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NUCLEAR REGULATORY COMMISSION ISSUANCES

April 1994

This report includes the issuances received during the specified period from the Commission (CLI), the Atomic Safety and Licensing Boards (LBP), the Administrative Law Judges (ALJ), the Directors' Decisions (DD), and the Denials of Petitions for Rulemaking (DPRM).

The summaries and headnotes preceding the opinions reported herein are not to be deemed a part of those opinions or have any independent legal significance.

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B. Paul Cotter, Jr., Chief Administrative Judge, Atomic Safety and Licensing Board Panel
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Issuances
In the Matter of

Docket No. 40-08027-MLA
(Source Material License
No. SUB-1010)

SEQUOYAH FUELS CORPORATION

April 1, 1994

The Commission grants the Native Americans for a Clean Environment and Cherokee Nation’s petition for review of the presiding officer’s order, LBP-93-25, 38 NRC 304 (1993), which allowed the Sequoyah Fuels Corporation to withdraw its license renewal application and terminated the proceeding. The Commission sets the issues and a schedule for review.

ORDER

The Native Americans for a Clean Environment and the Cherokee Nation (Petitioners) have filed a petition before the Commission, pursuant to 10 C.F.R. § 2.786(b), for review of the presiding officer’s Memorandum and Order, LBP-93-25, which allowed the Sequoyah Fuels Corporation (SFC) to withdraw its license renewal application and terminated the proceeding. 38 NRC 304 (1993). The NRC Staff and SFC oppose Commission review. The Petitioners also have filed a motion for leave to reply to the NRC Staff’s and SFC’s responses to the petition for review.
In accordance with section 2.786(d), the Commission has decided to grant review of LBP-93-25. The parties to the review proceeding shall be the Petitioners, SFC, and the NRC Staff. In reviewing LBP-93-25, the Commission is particularly interested in the parties' arguments on the following matters, which should be addressed in their briefs:

(1) What is the basis for the presiding officer's jurisdiction over decommissioning activities in a license renewal proceeding in which the licensee requests to withdraw its renewal application?

(2) Faced with a request to withdraw an application under 10 C.F.R. § 2.107(a), what actions may the presiding officer in a license renewal proceeding take? May a presiding officer deny the withdrawal of an application?

(3) Was a determination of the Licensee's compliance with 10 C.F.R. § 40.42(b) and (c) necessary to the presiding officer's decision on whether to permit the withdrawal of the renewal application? If so, has the Licensee satisfied the requirements of those regulations?

(4) Upon withdrawal of the license renewal application, does 10 C.F.R. § 40.42(e) maintain SFC's license in effect?

(5) What prejudice, if any, occurs to the intervenors' hearing rights under the Atomic Energy Act from the presiding officer's approval of the withdrawal of the renewal application?

In addressing these questions, the Petitioners' brief must clearly identify the errors of fact or law in LBP-93-25 on which the Petitioners rely, with appropriate citations to the portion of the record relied upon to support each assertion of error. The Petitioners' brief must be limited to those issues the Petitioners placed or sought to place in controversy in the proceeding. Responsive briefs must contain a reference to the portion of the record that supports each factual assertion made.

A brief in excess of 10 pages must contain a table of contents, with page references, and a table of cases (alphabetically arranged), statutes, regulations, and other authorities cited, with references to the pages of the brief where they are cited. Briefs must not exceed 30 pages, exclusive of pages containing the table of contents, table of citations, and any addendum containing statutes, rules,

1 We have accepted the Petitioners' reply for filing; however, our decision to take review of LBP-93-25 does not turn on the acceptance of their reply. Although much of the reply appears merely to reinforce arguments made in their initial petition for review, the Petitioners arguably raise some issues for the first time in their reply. Although we will not bar the Petitioners from pursuing in their brief filed in response to this Order arguments made in their reply, we caution that we expect Petitioners to provide in their original petition their full statement of reasons for why Commission review is warranted. SFC has asked for an opportunity to reply to the Petitioners' motion. We deny that request. To the extent that the Petitioners pursue arguments in their brief that are derived from their reply, SFC will suffer no prejudice, because SFC will have a full opportunity to rebut those arguments in its responsive brief. See Safety Light Corp. (Bloomsburg Site Decontamination and License Renewal Denials), CL1-92-13, 36 NRC 79, 85 (1992)
regulations, etc. A brief that fails to comply with the provisions of this Order may be stricken, either on motion of a party or by the Commission on its own initiative.

Within 30 days after service of this Order, the Petitioners may file their brief. Within 30 days after service of the Petitioners' brief, Staff and SFC may file a response. Within 15 days after service of the responsive briefs, the Petitioners may file a reply. If the Petitioners choose to reply, their reply brief shall be limited to 15 pages.

It is so ORDERED.

For the Commission

JOHN C. HOYLE
Assistant Secretary of the Commission

Dated at Rockville, Maryland,
this 1st day of April 1994.
UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

COMMISIONERS:

Ivan Selin, Chairman
Kenneth C. Rogers
Forrest J. Remick
E. Gail de Planque

In the Matter of Docket Nos. 50-424-OLA-3
GFOROGIA POWER COMPANY, et al. 50-425-OLA-3
(Vogtle Electric Generating Plant, April 7, 1994
Units 1 and 2)

The Commission reviews a licensing board decision, LBP-94-6, 39 NRC 105 (1994), which ordered the release of an investigation report prepared by the Nuclear Regulatory Commission (NRC) Office of Investigations (OI). Based upon the deliberative process privilege, the NRC Staff had sought to prevent discovery of the report and its factual exhibits until after an agency decision on possible enforcement action against the Licensee, the target of the investigation. The Commission affirms in part and reverses in part the licensing board’s order in LBP-94-6. The Commission finds the evaluative opinion portions of the report protected by the deliberative process privilege, but concurs with the licensing board that purely factual exhibits that do not reveal deliberative analyses are not protected.

RULES OF PRACTICE: INTERLOCUTORY REVIEW
(DISCOVERY ORDERS)

Review of a discovery order is warranted when the alleged harm would be immediate and could not be redressed through future review of a final decision of the licensing board.
RULES OF PRACTICE: DISCOVERY

Pursuant to 10 C.F.R. § 2.744, NRC documents must be produced if they are relevant to a proceeding and are not exempt from production under the listed exemptions found under 10 C.F.R. § 2.790(a). Even if a relevant document is exempt from disclosure pursuant section 2.790(a), the document must still be released if it is necessary to a proper decision in the proceeding and not reasonably obtainable from another source.

