milliliter). The second number represents the GC/MS confirmation test cutoff level (in nanograms per ml). If the first level is exceeded, a GC/MS test is given. If the second number is also exceeded, the test is positive.

Table A.2 Pre-rule drug program survey: Current plant practices

PLANT	CURRENT USE OF ON-SITE DRUG PRE-SCREENING	DRUGS CURRENTLY TESTED BEYOND RULE REQUIREMENTS	POST-RULE AVAILABILITY OF EAP TO CONTRACTOR
1	No	None	Yes
2	No	Pre-employ: Barbiturates Benzodiazepines Methaqualone	Yes
3	No	None	Missing data
4	No	No	Some have EAP
5	No	None	No
6	No	None except for follow-up testing (10 panel used) Marijuana Methadone Cocaine Barbiturates Opiates Methaqualone Phencyclidine Propoxyphene Amphetamine Benzodiazepines	Data unavailable
7	Yes - For cause	None	No
8	Yes	None	No
9	Yes	Follow-up testing (10 panel used) Marijuana Methadone Cocaine Barbiturates Opiates Methaqualone Phencyclidine Propoxyphene Amphetamine Benzodiazepines	No

Table A.3 Pre-rule sanctions applied for positive drug tests

PLANT	PRE-RULE SANCTIONS/ACTIONS UPON FINDING POSITIVE TEST
1	Same as now: 1st offense = treated as illness (for treatment and rehabilitation) 2nd offense = termination
2	Licensee employees never considered for access again Contractors = 6 month denial of access (hard to regain)
3	Pre-employment = no hire For-cause = review employee history, EAP input - determined length of suspension/termination
4	Contractor = terminated Permanent = access revoked; retested after 45 days, rehabilitation/assessment 2nd positive = termination
5	Data unavailable
6	Pre-access = no hire 1st positive = 10 day suspension without pay; mandatory EAP referral plus 24 month follow up. 2nd positive = termination
7	Any positive = termination Positive for alcohol = case by case
8	1st positive = Licensee employees sent to DAP; Contractors removed 2nd positive = termination 3rd positive [for alcohol] = termination
9	Case by case at first; 1986 - instituted 4-strike* rule 1st positive = nothing 2nd positive = 5 day suspension, EAP 3rd positive = 30 day suspension 4th positive = terminated 1986 - 3-strike rule, eliminating 1st step from the 4-strike rule 1988 - 2-strike rule 1st positive = 14 day suspension/rehabilitation 2nd positive = termination For-cause = immediate termination

* "Strike" indicates how many chances you have to test positive before being terminated.

Table A.4 Pre-rule and post-rule positive drug test results

PRE-RULE*		POST-RULE				
PLANT	% POSITIVE	# POSITIVE/TOTAL # TESTED	% POSITIVE # POSITIVE/ TOTAL # TESTED			
1	Not available		.81 25/3105			
2	4.3% positive		.40 18/4474			
3	6/88-12/88: THC = .15%	3/2060	.57 29/5103			
	1989: THC = .65%	18/2754				
	1989: Cocaine = .51%	14/2754				
4	1988: 2% positive (18 refusals) 1989: 1/2% positive (19 refusals)		1.19 96/8096			
5	1987-1989	THC	Cocaine	Opiates	Alcohol	1.82 83/4550
	Employee	9	5	5	3	
	Contractor	32	21	5	2	
	Pre-Access	9	1	2	0	
6	1985-1989: 2 positives				.62 14/2262	
7	Not releasable				1.26 85/5766	

* Differences in positive test rates between pre-rule and post-rule may be due to differences in types of testing used (e.g., random testing implemented post-rule).

Table A.4 Pre-rule and post-rule positive drug test results

PLANT	PRE-RULE*												POST-RULE	
	% POSITIVE - # POSITIVE												% POSITIVE	# POSITIVE/ TOTAL # TESTED
8	1987	Alcohol	THC	Cocaine	PCP	Opiates	Amphet.	THC & Alcohol	THC & Cocaine	THC & Amphet.			1.03	78/7556
	Employee	0	2	1	0	0	0	0	0	3				
	Contractor	2	42	5	0	0	0	1	3	0				
	1988	Alcohol	THC	Cocaine	PCP	Opiates	Amphet.	THC & Alcohol	THC & Cocaine	THC & Amphet.				
	Employee	0	7	0	0	0	0	0	0	7				
	Contractor	8	98	6	0	0	0	0	3	0				
	1989	Alcohol	THC	Cocaine	PCP	Opiates	Amphet.	THC & Alcohol	THC & Cocaine	THC & Amphet.				
	Employee	1	2	1	0	0	0	0	0	0				
	Contractor	5	62	4	0	0	0	0	0	0				
9	1984-1985 = 4.1% of those tested, tested positive 1986 = 3.0% 1987 = 2.6% 1988 = 2.2% 1989 = 1.4%												1.41	88/6241

CASE STUDIES

The nine plants included in the Pre-rule Drug Testing Survey are described below in case study form. Information obtained from each plant is described in a narrative format and summary pre-rule drug testing rates are presented.

Plant 1

Pre-rule drug testing at Plant 1 began in 1989; it included random, pre-access, pre-employment, and for-cause testing. Drugs included in the testing were amphetamine, barbiturates, benzodiazepines, cocaine, THC, methadone, methaqualone, opiates, phencyclidine, propoxyphene, and alcohol. GC/MS and EMIT clinical testing methods were employed at a local lab which was not NIDA certified. An EAP was offered as another component of the program, and limited training was provided. Drug searches were conducted during for-cause situations only.

Sanctions imposed prior to 1990 were identical to post-rule sanctions; first offense employees were treated as ill and given treatment for drugs or alcohol addiction and second-time offenders were terminated. Information was not available concerning the positive drug test rates under the pre-rule program.

Two differences between the pre-rule and post-rule testing at Plant 1 were identified. The first involved the drugs tested for; two drugs were added to the panel during the first six months after the rule was initiated. Since no positive tests were found for these two drugs, they were removed from the test panel. Second, the post-rule cutoff level for marijuana is higher than the pre-rule level.

Plant 2

Pre-rule drug testing began in 1986 at Plant 2 and included pre-access and pre-employment tests. Testing was conducted for the following drugs: amphetamine, barbiturates, benzodiazepines, cocaine, methaqualone, opiates, phencyclidine, THC, and alcohol. GC/MS and EMIT clinical testing methods were conducted at an outside lab. The program did not consist of any additional elements for utility employees.

Under the pre-rule program the positive drug test rate for this plant was 4.3 percent. Following a positive drug test during pre-rule testing, utility employees were permanently denied access while contractor employees were denied access for a minimum period of six months.

The primary difference between the pre-rule and post-rule drug testing was the inclusion of random drug testing in the post-rule program.

Plant 3

Plant 3 began pre-rule drug testing in November of 1985 and tested for amphetamine, barbiturates, benzodiazepines, THC, cocaine, opiates, phencyclidine, methaqualone, and alcohol. Initial testing was conducted in pre-employment and for-cause situations and, beginning in 1988, all non-union employees who had unescorted access were tested. Thereafter, all employees were tested during their annual physical. On-site pre-screening and confirmations were conducted using GC/MS clinical testing methods. The program also included various forms of training for all employees, provided access to EAP, and included the use of dogs in drug searches.

Under the pre-rule program (1985-1989) the positive drug test rate was .46 percent. A positive test on pre-employment resulted in not hiring. On a for-cause positive test, the employee's complete employment history was reviewed and EAP staff helped to determine whether rehabilitation should be considered. Based on this input, employees were either suspended or terminated.

Plant 4

Pre-rule drug testing began in 1985 and included barbiturates, methaqualone, benzodiazepines, amphetamine, cocaine, THC, phencyclidine, and opiates. Testing was first conducted for pre-access and for-cause, and in 1987 random drug testing of 3 to 5 percent (annually) of employees was added. All tests were conducted using the EMIT clinical testing method. Initially the program included an EAP; in 1987 supervisory training was initiated.

The positive drug test rate under the pre-rule program was .2 percent in 1988 and .5 percent in 1989. Contractor employees were terminated after the first positive drug test; permanent utility employees had their access revoked and were retested after 45 days. Upon a second positive test permanent employees were terminated.

Plant 5

Plant 5 began pre-rule drug testing in 1986 and included pre-access, pre-employment, biannual, and for-cause situations. The pre-rule program included tests for amphetamine, cocaine, opiates, phencyclidine, THC, and alcohol, and provided utility employees with access to an EAP and training.

Permanent employees and contractors tested positive in 4 percent of all tests (excluding pre-access) for the period 1987-1989. For the same period 2 percent of all pre-access tests were positive. No information was available concerning sanctions taken following a positive test.

The major difference identified between pre-rule and post-rule testing was the inclusion of random testing in the post-rule program.

Plant 6

Plant 6 began pre-rule testing in late 1985 and tested for 14 substances; amphetamine, barbiturates, cocaine, methaqualone, opiates, THC, phencyclidine, propoxyphene, hydromorphone, pentazocine, phenmetrazine, phenothizines, quinine, and meperidine. Types of testing included for-cause, pre-employment, periodic (annually with employee physical), promotion, and follow-up after the first positive. All tests were performed at an outside lab using EMIT and GC/MS testing methods. The program included an EAP and behavioral observation training for supervisors.

Of all tests conducted in 1985-1989 only two were positive in Plant 6. Sanctions included a no-hire decision after a pre-access positive test, and a 10-day suspension without pay, mandatory EAP referral, and 24 months of follow-up testing after a first positive for utility employees. A second positive test resulted in termination.