RULES OF PRACTICE: PRIVILEGE (DELIBERATIVE PROCESS)

The deliberative process privilege protects inter- and intraagency communications reflecting advisory opinions, recommendations, and deliberations comprising part of a process by which governmental decisions and policies are formulated. The privilege may be invoked in NRC proceedings.

RULES OF PRACTICE: PRIVILEGE (DELIBERATIVE PROCESS)

The deliberative process privilege applies to information that is both predecisional and deliberative. A document is predecisional if it was prepared before the adoption of an agency decision and specifically prepared to assist the decisionmaker in arriving at his or her decision. Communications are deliberative if they reflect a consultative process.

RULES OF PRACTICE: PRIVILEGE (DELIBERATIVE PROCESS)

Factual material that does not reveal the deliberative process is not shielded by the deliberative process privilege. However, if facts are inextricably intertwined with the opinion portion, or otherwise would reveal the deliberative process of the agency, the facts may be exempt from disclosure.

RULES OF PRACTICE: PRIVILEGE (DELIBERATIVE PROCESS)

In a litigation context, the deliberative process privilege is a qualified, not absolute, privilege. The government's interest in confidentiality is balanced against the litigant's need for the information. The government agency bears the initial burden of showing that the privilege should be invoked. Once the applicability of the privilege has been established, the litigant seeking the information must demonstrate an overriding need for the material.

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RULES OF PRACTICE: PRIVILEGE (INVESTIGATORY MATERIAL)

Documents compiled in investigations and inspections whose production could reasonably be expected to interfere with enforcement proceedings may be exempt from disclosure under 10 C.F.R. § 2.790(a)(7)(i). This privilege protects investigatory files, including factual materials, from disclosure in order to prevent harm to either ongoing or contemplated investigations, or to prospective enforcement actions. The Commission itself may invoke the privilege.

MEMORANDUM AND ORDER

I. INTRODUCTION

In this decision the Commission decides the controversy among the parties over the disclosure of an investigation report prepared by the Nuclear Regulatory Commission (NRC) Office of Investigations (OI). The parties do not dispute that the OI report is relevant to the matters at issue in this license transfer proceeding. However, the NRC Staff has resisted disclosure of the entire report, including the underlying factual information, pending the outcome of the agency’s deliberations on possible enforcement action to be taken as a consequence of the investigative results. In LBP-94-6, 39 NRC 105 (1994), the Atomic Safety and Licensing Board denied the Staff’s request to delay disclosure and instead ordered prompt release of the easy-to-separate factual information in the report and release of the remainder of the report under a protective order.

This controversy is before the Commission on the “NRC Staff Motion for a Stay of the Licensing Board Order Releasing the Office of Investigations Report,” filed on March 14, 1994, and the Staff’s subsequent “Petition for Review of LBP-94-6 and/or Motion for Directed Certification,” which was filed on March 24, 1994. On March 18, 1994, the Commission sua sponte entered a temporary stay of the Licensing Board’s order. In Orders dated March 16 and 25, respectively, the Secretary of the Commission established a schedule for filing answers to the Staff’s stay motion and to the Staff’s petition for review. We have received answers to both Staff filings from the Licensee, Georgia Power Company (GPC), and the Intervenor, Allen L. Mosbaugh. Both parties oppose the Staff’s position with respect to the withholding of factual material appended.

1 In order to expedite our resolution of this controversy, the parties were permitted in their answers to the petition for review to provide arguments on both the question of whether review of LBP-94-6 should be granted and the question of whether LBP-94-6 should be sustained on its merits.
to the OI report. In a March 15 motion, Mr. Mosbaugh has also moved to strike the Staff’s stay motion.

Upon consideration of the parties’ filings and the record of this proceeding, the Commission hereby grants the Staff’s petition for review and, for the reasons stated in this Order, the Commission affirms in part and reverses in part the Licensing Board’s order in LBP-94-6. Because the Commission is rendering a decision on the merits of the controversy, we need not rule on the Staff’s stay motion and we dismiss it as moot. We also dismiss Mr. Mosbaugh’s motion to strike the Staff’s motion for a stay. As a consequence of these rulings, we are ordering the Staff to release the exhibits to the OI report within the time specified in section VII of this Order, and to release the OI report itself at the time of issuance of any enforcement action. The only information to be withheld, if any, is privacy information or the identity of any confidential sources.

II. PRELIMINARY PROCEDURAL MATTERS

A. The Staff’s Petition for Review

Although the Licensing Board’s order is interlocutory by nature, we have permitted limited exceptions to the general proscription against interlocutory appeals in 10 C.F.R. § 2.739(f) if a party can demonstrate that review is appropriate under one of the criteria in 10 C.F.R. § 2.786(g)(1)-(2). See Oncology Services Corp., CLI-93-13, 37 NRC 419, 420-21 (1993). The Staff has shown that review of LBP-94-6 is warranted under the first criterion in section 2.786(g).

At the heart of the Staff’s objection to the Licensing Board’s order to release the OI report is the Staff’s concern that premature release will adversely affect the agency’s ongoing deliberation concerning possible enforcement action. Because the adverse impact of that release would occur now, the alleged harm is immediate. The impact of the order to release a report that would otherwise be held in confidence is irreparable and could not be alleviated through future review of a final decision of the Licensing Board. Unlike most discovery orders, the instant order must be reviewed now or not at all.

B. Staff’s Motion for Stay and Mr. Mosbaugh’s Motion to Strike

The Commission is dismissing the Staff’s March 14 motion for a stay as moot. A stay motion under section 2.788 is intended as a means of obtaining interim relief pending a final determination of a petition for review. Because we are prepared to resolve the merits of the controversy over the release of the OI report and the Licensing Board’s order in LBP-94-6, a decision on the Staff’s
motion for a stay is unnecessary. In view of our dismissal of the Staff’s stay motion, Mr. Mosbaugh’s March 15 motion to strike the Staff’s motion may also be dismissed.

One last comment is warranted about the Staff’s stay motion. Although that motion was timely under our rules of practice, the Staff waited 10 days after service of the Licensing Board’s order to file its motion with the Commission. During this time the Staff was under an obligation pursuant to the Licensing Board’s order to begin releasing factual material contained in or appended to the OI report. Under these circumstances, and in the absence of any delay imposed by the Licensing Board with respect to the effectiveness of its order, the Staff should have initiated more promptly its request for a stay of the Licensing Board’s order, if only to seek an emergency temporary stay under 10 C.F.R. § 2.788(f) to preserve the status quo.

III. BACKGROUND ON THE DISCLOSURE CONTROVERSY

OI initiated an investigation in late 1990 into allegations that senior officials at the Georgia Power Company (GPC) made material false statements to the NRC about the reliability of the diesel generators at the Vogtle plant. On December 17, 1993, OI completed its investigation and issued a report for further Staff evaluation. Although the instant controversy arises out of the Staff’s motion to defer discovery, dated January 24, 1994, that motion was not the Staff’s first attempt to prevent access to the fruits of OI’s investigation. The Licensing Board granted two earlier Staff requests to defer production of certain tapes, transcripts, and other documents because the Staff believed their release would interfere with OI’s then-ongoing investigation.2

On January 24, 1994, the Staff moved to defer all discovery against the Staff pending its evaluation of the OI report for possible enforcement action and consultation with the Commission on any proposed action.3 In a prehearing conference held January 27, 1994, Mr. Mosbaugh’s counsel stressed that he needed to obtain the OI report to properly and expeditiously prepare his case in this proceeding. Counsel asserted that the report would serve as his “road map” to documents and for stipulations.4

Although Staff counsel indicated at the prehearing conference (Tr. at 169) that the Staff was willing to eventually release the entire OI report, the Staff

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2 See LBP-93-22, 38 NRC 189 (1993); Memorandum and Order (Motion to Compel Production of Documents by the Staff), at 6-7 (Aug. 31, 1993) (unpublished). On December 17, 1993, the Staff released some tapes and transcripts. See Letter from Charles A. Barth, NRC Staff Counsel, to Licensing Board (Feb. 18, 1994).
3 NRC Staff Motion to Defer Certain Prehearing Activities Until the Staff Has Formulated a Position (Jan. 24, 1994).
4 Prehearing Conference Tr. at 159 (Jan. 27, 1994).
maintained that disclosure before an enforcement decision had been reached could adversely affect the ability of the Staff and the Commission to deliberate concerning whether to institute an enforcement action against the Licensee. The Staff asserted that the OI report is privileged and protected from discovery as a “predecisional” document. The Staff maintained that a delay in release of the report would not prejudice the interests of the other parties and that other discovery activities could proceed.

The intervenor opposed Staff’s request for a delay in the report’s release. Mr. Mosbaugh argued that no deliberative process privilege attaches to the OI report. First, Mr. Mosbaugh emphasized that the privilege does not apply to purely factual materials. Second, he claimed that release of the document to the public would not cause harm to the agency because the report does not contain “candid” or “personal” remarks, and because the authors of the report expected public dissemination of their remarks and, therefore, would not be affected by early disclosure of the report.

GPC supported the Staff’s position, but only insofar as it understood the Staff to be seeking protection of the opinions, conclusions, and recommendations within the OI report. To this extent, GPC conceded that the Staff’s claim of privilege to withhold the report as a predecisional, deliberative document appeared valid, and GPC did not believe that Mr. Mosbaugh had demonstrated a sufficient interest in obtaining the OI report prior to an NRC decision on enforcement action. GPC suggested that the Licensing Board could release the OI report to the parties under a protective order that would restrict public access until the NRC’s enforcement decision had been made.

In LBP-94-6, the Licensing Board found that no privilege protected factual information in the OI report if such information was “not inextricably intertwined with privileged communications.” LBP-94-6, 39 NRC at 109. As to the evaluative portions of the report, the Board reasoned that because OI’s opinions ultimately would be released in this proceeding, disclosure of OI’s evaluations under protective order would have “no additional detrimental impact on discussion in the agency.” Id.

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6 NRC Brief on Release of OI Report, supra, at 2.
8 Id. at 11.
9 See GPC’s Brief Concerning NRC Staff Release of Certain Investigatory Material at 5 (Feb. 4, 1994). GPC assumed that the Staff was about to release transcripts and other factual material gathered or reviewed by OI.
10 See id. at 5-8.
11 Id. at 9.
The Licensing Board weighed the interests of the parties, and concluded that the intervenor and GPC would suffer greater harm from a delay in disclosure of the OI report than Staff would suffer in its deliberations if the report were promptly released. *Id.* at 110. Although the Board doubted the applicability of the deliberative process privilege to the OI report, the Board granted Staff until April 4, 1994, to release the nonfactual portions of the OI report, and also ordered that this disclosure be subject to protective order. *Id.* at 109.

IV. THE PARTIES' ARGUMENTS BEFORE THE COMMISSION

In its petition for review, the Staff claims that the Licensing Board overvalued GPC and the Intervenor's interests in discovery. Petition for Review at 8-10. The Staff asserts that the agency's interest in discharging its enforcement obligations "without the distractions or confusion caused by the premature release of preliminary agency enforcement materials" outweighs the parties' need for disclosure of the report. *Id.* at 7-8. The Staff also argues that the Board's decision is contrary to a longstanding agency practice, reflected in the Staff's Enforcement Manual (section 5.3.4.h), of only releasing investigative material after enforcement action has been taken, and to the "spirit" of the Commission's Statement of Policy on Investigations, Inspections, and Adjudicatory Proceedings, 49 Fed. Reg. 36,032 (Sept. 13, 1984). See Petition for Review at 5.

Both GPC and Mr. Mosbaugh oppose the Staff’s position, particularly with regard to the factual material gathered by OI. GPC argues that the Staff’s withholding of the purely factual information in the OI report is contrary to law and that continued delay in releasing this material is prejudicial to GPC's interests. GPC seeks only the factual material — i.e., OI records of interviews of NRC Staff personnel and the transcripts of OI’s interviews of GPC personnel. The intervenor opposes a further delay in release of the OI materials and also emphasizes a particular need for the interviews, depositions, and other factual material collected by OI.

V. DISCOVERY RULES

The rule governing the production of NRC documents in formal administrative proceedings is set forth in 10 C.F.R. §2.744. Under this rule, NRC documents must be produced if they are relevant to a proceeding and not exempt

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12 GPC's Response to NRC Staff Petition for Review of LBP-94-6 and/or Motion for Directed Certification at 3-6 (Mar. 30, 1994).
13 Intervenor's Answer to NRC Staff's Petition for Review of LBP-94-6 and/or Motion for Directed Certification at 9 (Mar. 30, 1994).
from production under the listed exemptions found under 10 C.F.R. § 2.790(a). Even if a document is exempt from disclosure pursuant to section 2.790(a), the document must still be released if it is “necessary to a proper decision in the proceeding” and “not reasonably obtainable from another source.” 10 C.F.R. § 2.744(d).