Pre-rule and post-rule testing programs differ in several ways. FFD staff indicated that the post-rule program is more "codified" (e.g., systematic), is more expensive, and allows management less flexibility than the pre-rule program. The addition of random testing causes logistical problems since there are two sites and only one drug testing location. Finally, the inclusion of alcohol in the post-rule program was identified as a difference and a problem due to ambiguity concerning appropriate sanctions.

Plant 7

Drug testing under a pre-rule program at Plant 7 began in 1986. Initial testing included pre-employment and for-cause, with random testing added in 1989. Drug tests included amphetamine, cocaine, opiates, phencyclidine, and THC. Using EMIT clinical testing methods, all tests, with the exception of for-cause tests, were sent to a lab. For-cause tests were conducted on-site. The program also included access to an EAP, searches, and the use of dogs for drug searches.

All positive tests, excluding those for alcohol, resulted in termination. Positive alcohol test results were dealt with on a case-by-case basis. No information was available concerning positive drug test rates under the pre-rule program.

FFD staff interviewed indicated that the post-rule program provides equal treatment of every employee and involves everyone in testing. FFD staff also noticed an increase in EAP use for the six months prior to enactment of the rule.

Plant 8

The pre-rule testing program at Plant 8 began in 1984. Testing included pre-employment, pre-access, and for-cause situations, with random testing at 20 percent of the work force. Drugs included were amphetamine, cocaine, THC, phencyclidine, opiates and alcohol. The EMIT clinical testing methodology was used off-site until 1986. On-site testing began in 1986 using the EMIT methodology, with a switch to the FPIA methodology in 1988. The program offered EAP and supervisory training to utility employees.

Permanent employees tested positive in 1.7 percent of all drug tests for the period 1987-1989. For the same period 3.1 percent of all contractor drug tests were positive. For the first positive test result, an employee was referred to an EAP and suspended for 14 days. Contractors were denied access after a positive drug test. A second positive test for an employee resulted in termination. For alcohol tests, an employee was terminated after the third positive test.

Two differences between the pre-rule and post-rule testing programs were cited. First, more training is now available for employees. Second, employees must come in more often for random tests.

Plant 9

Plant 9 initiated a drug testing program in September, 1984. Ten drugs were included in pre-rule drug testing: amphetamine, barbiturates, benzodiazepines, cocaine, methadone, methaqualone, opiates, phencyclidine, propoxyphene, and THC. Pre-access, annual, and for-cause testing was conducted under the program. Pre-screen analysis using EMIT methodology began in 1985, and GC/MS was used as it became available. The program included access to an EAP and introductory (one-time only) training until 1987, when training began to be provided annually. Dogs for drug searches have also been used in Plant 9.

Positive drug test rates for each year of the pre-rule program are as follows: 4.1 percent positive for 1984-1985; 3.0 percent in 1986; 2.6 percent in 1987; 2.2 percent positive in 1988; and 1.4 percent were positive in 1989. Initially sanctions were administered on a case-by-case basis. In May 1986 a four-"strike" (e.g., positive drug test) rule was established: on the first positive test no sanctions were administered; for the second positive test the employee was referred to treatment and suspended for 5 days; a third positive test resulted in a 30-day suspension; termination followed a fourth positive test. A three-strike rule was implemented in December, 1986, which eliminated the previous first strike. In November of 1988 a 2-strike rule was established: on the first positive test the employee was sent to rehabilitation, and suspended for 14 days; a second strike resulted in termination. Any positive results from for-cause testing resulted in immediate termination.

The primary difference cited between pre-rule and post-rule testing is that the rule has led to increased employee acceptance of a drug-testing program. In addition, the presence of the post-rule audits, inspections, and reporting were cited as having helped increase the quality of testing.

APPENDIX B

REPORT ON ON-SITE SCREENING, GC/MS CONFIRMATION, AND MRO CONFIRMED TESTS

The use of on-site screening tests as the basis for removal from duties covered by 10 CFR Part 26 is an issue currently being considered by the U.S. Nuclear Regulatory Commission (NRC). The NRC has proposed a revision to 10 CFR 26.24(d) that would prohibit licensees from taking any action based solely on a presumptive positive result from an on-site screening test. The key question is whether the increased benefit to public health and safety associated with removing individuals from duty who test positive on the initial screening test exceeds the harm done to those individuals who then are subsequently found to test negative on the GC/MS confirmation test. One technical issue associated with this question pertains to the accuracy and reliability of the on-site screening test. If the tests are highly reliable, only a few employees will be removed and then found not to be positive. Unfortunately, there is a lack of carefully controlled analyses of screening test accuracy and reliability in field applications similar to those encountered in the nuclear industry.

However, this report describes some initial data from on-site screening for drug use in ten nuclear utilities and compares those results to the results obtained by these utilities from GC/MS confirmation testing and Medical Review Officer (MRO) review of test results.

BACKGROUND

Testing for drugs of abuse in the workplace generally entails a series of steps. First, a low-priced screening test is conducted to identify urine samples with drug metabolites that are apparently above a predetermined level of concentration (cutoff level). Many nuclear utilities have found it useful to conduct screening tests on-site. Tests that are found to be positive using the screening technology are referred to as presumptive positive, pending a second, more rigorous testing of the sample through gas chromatography/mass spectrometry techniques (GC/MS). Finally, even the results from this highly accurate technique must be reviewed by an MRO to identify any legitimate medical explanations or potential problems with the testing process. Currently, federal agency testing programs prohibit personnel actions based solely on initial positive screening test results. The Department of Health and Human Services (HHS) Guidelines imply that on-site testing [see Section 2.5(d)(1) of the HHS Guidelines] and taking action before completing the MRO review process [see Section 2.7(a) of the HHS Guidelines] are prohibited. Assurance of this prohibition concerning federal employees was obtained by requiring each federal agency to develop a testing plan that was reviewed by both HHS and the U.S. Department of Justice.

These Federal agency programs differ from the NRC program in an important way, however. These programs were intended to be "demand reduction" programs and were not designed to achieve safety goals. The Federal testing process was designed to protect individual rights and to ensure that, if errors were made, the errors would favor the interest of the tested individual (other guidelines apply to the criminal justice system). Due to the centrality of safety concerns in the NRC's fitness-for-duty program, however, the criteria used in determining the desirable balance between protection of public health and safety and protection of employee rights may differ from the criteria in other programs. Some nuclear utilities have proposed that screening technology is sufficiently accurate and reliable, and public health and safety is so important that temporarily removing employees from duty based on a presumptive positive (screening) test is the most prudent and defensible course of action.

OVERVIEW

This report is based primarily on data received in response to a March 27, 1991 request for information made by the Commissioners to 10 utilities using on-site screening. The purpose of the report is to summarize the data received. Because the utilities currently are not required to collect such data on a routine basis, most did not have a system in place to collect them. Therefore, the accuracy of the data

cannot be assured. The report is descriptive; it does not make inferences or attempt to generalize beyond the data reported.

The report is organized into four sections:

- Description of the data
- Factors that may affect screening test results
- Screening, GC/MS, and MRO confirmed results of tests for the illegal drugs specified in 10 CFR Part 26 (THC, Cocaine, Opiates, Amphetamine, and PCP)
- Screening, GC/MS, and MRO confirmed positive results of tests for additional drugs.

Information regarding the results of specific testing programs is included in Appendix A.

DESCRIPTION OF THE DATA

Data from 10 utilities that represent the majority of the sites where on-site testing is conducted are included in this report. Table 1 lists the utilities that provided information. (Data from TVA and Commonwealth Edison were obtained prior to the Commission's status briefing of March 7, 1991, while the remaining eight utilities provided data in response to the Commissioners' request of March 27, 1991.) These utilities collected specimens at a total of 21 of the 27 sites known to NRC staff as having on-site testing. The utilities were geographically diverse, and all five regions were represented. The data reflected tests that were conducted on specimens collected during the calendar year 1990. During that time, a total of about 83,500 on-site screening tests were conducted by these utilities.

Utilities are not required to routinely collect the data that they provided for this report, and therefore most did not have a system established to collect and validate the data. However, the licensees provided the NRC with the data in as accurate and timely a manner as possible. We cannot, however, confirm the accuracy of the data. Therefore, the report provides only descriptive information about the data provided. The conclusions that might be drawn from the data used to generate this report are limited. Nevertheless, this report does provide an overview of what has happened in a sample that includes the majority of on-site screening tests administered to nuclear power plant workers.

FACTORS AFFECTING TESTING RESULTS

A large number of factors can potentially influence whether an individual tests positive on a screening test and whether that presumptive positive test is subsequently confirmed. The utilities in the sample reported three general factors that they believed to have affected test results from on-site screening. These were:

- use of lower cutoff levels
- use of different testing methodologies
- degradation of specimens.

While these factors were reported by the utilities as affecting results, they do not represent a comprehensive list of factors that may have affected test results. Further, the utilities did not provide systematic data to support their assumptions that these factors contributed to a lack of agreement between their on-site screening and the HHS lab confirmation testing results. These factors do, however, warrant some discussion.