In this case the NRC Staff relies on the exemption provided under 10 C.F.R. § 2.790(a)(5) for “[i]nteragency or intraagency memorandums or letters which would not be available by law to a party other than an agency in litigation with the Commission.” This exemption is similar to Exemption 5 under the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b). FOIA’s Exemption 5 shields from disclosure those documents normally privileged in civil discovery, including documents protected by the common law predecisional or deliberative process privilege. Jordan v. Department of Justice, 591 F.2d 753, 772 (D.C. Cir. 1978); see NLRB v. Sears, Roebuck & Co., 421 U.S. 132, 150-53 (1975); EPA v. Mink, 410 U.S. 73, 85-90 (1973). The deliberative process privilege may be invoked in NRC proceedings. Long Island Lighting Co. (Shoreham Nuclear Power Station, Unit 1), ALAB-773, 19 NRC 1333, 1341 (1984).

The deliberative process privilege is unique to the government and protects inter- and intraagency communications “reflecting advisory opinions, recommendations and deliberations comprising part of a process by which governmental decisions and policies are formulated.” Sears, 421 U.S. at 150 (quoting Carl Zeiss Stiftung v. V.E.B. Carl Zeiss, Jena, 40 F.R.D. 318, 324 (D.D.C. 1966), aff’d, 384 F.2d 979 (D.C. Cir.), cert. denied, 389 U.S. 952 (1967). At least three purposes for the privilege exist:

First, [the privilege] protects creative debate and candid consideration of alternatives within an agency, and, thereby, improves the quality of agency policy decisions. Second, it protects the public from the confusion that would result from premature exposure to discussions occurring before the policies affecting it had actually been settled upon. And third, it protects the integrity of the decision-making process itself by confirming that "officials would be judged by what they decided[,] not for matters they considered before making up their minds."

Jordan, 591 F.2d at 772-73 (en banc) (citation omitted).

The privilege applies only to information that is (1) “predecisional” and (2) “deliberative.” Petroleum Information Corp. v. Department of Interior, 976 F.2d 1429, 1434 (D.C. Cir. 1992). A document is predecisional if it was prepared before the adoption of an agency decision and specifically prepared to assist the decisionmaker in arriving at his or her decision. See Renegotiation Board v. Grumman Aircraft Engineering Corp., 421 U.S. 168, 184 (1975); Hopkins v. Department of Housing and Urban Development, 929 F.2d 81, 84 (2d Cir. 1991). For example, in Grumman Aircraft, Regional Boards conducted an investigation, and made analytical findings and recommendations in a report presented to a
Renegotiation Board which used the report in its deliberations, but was not bound by the report's conclusions or analysis. The Supreme Court found the Regional Board reports, which had no operative legal effect by themselves but were prepared to assist the Renegotiation Board's decision, "precisely the kind of predecisional deliberative advice and recommendations contemplated by Exemption 5." *Grumman Aircraft*, 421 U.S. at 184-87. See also *Hopkins*, 929 F.2d at 85 (HUD inspection reports were predecisional because inspectors themselves lacked authority to take final agency action).

Communications are deliberative if they reflect a consultative process. Protected documents can include analysis, evaluations, recommendations, proposals, or suggestions reflecting the opinions of the writer rather than the final policy of the agency. *See National Wildlife Federation v. United States Forest Service*, 861 F.2d 1114, 1118-19 (9th Cir. 1988). Deliberative documents "relate[] to the process by which policies are formulated." *Hopkins*, 929 F.2d at 84. However, a document need not contain a specific recommendation on agency policy to qualify as deliberative. *National Wildlife Federation*, 861 F.2d at 1118. A document providing "opinions or recommendations regarding facts" may also be exempt under the privilege. See *id*.

Factual material that does not reveal the deliberative process is not shielded by the privilege. *Norwood v. FAA*, 993 F.2d 570, 577 (6th Cir. 1993) (citing *EPA v. Mink*, 410 U.S. at 91 (1973)); *Coastal States Gas Corp. v. Department of Energy*, 617 F.2d 854, 867 (D.C. Cir. 1980). However, if facts are "inextricably intertwined" with the opinion portion, or otherwise would reveal the deliberative process of the agency, the facts may be exempt from disclosure. *See Hopkins*, 929 F.2d at 85; *Norwood*, 993 F.2d at 577.

In a litigation context, the deliberative process privilege is a qualified, not absolute, privilege. The government's interest in confidentiality is balanced against the litigant's need for the information. *See Northrop Corp. v. McDonnell Douglas Corp.*, 751 F.2d 395, 404-05 (D.C. Cir. 1984); *Carl Zeiss Stiftung*, 40 F.R.D. at 327; *Shoreham*, 19 NRC at 1341. The government agency — here the NRC Staff — bears the initial burden of showing that the privilege should be invoked. *See Coastal States*, 617 F.2d at 868. Once the applicability of the privilege has been established, the litigant seeking the information must demonstrate an overriding need for the material. *Shoreham*, 19 NRC at 1341.
VI. ANALYSIS

The deliberative process privilege applies to the OI report. The Staff has made a sufficient showing that the OI report is both a predecisional and deliberative document. As to its predecisional nature, the report is a step in the process leading to an agency decision on enforcement action. Based upon the report, the NRC will determine, in part, whether to take enforcement action. However, the report’s conclusions are neither precedential nor binding upon the NRC Staff or the Commission. We are thus satisfied that this document is predecisional. See generally Grumman Aircraft, 421 U.S. 168 (1975) (reports containing investigation results, analysis, and findings, and which were prepared to assist an agency decisionmaker in arriving at a final agency decision, were exempt from disclosure). The OI report is also a deliberative document. The report contains OI’s evaluative and subjective conclusions on the evidence accumulated during the investigations. For example, sprinkled throughout the report are investigators’ “notes,” providing evaluations of the reliability and significance of testimony. These subjective evaluations constitute a significant part of the deliberations that will lead to an agency enforcement decision.

Public scrutiny properly focuses upon the agency’s enforcement action and the evidence that forms the basis for the action. It strikes the Commission as inappropriate to permit scrutiny of the evaluative statements of OI investigators, even if limited to the other parties, before the Commission itself has had the opportunity to deliberate on any potential enforcement action. As Staff has asserted, the investigators’ conclusions may or may not be adopted as a basis for any proposed enforcement action. Ultimately, deliberations within the agency may be harmed by the piecemeal disclosure of evaluative conclusions of agency officials prior to an agency decision.