Table 1 Utilities and Sites Included in On-Site Screening Analysis

UTILITIES	SITES
Arkansas Power and Light Company	Arkansas 1
Commonwealth Edison	Braidwood 1 & 2 Byron 1 & 2 Dresden 2 & 3 LaSalle 1 & 2 Quad Cities 1 & 2 Zion 1 & 2
Entergy Operations	Waterford
Northeast Utilities	Millstone 1, 2 & 3 Haddam Neck
Pennsylvania Power & Light Company	Susquehanna 1 & 2
Philadelphia Electric Company	Limerick 1 & 2 Peach Bottom 2 & 3
Public Service Electric & Gas Company	Salem 1 & 2 Hope Creek
Southern California Edison	San Onofre 1, 2 & 3
Tennessee Valley Authority	Bellefonte Browns Ferry 1, 2 & 3 Sequoyah 1 & 2 Watts Bar 1 & 2
Union Electric Company	Callaway

Use of Lower Cutoff Levels

Many of the licensees using on-site testing use lower screening levels than specified by 10 CFR Part 26. In the case of marijuana,¹ the use of lower cutoff levels is expected to result in:

- a larger number of positive test results from the screening tests (see Information Notice 91-10)
- a higher percentage of specimens that screen positive on-site not being confirmed by the HHS laboratory testing procedure.²

The intent of the screening tests is to screen out absolute negatives while avoiding screening out any specimens that may have any possibility of being positive (i.e., avoiding false negatives). The GC/MS test is then used to determine the true positives from all presumptive positives. The use of lower cutoff levels on-site is expected to result in more specimens being sent to a HHS-certified laboratory for testing. If the HHS-certified laboratory used a higher cutoff for the initial test (screening test at the laboratory site), a number of presumptive positives may be screened negative and not sent to GC/MS for confirmatory testing. Thus, lower cutoff levels would be expected to result in on-site screening tests that were less likely to be confirmed by GC/MS confirmation--but with a lower risk of eliminating some potentially positive specimens.

Use of Different Testing Methodologies

The use of different instruments is a factor that may affect the results. A review of different instruments used in the industry is provided below. However, it appears that at this time a direct comparison between machines may be extremely difficult because wide variation occurs among the environments in which the machines operate. Therefore, it is unknown how this factor will affect the results.

All screening tests performed at a licensee's on-site testing facility and by a laboratory certified by the U. S. Department of Health and Human Services must use an immunoassay that meets the requirements of the Food and Drug Administration (FDA) for commercial distribution [see Section 2.7(e)(1) of Appendix A to 10 CFR Part 26 and Section 2.4(e)(2) of the HHS Guidelines].

There are four basic types of immunoassay:

- enzyme immunoassay (EIA), which uses a protein enzyme to produce a chemical reaction
- radioimmunoassay (RIA), which uses a radioactive labeled drug
- fluorescence polarization immunoassay (FPIA) processes
- antigen-antibody agglutination (AGAB) processes.

Utilities and testing laboratories have access to a significant number and variety of suppliers, test kits, and testing processes. Therefore, the number of drug screening options available to a licensee or testing laboratory is quite large. A test must, however, meet four factors to be acceptable:

¹Since very few licensees used lower cutoff levels for drugs other than marijuana, the effects of cutoff level differences for other drugs is unknown.

²The HHS laboratory conducts a screening test on each specimen and a GC/MS confirmation test on each specimen found presumptively positive. In some cases the presumptive positive from on-site screening is found negative in the HHS laboratory screening test and in other cases it is found negative in the GC/MS confirmation test.

- sensitivity - the ability to reliably detect low concentrations
- specificity - the ability to identify a single chemical component in a mixture of chemicals and biological materials
- adaptability to automation
- cost.

When considering these factors to choose from among the four basic types of immunoassay, those in the drug testing profession have generally preferred the EIA. Of the four basic immunoassay types that are available, only EMIT and FPIA were used by the utilities in the sample for on-site screening. The utilities most commonly used the EMIT process (a form of EIA) marketed by the SYVA Corporation. Abbott Laboratories markets the FPIA polarization process. Three of the ten utilities included in this study use the FPIA process.

These immunoassay types (EMIT and FPIA) may be conducted on a variety of machines. Although other instruments are available, the utilities in the sample used instruments from the following manufacturers: ROCHE, Hitachi, SYVA, and Abbott Laboratories.

Of those utilities using the EMIT immunoassay, most use additional reagents provided in "confirmation kits" to reduce the number of false positives for amphetamine caused by prescription and over-the-counter drugs or reactions with other substances. (The FPIA immunoassay does not require these additional reagents.) Two types of "confirmation kits" are available, polyclonal and monoclonal.³ The difference between the two is that the polyclonal kit produces a greater number of presumptive positives that are not confirmed by GC/MS testing because of interactions with other substances, such as methylphenidate and ephedrine. The monoclonal kit, on the other hand, does not react with these substances and results in fewer presumptive positive results on the initial screening test that are not confirmed by GC/MS testing.

The possible combinations of immunoassays, "confirmation kits," and instruments are quite large. Some utilities used more than one combination during 1990 because they switched to a different "confirmation kit" during the course of the year. Table 2 shows the combinations used by the ten utilities in the sample at the end of 1990. The numbers in the table represent the number of utilities using a particular combination, blanks connote no utility used the combination during 1990.

Some of the utilities reported switching to the monoclonal "confirmation kits" during the year. In one case (Southern California Edison), the percentage of presumptive positives for amphetamine declared positive by an MRO was 6.2 percent before the monoclonal kits were used, and 45.1 percent after their introduction to on-site prescreening.

The possible combinations used by the laboratories to conduct screening tests were also diverse (see Table 3). The amount of information for the laboratories was sparse compared to the information about

³The term "confirmation kit" is used for convenience. It does not connote that the polyclonal or monoclonal kits confirm or disconfirm the on-site prescreening. The confirmation kits are used to reduce the number of presumptive positives for amphetamines that will not be confirmed in an HHS-certified laboratory with GC/MS testing.

**Table 2 Combinations of Basic Immunoassay, "Confirmation Kit,"
and Testing Instruments**

Immunoassay	EMIT		FPIA
	Polyclonal "Confirmation Kit"	Monoclonal "Confirmation Kit"	No "Confirmation Kit" Needed
Instrument			
Abbott TDx			2
Abbott ADx			1
Hitachi		2	
SYVA ETS	1	3	
ROCHE	1		

* Hitachi makes multiple models. Two different models may have been used.

Table 3 Combinations of Basic Immunoassay, "Confirmation Kit," and Instruments Used by the Laboratories Serving the 10 Utilities in the Sample

Immunoassay	EMIT		FPIA
	No "Confirmation Kit" Reported*	Monoclonal "Confirmation Kit"	No "Confirmation Kit" Reported*
Instrument			
Abbott TDx			2
Hitachi**	3	3	
SYVA ETS	1		
Olympus 5000		1	

* The HHS certified laboratories are not required to use a "confirmation kit" for screening tests at the laboratories. Some laboratories use either monoclonal "confirmation kits," another immunoassay (e.g., FPIA), or submit all presumptive positives for GC/MS confirmation testing. It is currently unknown which approach each laboratory used.

** Hitachi makes multiple models of test equipment. Several different models may have been used.

the on-site prescreening of the utilities. For example, some utilities did not report if the laboratories used a "confirmation kit." One of the utilities, but none of the HHS laboratories, used a ROCHE instrument. One of the HHS-certified laboratories used an Olympus 5000 instrument, an instrument not used by any of the utilities for on-site screening.

Specimen Degradation

Another factor reported by some utilities that may have affected the results is specimen degradation, perhaps during shipping and associated with excessive heat, cold, or delay. Some utilities reported small numbers of specimens were degraded during the process, but they did not report how many. However, the MRO at one utility (Union Electric Company) reported that he believes 19 of the 21 presumptive positives not confirmed by GC/MS confirmation testing were not confirmed due to degradation of the samples during shipment. Although it is unknown at this time how these factors contributed to lack of agreement between on-site screening and certified lab tests, the National Institute on Drug Abuse indicated that sample degradation is unlikely if the specimens are tested within a reasonable period of time after collection. This is obviously an area that deserves closer scrutiny because of the opportunity to improve procedures for on-site testing.

SCREENING, GC/MS, AND MRO CONFIRMED POSITIVE RESULTS FOR ILLEGAL DRUGS SPECIFIED IN 10 CFR PART 26. (THC, COCAINE, OPIATES, AMPHETAMINE, AND PCP)

The utilities are required to test for the following drugs under 10 CFR Part 26:

- THC
- cocaine
- opiates
- amphetamine
- PCP.

Table 4 was compiled from the data reported by ten utilities concerning the five drugs for which testing is required. A total of 2,693 presumptive positives was identified through prescreening on-site during 1990 at the 10 utilities.

Of the 2,693 presumptive positives identified by on-site screening, 1,137 tested positive in the laboratory using GC/MS. However, not all presumptive positive specimens were given confirmatory tests in HHS-certified laboratories. Three reasons may have contributed to this condition: (1) some specimens were determined negative during screening at the HHS-certified laboratory, (2) some specimens close to the cutoff level during on-site testing degraded to the point where they were below the screening level at the laboratory, and (3) some specimens did not contain a sufficient quantity of urine to complete both the screening and confirmatory tests at the laboratory. It was also reported that one specimen was lost during shipment and was declared "no test."

Of the 1,137 specimens that were confirmed positive with GC/MS, MRO review of the laboratory reports and information provided by interviews with workers resulted in 811 MRO confirmed positive results. The remaining 326 results were found by the MROs to be attributable to responsible use. Reasons for responsible use included eating poppy seeds (in the case of opiates) and taking over-the-counter amphetamine (e.g., diet pills, nasal spray). The data concerning THC responsible use provided by two utilities also included the two tests declared negative by MRO because of testing procedure problems.