Protected communications include those “which would inaccurately reflect or prematurely disclose the views of the agency,” suggesting as the agency’s position that which as yet is merely opinion. Coastal States, 617 F.2d at 866. In the long run, the “efficiency of [g]overnment would be greatly hampered if . . . [g]overnment agencies were prematurely forced to ‘operate in a fishbowl.’” Petroleum Information, 976 F.2d at 1434 (quoting S. Rep. No. 813, 89th Cong., 1st Sess. 9 (1965)). Moreover, the Commission does not consider it appropriate to provide GPC, the target of the investigation and a potential target of any enforcement action, a copy of OI’s opinions and evaluations before

14 Because the Staff provided the Commission a copy of the OI report with its enforcement recommendations on March 22, we have been able to review the report in camera for the purpose of confirming whether it contains privileged material. See 10 C.F.R. § 2.744(c). Although we have been provided a listing of the exhibits to the OI report, we have not been provided the exhibits themselves, thus, we have not examined them in rendering this decision.
the Commission has had an opportunity to reach an enforcement decision. Accordingly, we find that Staff sufficiently has demonstrated that the deliberative process privilege is applicable to the opinion and analyses portions of the OI report.

However, we reject the Staff’s argument to the extent that Staff intends to assert that the entire OI report — including purely factual exhibits — may be withheld under the deliberative process privilege. Under the particular facts present here, there is no basis for withholding release of this factual material. The deliberative process privilege shields predecisional opinion, not purely factual information that does not reveal the substance of the predecisional opinion. Mink, 410 U.S. at 89; Norwood, 993 F.2d at 577. The Staff provides us with no reason to believe that the factual exhibits to the report are intertwined with OI’s analyses. Based on the descriptive listing of exhibits to the OI report, it appears that none of the exhibits can be withheld under a “predecisional” or “deliberative process” theory.

It also appears that the OI report itself (excluding exhibits) is not purely opinion material. The Staff has argued, however, that even facts contained in the OI report itself should be privileged because they reflect the investigator’s selection of what constitutes significant evidence and, thus, reveal aspects of the agency’s deliberative process. Petition for Review at 5 n.8. As Staff notes, factual summaries of evidence prepared to assist an administrator in the resolution of a complex question may reveal deliberative analysis and, consequently, may be within the scope of the exemption. See Montrose Chemical Corp. v. Train, 491 F.2d 63, 68 (D.C. Cir. 1974).

In other circumstances, it might be appropriate to order a further demonstration by the Staff of the basis for its assertion that the factual descriptions in the OI report should be withheld and to probe whether the report could be culled for release of any portions that do not reveal predecisional opinions and evaluations. However, as this case now stands, the Commission’s decision on enforcement action is imminent. Because the Staff does not seek protection of the report after an enforcement action is issued, we expect that the parties will obtain the entire OI report very shortly. In light of the imminent release of the OI report, and in the interest of avoiding further delay, the Commission does not consider a further in camera review or further redaction of the report to be necessary.

Although the deliberative process privilege under section 2.790(a)(5) does not protect factual materials that do not reveal any evaluation or analysis, a proper claim under section 2.790(a)(7)(i) would provide a basis for withholding the factual material compiled during the investigation. This privilege applies to

15 Indeed, GPC would obtain an advantage it ordinarily would not receive by being permitted access to the report before it is available to the general public if the Licensing Board’s ordered approach were followed.
those documents compiled in investigations and inspections whose production "[c]ould reasonably be expected to interfere with enforcement proceedings." 10 C.F.R. § 2.790(a)(7)(i). The privilege corresponds to Exemption 7(A) under FOIA, 5 U.S.C. §552(b)(7)(A), which protects investigatory files, including factual materials, from disclosure in order to prevent harm to either ongoing or contemplated investigations, or to prospective enforcement actions. See generally NLRB v. Robbins Tire & Rubber Co., 437 U.S. 214 (1978). For example, this privilege protects against the premature disclosure of information that could compromise investigative leads, result in harassment of witnesses, lead the target of an investigation to alter testimony or evidence, or “tip the hand” of the government’s case.16 Where the requisite harm to an investigation or the enforcement process is shown, this privilege shields even purely factual material.

The Staff does not rely on the privilege in section 2.790(a)(7)(i) as a basis for withholding the report. Although this “investigatory” privilege may be invoked at any time prior to completion of enforcement action, we understand Staff to argue only that premature release of the factual exhibits to the OI report would harm the agency’s deliberative process, not that either the integrity of an NRC investigation or the NRC’s ability to prosecute an enforcement action will be compromised by the early disclosure. Although in other circumstances the Commission itself may see an enforcement-related need to invoke the privilege, the Commission is not exercising its discretion under the particular facts of this case.17 Accordingly, we direct the Staff to make available to the intervenor and GPC the report’s purely factual exhibits. We will permit a brief period of time prior to release for the Staff to review the exhibits to ensure that personal privacy information or the identity of confidential sources, if any, has been redacted.

Although we find the deliberative process privilege applicable to the opinion portions of the OI report, we still must balance the interests to be protected against the parties’ asserted need for these portions of the report. In balancing the interests at issue, the Licensing Board may have overlooked the interests of the Commission in maintaining the confidentiality of deliberative materials. The premature release of deliberative agency communications, which may or may not be adopted by the Commission, particularly before the agency has reached a

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17 Not only may we invoke the privilege to protect our own investigatory and enforcement processes, but we may also apply the privilege to prevent premature disclosure of information related to a matter that has been referred or is being evaluated for referral to the United States Department of Justice for possible criminal prosecution. In this particular case, we understand that the Department of Justice has already declined prosecution.
final enforcement decision, poses the risks of harm that the deliberative process privilege is intended to prevent. The privilege is designed to foster the quality of the decisionmaking process.

In contrast, neither Mr. Mosbaugh nor GPC has shown an overriding interest in disclosure of the protected portions of the OI report. Indeed, GPC has not insisted on access to the report itself at this time. Mr. Mosbaugh has stated that he has particular need of the interviews and depositions conducted by OI.18 Given that Mr. Mosbaugh will rely on the evidence underlying the OI investigation, we do not believe that a delay in the release of the OI report pending the Commission’s deliberations on possible enforcement action will cause Mr. Mosbaugh any appreciable detriment. Mr. Mosbaugh’s counsel is certainly free to fashion his own “road map” to his case from the factual exhibits.

Moreover, immediate disclosure of the entire report is not “necessary to a proper decision in the proceeding.” The Commission expects to complete its review of the OI report expeditiously, whereupon Staff, which does not intend to protect the report permanently, will release the entire report. Therefore, all parties will have unfettered access to the entire report within a very short period of time. Despite the Licensing Board’s emphasis on the need for a “prompt determination of this proceeding,” we do not perceive any such need to outweigh the interest in the integrity of the agency’s enforcement deliberations. The Board is under no statutory or regulatory deadline to conclude this proceeding. As we understand the Board’s most recent scheduling order (issued February 1, 1994), the depositions scheduled for April are focused on the alleged illegal transfer of the license, an issue not covered by the OI report.19 There is simply no urgency in this proceeding that cannot accommodate an additional minor delay in release of the report.

VII. CONCLUSION AND ORDER

As discussed in this decision, the Commission agrees with the Licensing Board that factual exhibits to the OI report should be released to the parties. We disagree with the Licensing Board to the extent that it required disclosure of the portions of the OI report containing OI’s evaluations and opinions prior to the conclusion of the agency’s deliberations on enforcement action.

Therefore, consistent with the foregoing opinion, the Commission hereby orders:

18 Intervenor’s Response to NRC Staff Motion for a Stay of the Licensing Board Order Releasing the Office of Investigations Report at 4 (Mar 22, 1994).
19 If necessary, depositions may be reasonably delayed if the parties believe that the OI report will be relevant to this issue. Alternatively, new information in the OI report could be grounds for requesting a followup deposition of a particular witness.
1. The NRC Staff's petition for review, dated March 24, 1994, is granted.
2. The NRC Staff's motion for stay of I.BP.94-6, dated March 14, 1994, is dismissed.
3. The intervenor's motion to strike, dated March 15, 1994, is dismissed.
4. The Atomic Safety and Licensing Board's order in I.BP.94-6 is affirmed in part and reversed in part.
5. Within 7 days of the date of this order, the NRC Staff shall make available to the parties for inspection and copying the documents and materials identified in the list of exhibits to the OI report (Case No. 2-90-020R). Appropriate redactions may be made to protect personal privacy information or the identity of confidential sources.
6. At the time of issuance of an enforcement action (or upon a decision to take no enforcement action) related to the matters within the scope of the investigation, the NRC Staff shall make available to the parties for inspection and copying OI's report of investigation (Case No. 2-90-020R). Appropriate redactions may be made to protect personal privacy information or the identity of confidential sources.

It is so ORDERED.

For the Commission\(^2\)

JOHN C. HOYLE
Assistant Secretary of the Commission

Dated at Rockville, Maryland,
this 7th day of April 1994.

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\(^2\)Commissioner de Planque was not present for the affirmation of this order. If she had been present, she would have approved it.
Atomic Safety and Licensing Boards Issuances

ATOMIC SAFETY AND LICENSING BOARD PANEL

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Robert M. Lazo,* Deputy Chief Administrative Judge (Executive)
Frederick J. Shon,* Deputy Chief Administrative Judge (Technical)

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Dr. George F. Tidley
Sheldon J. Wolfe

*Permanent panel members
Before us for consideration is a proffer by Intervenor Citizens Against Nuclear Trash (CANT), on January 18, 1994, of three contentions additional to those previously admitted in this proceeding. LBP-91-41, 34 NRC 332 (1991).

CANT’s Contention T alleges that the design of the Claiborne Enrichment Center (CEC) is invalid because it relies for cooling purpose on trichlorofluoromethane which has been banned by the Environmental Protection Agency. Contention U alleges that the Draft Environmental Impact Statement (DEIS) is inadequate because the Nuclear Regulatory Commission (NRC) failed to consult with other appropriate federal agencies regarding the proposed project as required by the National Environmental Policy Act (NEPA). Contention W
alleges that the DEIS is inadequate because it fails to address the impacts, costs, and benefits of ultimate disposal of depleted uranium hexafluoride (DUF₆) tails, or the cumulative and generic impacts of DUF₆ disposal.

Applicant Louisiana Energy Services, L.P. (LES) filed a response, dated January 31, 1994, requesting that Contentions T and U should be rejected outright. As to Contention W, Applicant believes that it has merit only as a comment on the DEIS and should be incorporated in that process.

Staff filed a response dated February 4, 1994, in which it requested that the three proffered contentions be rejected.

On February 11, 1994, CANT filed a motion for leave to file a reply to the LES and Staff responses. As part of its motion, Intervenor withdrew proffered Contentions T and U. CANT's motion was accompanied by its reply of the same date.

LES did not respond to the CANT motion for leave to file a reply. Staff, in an answer dated February 28, 1994, did not oppose CANT's motion for leave to reply to the responses opposing Contention W.

I. THE MOTION FOR LEAVE TO REPLY TO LES'S AND STAFF'S RESPONSES

We grant CANT's motion for leave to reply to Applicant's and Staff's responses to the proffered contentions. As stated by Staff, it is well established that before any decision is made on the admissibility of any contention in an NRC licensing proceeding, the proponent of the contention must be given the opportunity to be heard in response to any opposition to the contention. Houston Lighting and Power Co. (Allens Creek Nuclear Generating Station, Unit 1), ALAB-565, 10 NRC 521, 524 (1979); Long Island Lighting Co. (Shoreham Nuclear Power Station, Unit 1), LBP-81-18, 14 NRC 71, 73 (1981).

We also approve the withdrawal of Contentions T and U and note that CANT's action relieves the Licensing Board of an unnecessary burden.

II. CONTENTION W

A. Pertinent Regulatory Requirements

An admissible contention must meet the requirements of 10 C.F.R. § 2.714(b)(2), which provides:

(2) Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide the following information with respect to each contention:

(i) A brief explanation of the bases of the contention.
(ii) A concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing, together with references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion.

(iii) Sufficient information (which may include information pursuant to paragraphs (b)(2)(i) and (ii) of this section) to show that a genuine dispute exists with the applicant on a material issue of law or fact. This showing must include references to the specific portions of the application (including the applicant’s environmental report and safety report) that the petitioner disputes and the supporting reasons for each dispute, or, if the petitioner believes that the application fails to contain information on a relevant matter as required by law, the identification of each failure and the supporting reasons for the petitioner’s belief. On issues arising under the National Environmental Policy Act, the petitioner shall file contentions based on the applicant’s environmental report. The petitioner can amend those contentions or file new contentions if there are data or conclusions in the NRC draft or final environmental impact statement, environmental assessment, or any supplements relating thereto, that differ significantly from the data or conclusions in the applicant’s document.