Table 4 Results of Drug Tests for 10 Utilities for Five Types of Drugs That Utilities Are Required to Test

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed Positives	Responsible Use	Declared Positives
THC	778	492	2	490
Cocaine	290	260	0	260
Opiates	655	332	319	13
Amphetamine	887	50	5	45
PCP	83	3	0	3
TOTAL	2,693	1,137	326	811

The drugs with the greatest number of presumptive positives were amphetamine, THC, and opiates. More than twice as many presumptive positives were found for each of these drugs than for cocaine, the next most frequent drug. For amphetamine and opiates, however, only a small number of the confirmed positives reported by the laboratory were eventually declared positive by an MRO. In contrast, most of the laboratory confirmed positives for THC, cocaine, and PCP were declared positive by an MRO.

Table 5 compares the tests that are performed during the process as a function of chronologically preceding tests. The comparisons in the table are represented as percentages. For example, the column on the extreme left of the table shows the number of on-site presumptive positives divided by the total number of prescreening tests done on-site.

The number of prescreening presumptive positives compared to the total number of tests is 3.2 percent for the entire sample. This is a strong indication that prescreening on-site reduces costs that would be incurred in testing more than 80,000 specimens in the laboratory. In addition, there are costs and system vulnerabilities related to the shipment of specimens and accounting procedures associated with HHS lab testing.

The degree of agreement between prescreening tests and GC/MS confirmation tests varies widely by drug type. Presumptive positives for cocaine are confirmed by the laboratories almost 90 percent of the time. On the other hand, the laboratory confirmation rate of presumptive positives for amphetamine and PCP is less than 10 percent. The confirmation rate for amphetamine may be attributable to interactions with other substances despite the use of "confirmation kits." Also, other drugs have been shown to produce false screening positives for PCP, such as chlorpromazine, thioridazine, and dextromethorphan. The latter drug, dextromethorphan is a common ingredient in many over-the-counter cough suppressants. This drug could, therefore, account for presumptive positives and GC/MS results being divergent.

There is a very high rate of agreement between the MROs' decisions and the laboratory GC/MS confirmed positives, except for opiates. For opiates, MROs found a high number of alternative explanations, such as eating poppy seeds and ingesting legally prescribed cough suppressants that contain opiates.

Utilities differed in the cutoff levels used for on-site screening tests (for determining presumptive positives) for THC. Of the ten utilities, two used a 20ng/ml cutoff level, six used a 50ng/ml cutoff level, and two used the 100ng/ml maximum cutoff level allowed by 10 CFR Part 26 (see Table 6). Two utilities also used a lower cutoff level (10ng/ml) for GC/MS confirmation testing; the other eight utilities used the 15ng/ml GC/MS cutoff level required by 10 CFR Part 26.

In general, the expected lower GC/MS confirmation rate for utilities using lower cutoff levels for screening was reflected in the outcomes. For the eight utilities using the 15ng/ml GC/MS cutoff level, those using a 20ng/ml for on-site screening had a 52.9% confirmation rate, those using a 50ng/ml for on-site screening had a 78.6% confirmation rate, and those using a 100ng/ml for on-site screening had a 88.5% confirmation rate. The very low percentage of MRO declared positives for the HHS-certified laboratories using a 10ng/ml cutoff level for GC/MS confirmation testing was anomalous for unknown reasons.

**Table 5 Percent Positive Rates at Successive Steps
in the Testing Process for 10 Utilities**

Drug	On-site Presumptive Positives/Total Number of Prescreen Tests	Laboratory GC/MS Confirmed Positives/ On-site Presumptive Positives	MRO Declared Positives/ On-site Presumptive Positives	MRO Declared Positives/ Laboratory GC/MS Confirmed Positives
THC	.9	63.2	62.9	99.6
Cocaine	.3	89.7	89.7	100.0
Opiates	.8	50.7	2.0	3.9
Amphetamine	1.1	5.6	5.1	90.0
PCP	.1	3.6	3.6	100.0
TOTAL	3.2	42.2	30.1	71.3

Table 6 Results of Different Cutoff Levels for THC

Number of Utilities Using the Cutoff Level	On-Site Screening Positives (ng/ml)	Laboratory Confirmation (ng/ml)	On-Site Prescreen Positives	Laboratory GC/MS Confirmed Positives	MRO Declared Positives	MRO Declared Positives/On-Site Screened Positives
2	20	15	346	183	183	52.9%
4	50	15	173	*138	*136	78.6%
2	100	15	131	116	116	88.5%
2	50	10	128	55	55	43.0%

*The MROs declared two specimens not to be positive because of problems with the test procedure.

SCREENING, GC/MS, AND MRO CONFIRMED POSITIVE RESULTS FOR ADDITIONAL DRUGS

Some utilities voluntarily test for other drugs that may cause impairment. These drug tests are not required by 10 CFR Part 26. A number of types of substances exist in the drug classes discussed in this section, but the utilities only reported results for general classes of drugs (e.g., barbiturates and benzodiazepines). The utilities also did not report the cutoff levels that were used for on-site prescreening. Therefore, the data reported for each class of drugs may be the result of several different testing procedures. For the purpose of this report, the data provide some information regarding the percentage of tests found presumptive positive on-site that are eventually confirmed by the MRO. Six of the utilities reported testing for a broader panel of drugs than the five specified in the rule. Additional drugs tested included:

- barbiturates
- benzodiazepines
- methadone
- methaqualone
- propoxyphene.

Of these utilities testing for additional drugs, all 6 found presumptive positives for benzodiazepines, 5 found presumptive positives for barbiturates, 2 found presumptive positives for methadone, 2 found presumptive positives for methaqualone, and 2 found presumptive positives for propoxyphene. Table 7 lists the number of presumptive positives, the number of laboratory GC/MS confirmed specimens, and the disposition by an MRO of the GC/MS confirmed specimens. There were a total of 165 on-site prescreen positive results for barbiturates, 274 prescreen positive results for benzodiazepines, 3 on-site prescreened positive results for methadone, 0 positive on-site prescreened positive results for methaqualone, and 13 on-site prescreened positive results for propoxyphene.

Most important, in Table 7, is that only 10 MRO declared positive cases occurred across all the additional drugs tested, 2 for barbiturates and 8 for benzodiazepines. No specimens were declared positive by an MRO for methadone, methaqualone, and propoxyphene. MROs found alternative explanations for why barbiturates and benzodiazepines were found in some specimens. Both types of drugs are commonly prescribed by a physician.

In the case of benzodiazepines, the number of MRO decisions does not equal the number of laboratory confirmed positives. We do not have an explanation for that difference at this time.

Overall, the percentages are uniformly low for all drugs in all categories. Three drug types did not have a single GC/MS confirmed positive or MRO declared positive. Table 8 shows the percentages for several steps in the testing procedure for drugs for which the utilities voluntarily test. Also, for the two drugs for which a relatively large number of on-site presumptive positives were found (barbiturates and benzodiazepines), the percentage of MRO declared positives was less than 1 percent of the number of on-site presumptive positives.

Table 7 Results of Drug Tests for 10 Utilities for Five Types of Drugs That Utilities Voluntarily Test

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed Positives	Responsible Use	Declared Positive
Barbiturates	165	106	104	2
Benzodiazepines*	274	165	159	8
Methadone	3	2	2	0
Methaqualone	0	0	0	0
Propoxyphene	13	11	11	0
TOTAL	455	284	276	10

Note: Not all utilities test for all of these drug types.

- * The data concerning benzodiazepine MRO decisions also included the negative tests that were caused by testing procedure problems.

**Table 8 Comparison of the Percentages at Several Steps for Utilities
Reporting On-Site Presumptive Positives**

Drug	On-site Presumptive Positives/Total Number of Prescreen Tests	Laboratory GC/MS Confirmed Positives/ On-site Presumptive Positives	MRO Declared Positives/ On-site Presumptive Positives	MRO Declared Positives/ Laboratory GC/MS Confirmed Positives
Barbiturates	.5	64.2	.01	.02
Benzodiazepines	.5	60.2	.03	.05
Methadone	.02	66.7	0.0	0.0
Methaqualone	0.0	0.0	0.0	0.0
Propoxyphene	.09	84.6	0.0	0.0

SUPPORTING DATA

**Table B.1 Breakdown of Screening/Confirmation Data
for Arkansas Power and Light***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	76	65	1	64
Cocaine	7	7	0	7
Opiates	33	24	24	0
Amphetamine	25	3	0	3
PCP	2	0	0	0
TOTAL	143	99	25	74

* Arkansas Power and Light used the FPIA immunoassay on a Abbott Laboratories TDx instrument to screen on-site. The HHS certified laboratory used the FPIA immunoassay on an Abbott Laboratories TDx.

**Table B.2 Breakdown of Screening/Confirmation Data
for Commonwealth Edison***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	325	171	0	171
Cocaine	94	73	0	73
Opiates	125	50	48	2
Amphetamine	249	2	2	0
PCP	69	1	0	1
TOTAL	862	297	50	247

- * Commonwealth Edison used the EMIT immunoassay on a SYVA ETS instrument with polyclonal "confirmation kits" for on-site testing. The HHS certified laboratory used the EMIT immunoassay on a Hitachi instrument with monoclonal "confirmation kits."

**Table B.3 Breakdown of Screening/Confirmation Data
for Entergy Operations***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	12	4	0	4
Cocaine	1	1	0	1
Opiates	18	11	11	0
Amphetamine	11	0	0	0
PCP	8	0	0	0
TOTAL	50	16	11	5

- * Entergy Operations used the FPIA immunoassay on an Abbott Laboratories TDx instrument. For on-site testing the HHS certified laboratory used the FPIA immunoassay on an Abbott Laboratories TDx instrument.