In the case of a nontimely filing, which this is, under 10 C.F.R. § 2.714(a)(1), a licensing board cannot entertain the contention absent a balancing of the following factors in favor of the petitioners:

(i) Good cause, if any, for failure to file on time.
(ii) The availability of other means whereby the petitioner’s interest will be protected.
(iii) The extent to which the petitioner’s participation may reasonably be expected to assist in developing a sound record.
(iv) The extent to which the petitioner’s interest will be represented by existing parties.
(v) The extent to which the petitioner’s participation will broaden the issues or delay the proceeding.

In amending the applicable regulation on August 11, 1989, the Commission indicated that the amendments do not constitute a substantial departure from then-existing practice in licensing cases. 54 Fed. Reg. 33,170-71.

Existing practice has been that the five factors are not weighed equally, nor do all of them have to be evaluated favorably to the proponent of a late-filed contention in order for the contention to be accepted.

Good cause for late filing has been described as the most significant. Absent good cause, a petitioner must make a stronger showing on the other factors in order to have a contention accepted. Detroit Edison Co. (Enrico Fermi Atomic Power Plant, Unit 2), ALAB-707, 16 NRC 1760, 1765 (1982).

B. Contention W

CONTENTION W: The DEIS Is Inadequate Because It Fails to Address the Impacts, Costs, and Benefits of Ultimate Disposal of DUF₆ Tails, or the Cumulative and Generic Impacts of DUF₆ Tails Disposal.

According to the DEIS, the 3,830 metric tons ("tonnes") of depleted uranium hexafluoride ("DUF₆") tails produced annually by the CEC will be converted to triuranium oxide (U₃O₈). DEIS at 2-31. However, the DEIS contains no information whatsoever regarding the nature and environmental impacts of the process for converting DUF₆ to U₃O₈, or the impacts of permanently disposing of these U₃O₈ tails. Given this utter lack of information, it is also impossible to determine from the DEIS the basis for the NRC's estimate that tails disposal will cost $12.6 million/year. DEIS at 2-31. In any event, the NRC does not even appear to have factored the $12.6 million estimate into its cost-benefit analysis. See DEIS § 4.5.

Moreover, the NRC has failed to evaluate the cumulative and generic impacts of adding to the huge (and growing) national inventory of DUF₆ tails, for which the U.S. government has yet to identify an acceptable means of disposal. The NRC, in consultation with the Department of Energy, should be required to evaluate these impacts before LES can be licensed to produce more DUF₆.

As its basis for the contention, CANT asserts that NEPA requires an Environmental Impact Statement (EIS) to be comprehensive and assess all reasonably foreseeable, cumulative impacts of a proposed project. It alleges that the DEIS contains virtually no information on the environmental impacts of the conversion of the DUF₆ to U₃O₈ and disposal of the enormous quantity of tails to be generated.

As examples, CANT alleges that the DEIS does not identify or discuss the process by which LES plans to convert DUF₆ to U₃O₈ and what the significant adverse environmental impacts and costs would be.

Intervenor states that the DEIS also fails to identify the means for long-term storage of U₃O₈, or evaluate its environmental impacts. It also asserts that in violation of NEPA, the DEIS fails to address the cumulative or generic impacts of LES's proposal to add over 10,000 tonnes of DUF₆ tails to the existing national inventory from other uranium enrichment plants.

CANT submits that the issue should be addressed in a generic environmental impact statement by the NRC and the Department of Energy (DOE). Contention W is supported by an affidavit from Arjun Makhijani, Ph.D. Dr. Makhijani is president of the Institute for Energy and Environmental Research and claims expertise in the fields of nuclear engineering and atmospheric protection in relation to the stratospheric ozone layer.

Intervenor states that it has satisfied the late-filed contention standard. It relies on that part of 10 C.F.R. § 2.714(b)(2)(iii) which provides that:

On issues arising under the National Environmental Policy Act, the petitioner shall file contentions based on the applicant's environmental report. The petitioner can amend those
contentions or file new contentions if there are data or conclusions in the NRC draft or final environmental impact statement, environmental assessment, or any supplements relating thereto, that differ significantly from the data or conclusions in the applicant’s document.

CANT asserts that the contention satisfies the above and the 10 C.F.R. § 2.714(a)(1)(i) good-cause standard. It contends that the DEIS for the first time states that the NRC or LES has specifically identified the conversion of DUF₆ to U₃O₈ as the chosen means for the disposal of the DUF₆ tails at the CEC.

CANT stated that the DEIS differs from the data and conclusions in Applicant’s document. It asserts that, in the Environmental Report (ER), LES states that it is still hopeful to sell the tails but is vague as to the means of disposal if they are unmarketable. CANT quotes from the ER that “UF₆ conversion and disposal options will vary,” will be “accomplished elsewhere,” and will involve conversion to “a stable, non-volatile uranium compound prior to disposal.” ER 4.4.2.7 Disposal, at 4.4-11 (October 1993).

Intervenor states that the preparation of the contention required it to obtain expert assistance from Dr. Makhijani who was not available to CANT until after the winter holidays. The contention was said to be filed as soon as possible after Dr. Makhijani became available.

CANT alleges as to factor (ii) that there is no other means by which CANT’s interest can be protected because it is the only proceeding in which the environmental impacts of the CEC will be considered under NEPA.

It asserts as to factor (iii) that Intervenor’s participation can be expected to aid in the development of a sound record with regard to this issue. It will rely on the asserted expertise of Dr. Makhijani in this area.

As to factor (iv), it states that it is the only citizen intervenor group admitted in the proceeding and that there is no other party to represent its interest.

It acknowledges under factor (v) that admission of the contention may broaden the issues and delay the conclusion but it does not expect that it will be in a significant manner. It points to Contention B which challenges the adequacy of LES’s decommissioning cost estimates. CANT asserts that the scope of that contention necessarily includes factual issues raised by Contention W regarding the cost of the DUF₆ conversion and disposal so that the admission of the subject contention will not broaden the factual aspects. It would introduce a new legal issue.

Intervenor contends that the factors weigh in favor of admission.

Applicant’s Position

LES asserts that Contention W is a comment on the DEIS and should be incorporated in the comment process. It also claims that, in light of the
comment process, the filing of a contention is premature. Applicant states that if Intervenor’s comment is not incorporated in the Final Environmental Impact Statement (FEIS) or if it is not resolved to Intervenor’s satisfaction, CANT can pursue the matter at a later time. Applicant concedes that additional discussion of environmental effects of DUF₆ disposition would be appropriate in the FEIS.