**Table B.4 Breakdown of Screening/Confirmation Data
for Northeast Utilities***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	45	36	0	36
Cocaine	32	28	0	28
Opiates	55	45	44	1
Amphetamine	17	1	0	1
PCP	0	0	0	0
TOTAL	149	110	44	66

- * Northeast Utilities used the EMIT immunoassay on a SYVA ETS instrument with monoclonal "confirmation kits" to screen on-site. The HHS certified laboratory used the EMIT immunoassay on a Hitachi instrument.

**Table B.5 Breakdown of Screening/Confirmation Data
for Pennsylvania Power and Light Company***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	11	3	0	3
Cocaine	3	3	0	3
Opiates	16	11	11	0
Amphetamine	22	1	0	1
PCP	1	0	0	0
TOTAL	53	18	11	7

- * Pennsylvania Power and Light Company used the EMIT immunoassay on a SYVA ETS instrument with monoclonal "confirmation kits" to screen on-site. The HHS certified laboratory used the EMIT immunoassay on a Hitachi instrument.

**Table B.6 Breakdown of Screening/Confirmation Data
for Philadelphia Electric Company***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	54	50	0	50
Cocaine	63	59	0	59
Opiates	68	48	45	3
Amphetamine	73	4	0	4
PCP	0	0	0	0
TOTAL	258	161	45	116

- * Philadelphia Electric Company used the EMIT immunoassay on a Hitachi instrument with monoclonal "confirmation kits" to screen on-site. The HHS certified laboratory used the EMIT immunoassay on an Olympus 5000 instrument with monoclonal "confirmation kits."

**Table B.7 Breakdown of Screening/Confirmation Data
for Public Service Electric & Gas Company***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	40	33	1	32
Cocaine	32	32	0	32
Opiates	71	41	41	0
Amphetamine	25	5	0	5
PCP	2	1	0	1
TOTAL	170	112	42	70

- * Public Service Electric & Gas Company used the EMIT immunoassay on a Hitachi instrument with monoclonal "confirmation kits" to screen on-site. The HHS certified laboratory used the EMIT immunoassay on a Hitachi instrument. The utility and laboratory use different models of Hitachi instruments.

**Table B.8 Breakdown of Screening/Confirmation Data
for Southern California Edison***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	117	52	0	52
Cocaine	21	21	0	21
Opiates	79	48	48	0
Amphetamine	164	30	0	30
PCP	0	0	0	0
TOTAL	381	151	48	103

- * Southern California Edison used the EMIT immunoassay on a ROCHE COGAS FARA instrument with polyclonal "confirmation kits" to screen on-site. The HHS certified laboratory used the EMIT immunoassay on a Hitachi instrument with monoclonal "confirmation kits."

**Table B.9 Breakdown of Screening/Confirmation Data
for Tennessee Valley Authority***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	77	66	0	66
Cocaine	33	32	0	32
Opiates	184	49	42	7
Amphetamine	300	4	3	1
PCP	0	0	0	0
TOTAL	594	151	45	106

- * Tennessee Valley Authority used the EMIT immunoassay on a SYVA ETS instrument with monoclonal "confirmation kits" to screen on-site. The HHS certified laboratory used the EMIT immunoassay on a SYVA instrument.

**Table B.10 Breakdown of Screening/Confirmation Data
for Union Electric Company***

	On-Site	Laboratory	MRO Decision	
Drug	Prescreen Positives	GC/MS Confirmed	Responsible Use	Positive
THC	21	12	0	12
Cocaine	4	4	0	4
Opiates	6	5	5	0
Amphetamine	1	0	0	0
PCP	1	1	0	1
TOTAL	33	32	5	17

- * Union Electric Company used the FPIA immunoassay on an Abbott Laboratories ADx instrument to screen on-site. The HHS certified laboratory used the EMIT immunoassay on a Hitachi instrument with monoclonal "confirmation kits."

APPENDIX C

DETECTION EFFECTIVENESS OF FITNESS-FOR-DUTY RANDOM TESTING RATES AND FEATURES: ANALYTIC COMPARISON OF NINE SELECTED ALTERNATIVES

1 INTRODUCTION

The optimal random drug testing program is one that maximizes both detection and deterrence of substance abuse while minimizing monetary and social costs (e.g., employee morale). The ability to design an optimal program for the nuclear power industry is currently constrained by lack of information about patterns of drug use at nuclear facilities. Both the types of drugs and the frequency with which they are used will determine the relative detection effectiveness of different testing programs with disparate random testing rates and feature alternatives. Consequently, some approaches may be more detection effective if the population is made up of continuous users, while others may be more appropriate if the population is made up primarily of occasional drug users.

A simulation modeling approach was adopted to investigate the importance of user and program characteristics for detection effectiveness. A model was specified using nine alternative random testing rates and three different plausible drug user distributions. The model was then used to estimate the proportion of drug users in the population that would remain undetected for each possible combination of program and drug user characteristics. Further, detection rates were modeled for occasional drug user distributions which vary in frequency of drug use (once a year, twice a year, four times a year, and twelve times a year).

It is important to note at this point that detection effectiveness and deterrence effectiveness are very different things. Detection effectiveness refers to the probability of detecting drug use in a plausible user distribution. It does not include relative suppressions of use, i.e., deterrence effects. While this modeling effort allows us to estimate the detection effectiveness associated with various programs and user distributions, it does not allow us to predict the actual percentage of the population using drugs (since this percentage depends on the type and frequency of drug use) nor does it allow us to estimate what kinds of deterrence effects these programs may be having on the various user populations. Suggestions for further study into the area of deterrence are discussed in the final section of this appendix.

2 METHOD

This section describes the statistical modeling used to analytically evaluate the effects of testing alternatives and user distributions. Characterized in turn are: nine testing rate and feature alternatives (Section 2.1), three plausible user distributions (Section 2.2), and the modeling procedure used to evaluate the effects of the testing alternatives under each user distribution (Section 2.3).

2.1 Testing Rate and Feature Alternatives

The NRC fitness-for-duty (FFD) rule (10 CFR Part 26) currently requires that all personnel having unescorted access to protected areas of power reactors be subject to random testing for certain drugs and alcohol. Annual random testing must be conducted at a rate such that the number of tests at least equals the average number of covered personnel. This analysis was conducted using the following nine testing rate alternatives which contain sampling approaches with rates both above and below this current minimum 100% requirement:

- 100% Standard Approach -- this is achieved through 52 weekly testings of a completely random selection of a balancing fraction ($1/52$) of the covered personnel.¹
- 100% Tailored Approach -- this is similar to the 100% Standard Approach in that there are weekly random testings of about $1/52$ of the covered personnel, but the selection rate for recently tested personnel (within a calendar year time frame) is half that for untested personnel.²
- 100% Tailored Two Year Cycle Approach -- this is similar to the 100% Tailored Approach in that there are weekly random testings of about $1/52$ of the covered personnel, and the selection rate for recently tested personnel is half that for untested personnel, but the process continues for two calendar years rather than ending at the end of one calendar year.
- 25% Standard Approach -- this is achieved through weekly testings of a completely random selection at one quarter of the 100% Standard Approach fraction of the covered personnel currently working ($0.25/52$).
- 25% Tailored Approach -- this is similar to the 100% Tailored Approach in that the selection rate for recently tested personnel (within a calendar year time frame) is half that for untested personnel, but there are weekly random testings of about $.25/52$ of the covered personnel.
- 50% Standard Approach -- this is achieved through weekly testings of a completely random selection at half the 100% Standard Approach fraction of the covered personnel currently working ($0.50/52$).
- 50% Tailored Approach -- this is similar to the 100% Tailored Approach in that the selection rate for recently tested personnel (within a calendar year time frame) is half that for untested personnel, but there are weekly random testings of about $0.50/52$ of the covered personnel.
- 150% Standard Approach -- this is achieved through weekly testings of a completely random selection 50% greater than the 100% Standard Approach fraction of the covered personnel currently working ($1.5/52$).
- 150% Tailored Approach -- this is similar to the 100% Tailored Approach in that the selection rate for recently tested personnel (within a calendar year time frame) is half that for untested personnel, but there are weekly random testings of about $1.5/52$ of the covered personnel.

These nine testing alternatives will allow initial exploration of the effects of various sampling strategies and rate variations. Because they include both higher and lower rates of testing than

¹ This approach is similar to that currently most frequently applied in the nuclear industry. Some utilities, however, currently employ an approach similar to the 100% Tailored Approach.

² The Tailored Approach was suggested by Barnes et al. (1988). They showed that a greater percentage of personnel would be tested using such an approach than would using the random approach advocated by other authors (e.g., Burtis, Owings, & Lette, 1987).

is currently required by the NRC rule, a realistic assessment can be made of possible programs using testing rates that range around the required rate.

2.2 Plausible Drug User Distributions

The distribution of drug users, by type of drug used and frequency of use, has a substantial impact on the estimates of the total number of drug users that would be expected in the licensee employee population. These effects are discussed below.

2.2.1 Three drug user distributions were selected based upon their consistency with recent detection rate experience from random testing of licensee employees reported at the end of the first year of testing under the FFD rule (Durbin et al., 1991a).³ Specifically, these distributions were chosen for use in this study because they yield an overall first year positive rate of 0.3 percent under a 100% Standard Approach.⁴ Because of this overall consistency, these distributions may be deemed plausible though differing in specific detection details regarding the mix of detected drugs (in other than the Continuous Drug User distribution). The discussions of occasional user distributions here are based on very low (2 times per year) occasional use. The effects of using more frequent occasional user distributions are discussed in Section 2.2.2, below. The three user distributions are:

- Continuous Drug Users -- this first distribution is composed of (1) 0.47 percent of persons who use drugs so frequently that their use is continuously detectable (e.g., more often than once every two weeks for marijuana or every half week for cocaine) and (2) the remaining 99.53 percent, who are continuously drug free.
- Occasional Drug Users: Long Duration Drugs -- this second distribution is composed of (1) 4 percent who use on the average of only twice a year a drug that remains detectable for a relatively long duration (e.g., marijuana with a two week "window" of post-use detectability) and (2) 96 percent nonusers.
- Occasional Drug Users: Short Duration Drugs -- this third distribution is composed of (1) 15 percent who use on the average of only twice a year a drug that remains detectable for a relatively short duration (e.g., cocaine and other drugs which average a 3.5-day "window" of post-use detectability) and (2) 85 percent nonusers.

Note that forming a combined distribution with half drawn from the Long Duration and Short Duration drug users groups will yield a mix of detected drugs consistent with that reported by Durbin et al. (1991a). Various other combinations could be developed as well. For example, if one-third of the positives came from each of the three categories, a 0.3 percent positive rate would result from 0.16 percent drawn from Continuous Users, 1.6 percent drawn from Occasional Users: Long Duration Drugs, and 5 percent drawn from Occasional Users: Short

³ Licensee employees experienced a 0.28 percent positive rate for random testing during 1990. This result was rounded to 0.3 percent for the purposes of this analysis.

⁴ Determination of the specific percentages of users in the three user distributions was accomplished analytically. Continuous Drug Users, for example, would be detected if tested. However, only about 63.6% of nuclear plant personnel are tested over a one-year period using a 100%-Standard-Approach (see Burtis et al., 1987; Barnes et al., 1990). Hence, the 0.3% detected users found by Durbin et al. (1991) corresponds to only 63.6% of the user population. Thus, the actual percentage of continuous users is approximately 0.47%.

Duration Drugs. The three distribution alternatives chosen provide for an initial comparison of the differing effects of continuous and occasional distributions on user detection.

- 2.2.2** The twice-a-year drug use frequency assumed in the two occasional user distributions was chosen arbitrarily, as noted above. Until the actual percentage of user type and frequency of drug use is determined by future research, we can only estimate detection rates. Of these two factors, frequency of use has the largest impact on the rate at which users are detected. The more often an occasional user uses a drug, the more likely random testing will detect that drug use.

Figure 1 shows numerical examples of this relationship by relating frequency of drug use to the number of users of both short and long duration drugs who would have to be in the population to match the 0.3 percent detection rate that occurred during the first year of program operation.⁵ The data presented in this figure were calculated assuming that the 100% Standard Approach is the testing approach being used. As shown in Figure 1, only 0.47 percent of the population would actually have to be drug users to obtain an annual detection rate of 0.3 percent if all users were continuous users. If the population were made up entirely of occasional users of short duration drugs (with a 3.5-day window of detectability) using drugs twice a year, however, users would be detectable only about seven days out of the whole year. In order to obtain a detection rate of 0.3 percent with this population, 15.75 percent of the population would actually have to be using drugs. If, however, users of short duration drugs used as frequently as 12 times a year, there would be 42 days in the year on which each would be detectable. In this case, only about 2.75 percent of the population would have to be using drugs in order to obtain a 0.3 percent detection rate. The same relationship between frequency of drug use and detectability holds for users of long duration drugs. As shown in the figure, as many as 4.05 percent of the population would have to be twice-a-year users of long duration drugs to obtain a 0.3 percent annual detection rate. If such people used drugs 12 times a year, however, only 0.81 percent of the population would have to be users to obtain that detection rate. As will be discussed in Section 3.3, the numbers and types of users also have an impact on the proportions of those detected by different random testing approaches over a five year period.

2.3 Evaluation Procedure

An iterative modeling procedure was used to evaluate the progressive week-to-week effectiveness of each testing alternative over a five-year period. Figure 2 illustrates the flow of this process which begins with input user distribution characteristics (e.g., Occasional Drug User: Long Duration). Incrementally, this is then followed by three steps for each week of testing until the last (52nd) week in a year is reached: (1) evaluation of the weekly proportion of detected users,⁶ (2) evaluation of the cumulative proportion of detected users, and (3)

⁵ Since not everyone is tested in a one year period with the 100% Standard Approach, it is expected that the actual number of users is slightly higher than the number of users detected.

⁶ This weekly detected proportion, $p(d)$, is computed using the relationship: $p(d) = p_t \cdot p_u \cdot p_d$ where p_t is the weekly testing rate (e.g., a constant 1/52 for "100% Standard"), p_u is the proportion of users currently in population (e.g., 4% initially for "Occasional Users: Long Duration Drugs"), and p_d is the constant proportion of the year that users are detectable (e.g., 2/52 for "Occasional Users: Long Duration Drugs"). Tailored testing evaluations require two computations using the $p(d)$ relationship, one for the previously tested and one for the untested.

Figure 1 Calculated percentage of population using drugs by annual frequency of drug use to obtain 0.3 percent detection rate

Figure 2 General flow of evaluation procedure

characterization of the remaining user distribution (relative proportions of users and total remaining). After the last week in the year is reached, the relative proportion of remaining users is computed and the result is documented as the annual remaining proportion of users. This process is then continued until reaching the last (5th) year. This process was used for each of the nine testing approaches. This simulation allows for the calculation of the percentage of detected users over the five year span. Comparison of testing programs across user distributions is made on the basis of percent detected at the end of the five-year time span.

3 RESULTS

This section evaluates the effectiveness, in terms of detection, of the nine alternative testing approaches as applied to each of the three user distributions. Detection effectiveness is measured by the extent to which the various user populations are detected over a five year period. A total population of users and nonusers of 1,000 people was chosen to portray the numeric results for each of the three distributions in Tables C.1 through C.7. This 1,000-person assumed population is similar to the actual average number of licensee employees subject to random testing in each licensee power plant. Licensee program performance reports indicate that, on average, there were 1,186 licensee employees covered by each program performance report from licensees during 1990 (Durbin et al., 1991a). The results of this analysis, therefore, provide a fairly close approximation of the impacts of the testing alternatives as applied to groups similar in number to that of employees within FFD programs, given the assumed drug use characteristics of the three user distributions.

There are three consistent findings of these analyses. First, the more tests done in a single year, the more rapidly the expected number of users decreases, regardless of drug used or user type. Second, tailored approaches are more efficient than standard approaches in reducing the expected number of drug users in the population. Note, for example, that although a 100% Standard Approach and a 100% Tailored Two Year Cycle Approach each require the same number of tests per year, the 100% Tailored Two Year Cycle Approach reduces the expected number of drug users (regardless of user type) somewhat more rapidly. Third, assumptions regarding the type of drug used and the frequency of use greatly affect the length of time required to effectively eliminate drug users from a population. That is, the number of times an individual uses a drug over the course of a year and the length of time that drug stays in the system affect the probability of detection for an individual. The degree to which these two variables affect the probability of detection can best be demonstrated by examining the two extreme cases as measured by type and frequency of drug use. Because continuous users (of both long and short duration drugs) are at risk of having their drug use detected 365 days per year, all testing approaches effectively eliminate users of this type over a five year period. In fact, the majority of continuous users will have been eliminated by the end of the second year of testing, no matter which testing approach is used. In contrast, none of the testing approaches examined here is particularly effective at eliminating users of short duration drugs who use only two times per year. This ineffectiveness is due to these users being at risk of having their drug use detected only seven days per year.

3.1 Continuous Drug Users

Each cell in Table C.1 contains the percentage and number (in parentheses) of undetected users remaining in the population after each of the nine alternative testing approaches was applied to the Continuous Drug Users distribution. At the beginning of the period in Year 0, this

Table C.1 Percentage and number of users (per 1,000) remaining as a function of testing approach and duration for continuous users

TESTING APPROACH	YEARS OF TESTING					
	0	1	2	3	4	5
100% Standard	100% (4.71)	36.4% (1.71)	13.3% (0.62)	4.8% (0.23)	1.8% (0.08)	.6% (0.03)
100% Tailored	100% (4.71)	27.5% (1.30)	7.6% (0.36)	2.1% (0.10)	.6% (0.03)	.2% (0.009)
100% Tailored, 2 Year Cycle	100% (4.71)	27.5% (1.30)	4.5% (0.21)	1.3% (0.06)	.06% (0.003)	.02% (0.001)
25% Standard	100% (4.71)	77.8% (3.67)	60.64% (2.85)	47.2% (2.22)	36.7% (1.73)	28.6% (1.34)
25% Tailored	100% (4.71)	76.6% (3.61)	58.7% (2.76)	44.9% (2.12)	34.4% (1.62)	26.4% (1.24)
50% Standard	100% (4.71)	60.5% (2.86)	36.6% (1.73)	22.2% (1.04)	13.4% (0.63)	8.1% (0.38)
50% Tailored	100% (4.71)	56.6% (2.67)	32.1% (1.54)	18.1% (0.85)	10.3% (0.48)	5.8% (0.27)
150% Standard	100% (4.71)	21.8% (1.03)	4.8% (0.22)	1.0% (0.05)	.2% (0.009)	.05% (0.002)
150% Tailored	100% (4.71)	11.5% (0.54)	1.3% (0.06)	.2% (0.009)	.02% (0.001)	<.01% (<0.001)

distribution originally contained 0.47 percent continuously detectable users, or 4.71 users per 1,000 persons. The results in Table C.1 indicate that the 150% Tailored Approach would be the most effective in detecting continuous users insofar as it reduces the population of users most rapidly and produces the lowest absolute number of users--0.001 person--left in the population after five years. For practical purposes, however, all approaches except for the 25% Standard and 25% Tailored would be essentially equivalent in detection effectiveness in that they all eliminate essentially all continuous users after five years. The 25% Standard Approach would be the least effective of all the approaches in that it would leave 1.34 continuous users--or 29 percent of the original user population--at the end of Year 5. Differences among the alternatives are most pronounced at the end of the first year. At that time, the 25% Standard still has 3.7 remaining users versus 0.5, 1.0, 1.3, and 1.3 users for the 150% Tailored, 150% Standard, 100% Tailored, and 100% Tailored 2 Year Cycle Approaches, respectively.

It should be noted that the data presented in Table C.1 indicate that the majority of continuous users will have been eliminated after two years under the 100% Standard Approach. Because licensees will have been testing on a random basis for at least two years prior to any change in testing rates that the Commission may consider, we would expect that all continuous users (except for a relatively few coming into the workforce or becoming continuous users after the first two years of the program) will have been detected before the testing rates are changed. If that is indeed the case, there would be little reason to consider efficiency in the detection of continuous users when reviewing the merits of alternative random testing rates.

3.2 Occasional Drug Users: Long Duration Drugs

Each cell in Table C.2 contains the percentage and number (in parentheses) of undetected users remaining in the population after each of the nine alternative testing approaches was applied to the Occasional Drug Users: Long Duration Drugs distribution. Occasional users of long duration drugs, it will be recalled, would constitute 4 percent of the population and be assumed to use long duration drugs, such as marijuana, with two-week windows of post-use detectability twice a year. This table shows that the initial expected 40 users per 1,000 persons in Year 0 would be reduced to between 22 and 37--or between 56 percent and 91 percent of the original users--by the end of Year 5. Again, the 25% Standard Approach performed least well with an expected 37 remaining users. This contrasts with 22 remaining users for both the 150% Standard and the 150% Tailored.

The 100% Tailored 2 Year Cycle appears to be the most efficient of the alternative testing approaches as applied to this user distribution. While the 150% Standard and 150% Tailored Approaches identify a few more users than the 100% Tailored 2 Year Cycle Approach--22 versus 25--the difference in reduction is low relative to the number of tests performed.

3.3 Occasional Drug Users: Short Duration Drugs

Each cell in Table C.3 contains the percentage and number (in parentheses) of undetected users remaining in the population after each of the nine alternative testing approaches was applied to the Occasional Drug Users: Short Duration Drugs distribution. In this distribution it is assumed that 15 percent of the population uses a short duration drug, such as cocaine, twice a year. Use of cocaine and other short duration drugs allows an average 3.5-day window of post-use detectability. Table C.3 shows that all testing approaches perform relatively poorly for this distribution. Of the initial expected 158 users in Year 0, between 137 and 154--or between 87 percent and 98 percent--would be expected to remain undetected at the end of Year 5. Not unexpectedly, the 25% Standard and 25% Tailored Approaches again performed the poorest,

Table C.2 Percentage and number of users (per 1,000) remaining as a function of testing approach and duration for occasional users of long duration drugs

TESTING APPROACH	YEARS OF TESTING					
	0	1	2	3	4	5
100% Standard	100% (40)	92.6% (37)	85.7% (34)	79.4% (32)	73.5% (29)	68.1% (27)
100% Tailored	100% (40)	92.5% (37)	85.6% (34)	79.2% (32)	73.3% (29)	67.9% (27)
100% Tailored, 2 Year Cycle	100% (40)	92.5% (37)	85.6% (34)	79.2% (32)	67.7% (27)	62.7% (25)
25% Standard	100% (40)	98.1% (40)	96.2% (38)	94.4% (38)	92.6% (38)	90.8% (37)
25% Tailored	100% (40)	98.1% (39)	96.2% (38)	94.4% (38)	92.6% (37)	90.8% (36)
50% Standard	100% (40)	96.2% (38)	92.6% (37)	89.1% (36)	85.7% (34)	82.5% (32)
50% Tailored	100% (40)	96.2% (38)	92.5% (37)	89.0% (36)	85.6% (34)	82.4% (33)
150% Standard	100% (40)	89.1% (36)	79.4% (32)	70.7% (28)	63.0% (25)	56.1% (22)
150% Tailored	100% (40)	89% (36)	79.1% (32)	70.4% (28)	62.6% (25)	55.7% (22)

Table C.3 Percentage and number of users (per 1,000) remaining as a function of testing approach and duration for occasional users of short duration drugs

	YEARS OF TESTING					
TESTING APPROACH	0	1	2	3	4	5
100% Standard	100% (158)	98.1% (155)	96.2% (152)	94.4% (149)	92.6% (146)	90.8% (143)
100% Tailored	100% (158)	98.1% (155)	96.2% (152)	94.4% (149)	92.6% (146)	90.8% (143)
100% Tailored, 2 Year Cycle	100% (158)	98.1% (155)	96.2% (152)	94.4% (149)	90.8% (143)	89.1% (141)
25% Standard	100% (158)	99.5% (157)	99.0% (156)	98.6% (155)	98.1% (154)	97.6% (154)
25% Tailored	100% (158)	99.5% (157)	99.0% (156)	98.6% (155)	98.1% (154)	97.6% (154)
50% Standard	100% (158)	99.0% (156)	98.1% (155)	97.2% (154)	96.2% (152)	95.3% (151)
50% Tailored	100% (158)	99.0% (156)	98.1% (155)	97.2% (154)	96.2% (152)	95.3% (151)
150% Standard	100% (158)	97.2% (154)	94.4% (149)	91.7% (145)	89.1% (141)	86.6% (137)
150% Tailored	100% (158)	97.2% (154)	94.4% (149)	91.7% (145)	89.1% (141)	86.5% (137)

detecting only 4 users over five years. The other alternatives, however, were only slightly more effective with respective remaining users of from 137 to 151.

As with the long duration drug distribution, the 150% Standard and 150% Tailored Approaches appear to be the most detection effective. Yet, because of the higher number of tests done relative to the low number of users identified, another approach, such as the 100% Tailored 2 Year Cycle Approach with 141 remaining users, may be preferred.

3.4 Effects of Different User Frequencies on the Reduction of the Population of Drug Users Over Time

Sections 3.1, 3.2, and 3.3 discuss the effects of different random testing rates over time based on the assumption that occasional users are using drugs only twice a year. As noted above, the frequency with which occasional users use drugs affects the likelihood of detecting and removing drug users from the population. Tables C.4 through C.7 show the effects of altering the frequency of occasional short and long duration drug use for the 100% Standard and the 50% Standard Approaches. Each table compares the decrease in the population of drug users per 1,000 employees who use 2 times a year, 4 times a year, 12 times a year, and continuously over a five-year period. Table C.4 charts these changes for the 100% Standard Approach for occasional users of long duration drugs. Table C.5 charts these changes for the 50% Standard Approach for occasional users of long duration drugs. Table C.6 charts these changes for occasional users of short duration drugs using the 100% Standard Approach, while Table C.7 charts the 50% Standard Approach for occasional users of short duration drugs.

Although frequency of use affects the start values substantially (the estimates of the size of the population using drugs based on a 0.3 percent positive test rate), there is not a substantial difference in the reduction in the number of drug users in the population between a 100% random testing rate or a 50% random testing rate over a five-year period for either short duration or long duration drugs. As can be seen in Table C.6, for example, over a five-year period the change in the number of occasional users of short duration drugs drops from 157.5 to 143.1 users in a population of 1,000. This represents a decrease of 15 drug users over a five-year period, or three occasional users per year. For this type of drug user, detection seems ineffective at reducing drug use. However, it may be that annual detection of three people per 1,000 (roughly the number of people in a plant) can have a large deterrence effect. Other occasional drug users who know an identified user may realize that they can also be identified, even at a very low drug use frequency.

4 DISCUSSION AND RECOMMENDATIONS

The effectiveness of nine alternative random-drug-testing rates and program features was statistically modeled and compared across three plausible user distributions. Results of this comparison point to the great importance of the underlying distributions of users. In addition, the results provide a basis for future empirical evaluation of the relative deterrence effectiveness that could be produced by the nine testing alternatives. These results and insights are discussed below in Section 4.1, followed by recommendations for future research in Section 4.2.

Table C.4 Number of users (per 1,000) remaining as a function of frequency of use for users of long duration drugs

100% Standard

DURATION FREQUENCY	START	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
2 TIMES/YEAR	40.5	37.5	34.7	32.1	29.8	27.6
4 TIMES/YEAR	21.0	18.0	15.4	13.2	11.3	09.7
12 TIMES/YEAR	08.1	05.1	03.2	02.0	01.3	00.8
CONTINUOUS	04.7	01.7	00.6	00.2	00.1	00.03

Table C.5 Number of users (per 1,000) remaining as a function of frequency of use for users of long duration drugs

50% Standard

DURATION FREQUENCY	START	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
2 TIMES/YEAR	40.5	39.0	37.5	36.1	34.7	33.4
4 TIMES/YEAR	21.0	19.4	18.0	16.7	15.4	14.3
12 TIMES/YEAR	08.1	06.4	05.1	04.0	03.2	02.5
CONTINUOUS	04.7	02.9	01.7	01.0	00.6	00.4

Table C.6 Number of users (per 1,000) remaining as a function of frequency of use for users of short duration drugs

100% Standard

DURATION FREQUENCY	START	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
2 TIMES/YEAR	157.5	154.5	151.6	148.7	145.8	143.1
4 TIMES/YEAR	79.5	76.5	73.6	70.8	68.2	65.6
12 TIMES/YEAR	27.5	24.5	21.8	19.4	17.3	15.4
CONTINUOUS	04.7	01.7	00.6	00.2	00.1	00.03

Table C.7 Number of users (per 1,000) remaining as a function of frequency of use for users of short duration drugs

50% Standard

DURATION FREQUENCY	START	YEAR 1	YEAR 2	YEAR 3	YEAR 4	YEAR 5
2 TIMES/YEAR	157.5	156.0	154.5	153.0	151.6	150.1
4 TIMES/YEAR	79.5	78.0	76.5	75.0	73.6	72.2
12 TIMES/YEAR	27.5	26.0	24.5	23.1	21.8	20.6
CONTINUOUS	04.7	02.9	01.7	01.0	00.6	00.4

4.1 User Distributions and Sampling Alternatives

The relative detection effectiveness of the nine testing alternatives was found to be quite consistently ordered when compared across the three user distributions. For each distribution (with one exception), the 150% Tailored Approach yielded the somewhat larger numbers of detected users, followed in ascending order by the 150% Standard Approach, 100% Tailored 2 Year Cycle Approach, 100% Tailored Approach, 100% Standard Approach, 50% Tailored Approach, 50% Standard Approach, 25% Tailored Approach, and the 25% Standard Approach. The only exception to this ordering occurred in the continuous user distribution where the 100% Tailored 2 Year Cycle Approach was slightly more effective than the 150% Standard Approach. The relative detection effectiveness of the 150% Tailored Approach and the 150% Standard Approach after five years of sustained testing typically varied little from other less resource-intensive alternatives.

It is important to note, however, that the alternatives (from the standpoint of detection, not deterrence) could be more definitely identified if the underlying user distribution throughout the nuclear power industry were determined.⁷ Information on the current industry-wide user distribution would support developing a rationale for selection of the most efficient testing alternatives.

Assessing the current user distribution would also provide guidance for fitness-for-duty programs. For example, random and other testing elements would be supported by the finding that the distribution is largely composed of continuous users. Alternately, a finding that the current user distribution is largely occasional users could argue for stressing assistance, educational, or deterrence elements of a fitness-for-duty program to reduce the impetus for drug use.⁸ This would follow from the difficulties of detecting occasional users. As occasional users are suspected to constitute a substantial portion of the current user distribution, a concurrent effort to assess the deterrence effectiveness of the nine testing alternatives appears warranted.

Also, since continuous users are effectively identified using any of the random testing rates, and since most new continuous users should be screened out using pre-access tests, very few continuous users will remain in the population by 1993. Thus, the users who licensee testing programs will be attempting to identify will mainly be occasional users. It is also likely that occasional users may begin to gravitate toward short duration drugs, since the short window of detectability makes these users more difficult to detect using random testing. Because none of the random testing alternatives was very effective at detecting occasional users of short duration drugs, it becomes especially crucial to determine which random testing rates and program elements provide deterrence effectiveness for these users.

If the NRC plans to adjust required testing rates, it will need to do so on the basis of a combination of both the detection and deterrent effects of a given testing program. Because deterrence can be measured by a reduction in the drug use beyond the direct effects provided by detection, the results of this study may be used as a baseline for assessing deterrence effectiveness. Thus, concurrent assessments of the deterrence effectiveness of the nine testing

⁷ The user distribution could be determined in a number of ways, including a combination of (1) debriefing of detected users and (2) extrapolation of detected distribution to the entire nuclear industry population.

⁸ This could include increased emphasis on Employee Assistance Programs (EAPs) to reduce the impetus for drug use to offset other personal problems.

alternatives and the current user distribution would contribute to (1) the identification of the most cost-effective testing alternative⁹ as well as to (2) meeting the broader goals of fitness-for-duty programs. Thus, the next area of effort should be inquiry into the deterrence effectiveness of various potential random testing programs.

4.2 Recommendations

It is recommended that the NRC obtain information regarding the distribution of users in the nuclear industry and examine the deterrence effects of various random testing programs in order to thoroughly evaluate the effectiveness of these programs. It has been demonstrated here that, for occasional users, expected detection rates are low and do not increase substantially for any of the testing program alternatives. Currently, little is known about the effects of different random testing programs on deterrence rates; they may vary across different distribution of drug users and different testing alternatives. If deterrence rates strongly depend on the testing program, then testing alternatives will affect deterrence rates even if they do not significantly impact detection rates. Thus, assessment of the deterrence effectiveness of various random testing programs is desirable to identify the most cost effective testing program and to meet the broader fitness-for-duty program goals.

To obtain information on deterrence rates for various random testing programs, a study could be conducted to examine the effects of different testing rates on deterrence at selected nuclear power plant sites. Differences between modeled detection rates and actual detection rates would show the impact of testing programs on deterrence rates. The format of such a study would be as follows:

1. Solicit several nuclear facilities to volunteer for participation in the study. Facilities should be included from all regions such that the sample will include plants with all types of contextual differences (e.g., population density, proximity to an urban area, etc.). Licensees with multiple plants would be preferred such that plants from a single licensee could be randomly assigned across testing approaches.
2. Each plant would be assigned to one of four testing programs. Preferably, eight sites would be selected with two sites using each of the testing approaches. Suggested testing approaches would be the 100% Standard, 100% Tailored 2 Year Cycle, 50% Tailored, and 150% Tailored Approaches.
3. Information on positive test rates, absenteeism rates, fitness-for-duty policy violations, and other information would be derived from monthly fitness-for-duty reports over a two-year time period. Contextual information would also be gathered on each plant at the outset of the study from sources such as census data.

In conjunction with this effort, the distribution of types of current drug users through the two-year study could be empirically determined through exit interviews and anonymous surveys. Having precise information on user distributions and how they change over time would lead to better estimates of detection and deterrence rates.

⁹ This report does not attempt to assess the cost effectiveness of various testing programs. A cost analysis would require assumptions regarding the cost/benefit of more rapidly removing users of drugs from the population and should include an assessment of relative deterrence. However, it should be noted that with regard to costs the reduction from a 100% random testing rate to a 50% random testing rate would not substantially impact the overall costs of the FFD program for utilities. The basic infrastructure of the FFD program (the personnel, EAP program, collection facilities, computer systems for random selection and notification, etc.) would not be substantially reduced. For the average program, this reduction would reduce the number of tests performed by about 500 a year.

BIBLIOGRAPHIC DATA SHEET

(See instructions on the reverse)

1. REPORT NUMBER
(Assigned by NRC. Add Vol., Supp., Rev.,
and Addendum Numbers, if any.)

NUREG/CR-5784

PNL-7795

BHARC-700/91/025

2. TITLE AND SUBTITLE

Fitness For Duty in the Nuclear Power Industry: A Review of
the First Year of Program Performance and an Update of the
Technical Issues

3. DATE REPORT PUBLISHED

MONTH

YEAR

September 1991

4. FIN OR GRANT NUMBER

I2007

5. AUTHOR(S)

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R. Martin, S. Martin /BHARC

6. TYPE OF REPORT

Technical

7. PERIOD COVERED (Inclusive Dates)

November 1990 to
August 1991

8. PERFORMING ORGANIZATION - NAME AND ADDRESS (If NRC, provide Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address; if contractor, provide name and mailing address.)

Battelle Human Affairs Research Centers
4000 NE 41st Street
Seattle, WA 98105

Under Contract to:
Pacific Northwest Laboratory
Richland, WA 99352

9. SPONSORING ORGANIZATION - NAME AND ADDRESS (If NRC, type "Same as above"; if contractor, provide NRC Division, Office or Region, U.S. Nuclear Regulatory Commission, and mailing address.)

Division of Reactor Inspection and Safeguards
Office of Nuclear Reactor Regulation
U.S. Nuclear Regulatory Commission
Washington, DC 20555

10. SUPPLEMENTARY NOTES

11. ABSTRACT (200 words or less)

This report presents an overview of the NRC licensees' implementation of the FFD program during the first full year of the program's operation and provides new information on a variety of FFD technical issues. The purpose of this document is to contribute to appropriate changes to the rule, to the inspection process, and to other NPC activities. It describes the characteristics of licensee programs, discusses the results of NRC inspections, updates technical information covered in previous reports, and identifies lessons learned during the first year. Overall, the experience of the first full year of licensees' FFD program operations indicates that licensees have functioning fitness for duty programs devoted to the NRC rule's performance objectives of achieving drug-free workplaces in which nuclear power plant personnel are not impaired as they perform their duties.

12. KEY WORDS/DESCRIPTORS (List words or phrases that will assist researchers in locating the report.)

Fitness For Duty	Drug Abuse
Substance Abuse	Drug Testing
Drugs	Program Performance Reports
Impairment	Statistics on Drug Abuse
Urinalysis	Statistics on Substance Abuse
Alcohol Abuse	Medical Review Officer
Alcohol Testing	Drug-Free Workplace
Chemical Testing	
Alcohol	

13. AVAILABILITY STATEMENT

Unlimited

14. SECURITY CLASSIFICATION

(This Page)

Unclassified

(This Report)

Unclassified

15. NUMBER OF PAGES

16. PRICE

END

**DATE
FILMED**

12/03/91