LES notes that the precise mode of decommissioning and DUF₆ disposal has not been determined by regulation and that applicant’s plans on DUF₆ disposition have changed over time. It has addressed possible methodologies and costs of disposal and has revised its decommissioning cost estimates to accommodate conversion to U₃O₈ and disposal at a burial facility. Applicant has not adopted a prescriptive position and considers it to be premature to expend resources analyzing a position, until one of the many viable options is determined to be the proper course to pursue. Applicant contends that this determination may not be feasible until well after the license is issued and in the interim only a general discussion of the environmental impact of DUF₆ disposal is reasonable and necessary.

Applicant denies the need for a generic EIS, considering that the application involves the NRC licensing of a single facility.

**Staff’s Position**

Staff states that it intends to respond to CANT’s assertions in the FEIS but opposes the acceptance of the contention.

Staff asserts that, contrary to CANT’s position that the ER never specifically identified to the public LES’s proposed method for disposal of the DUF₆ tails, the ER does so.

Staff relies on ER 4.4.4.1 Decommissioning Costs, Tails Disposal at 4.4-16. It estimates the annual tails disposal costs, which are based on converting UF₆ to U₃O₈, with subsequent disposal in a facility under cognizance of the NRC. The data regarding tails disposal first appeared in the tenth revision to the ER, dated May 1993. Staff claims that, since May 1993, LES has specifically identified conversion of DUF₆ to U₃O₈ as the chosen means for disposing of the DUF₆ tails at the CEC.

Staff contends that the DEIS does not contain any data or conclusions regarding conversions and disposal of DUF₆ that differ significantly from the data or conclusions that have been in the Applicant’s environmental report since May 1993. It contends that there is no good cause for CANT’s failure to raise its challenge earlier in the proceeding and that the late-filed contention should be rejected pursuant to 10 C.F.R. § 2.714(a)(1).

Staff contends that the five factors to be considered weigh against entertaining the contention. It asserts as to factor (i) that CANT has not shown why the information that was available much earlier in the ER could not have been acted
on previously. Staff concedes that factors (ii) and (iv) may favor admitting the contention but, like factor (i), factors (iii) and (v) weigh in favor of rejecting the contention. As to (iii) it argues that testimony on the inadequacy of the DEIS would be of no value because the FEIS will be the basis of Staff’s environmental finding. Staff does not consider factor (v) to support CANT because it alleges that the factual matters of concern are within the scope of an already admitted contention.

Staff asserts that the matter of LES providing financial assurance for tails disposition has already been admitted as part of Contention B, Decommissioning Plan Deficiencies, so that there is no reason to admit the issue for litigation as a separate contention. LBP-91-41, 34 NRC at 336-37.

**CANT’s Reply**

CANT responds to the LES argument that raising the issues by way of a contention is premature by stating that the regulations and case law mandate that contentions be filed at the earliest possible time. It cites in support *Public Service Co. of New Hampshire* (Seabrook Station, Units 1 and 2), LBP-89-4, 29 NRC 62, 70 (1989). Intervenor seeks consideration of the contention now and not after the issuance of the FEIS.

CANT reiterates that the ER at 4.4.2.7 Disposal makes no reference to the conversion of DUF₆ to U₃O₈, vaguely noting that DUF₆ will be converted to a stable, nonvolatile uranium compound. It argues that Staff’s reference to the conversion of DUF₆ to U₃O₈ elsewhere in the ER is buried in a separate section, ER 4.4.4.1 Decommissioning Costs, Tails Disposal at 4.4-16. It states that CANT cannot be expected to hunt through the application for hidden evidence that LES has chosen a specific tails disposition strategy, when LES has not stated that choice in the section where its plans for tails disposal are supposed to be identified. CANT stands by its position that the DEIS first apprised CANT of LES’s selection of a disposal method that would convert DUF₆ to U₃O₈.

CANT notes that Contention W extends beyond the issue of the financial costs of tails disposal and, therefore, contrary to Staff’s assertion, Contention W is not completely embraced in the scope of admitted issues in Contention B. CANT seeks a ruling from the Licensing Board that the broader issues in Contention W are admitted as well as a determination that the cost issue is already admitted.

**Discussion and Conclusion**

The DEIS dated November 1993 is the first document that unambiguously states what the disposition of the tails will be. “The removal and disposition of
the depleted UF₆ (DUF₆) generated at CEC will involve the conversion of DUF₆ to triuranium octoxide (U₃O₈) prior to disposal."

Applicant’s ER in the paragraph relating to disposal is noncommittal as to the method that will be employed. It speaks in terms of the possibility of the sale of the tails, by LES, that its conversion and disposal options vary and that the UF₆ will be converted to an unspecified stable nonvolatile uranium compound.

ER 4.4.2.7 Disposal.

The tenth change made to the ER in May 1993 as to decommissioning costs does not establish, as the DEIS does, that the UF₆ will be converted by LES to U₃O₈. Although the ER at 4.4.4.1 Decommissioning Costs provides under Tails Disposal that the decommissioning costs are based on the conversion of UF₆ to U₃O₈, it does not state that LES had selected that process for disposal.

The above description of the decommissioning falls under ER 4.4.4 DECOMMISSIONING COSTS AND FUNDING, at 4.4-14. It specifies that the section provides an estimation on decommissioning costs and is made to ensure that funding is available to cover the costs.

When one considers that the NRC has no regulatory requirement that there must be a concrete plan for the disposal of the depleted uranium, and that the applicable regulations only require that an applicant have a plausible strategy for the disposition of depleted uranium decommissioning, it is not at all clear that in basing its estimate of decommissioning costs on the conversion to U₃O₈, LES had prescriptively selected that method for disposal as the DEIS states.

We find that the DEIS on the issue of tails disposal contains data and conclusions that differ significantly from those in the ER and that under 10 C.F.R. § 2.714(b)(2)(iii) Intervenor is authorized to file a new contention, which it has done.

The right afforded under section 2.714(b)(2)(iii) to file a contention regarding the DEIS is not conditional. CANT can both file a contention and comment on the NRC impact statement. The information that underlies its contention is presently available and CANT has the regulatory authority to proceed. The argument that Intervenor should await the issuance of the FEIS before taking action is without merit. Intervenor need not waive its right to file a contention on the DEIS. Intervenor would be acting at its peril had it chosen to await the filing of the FEIS.

We weigh the five factors in 10 C.F.R. § 2.714(a)(1) to determine whether the contention should be entertained in Intervenor’s favor.

(i) CANT had good cause for failure to file on time. The information that forms the basis of the contention first became available in the DEIS dated November 1993. CANT stated that it needed to employ the expertise of Dr.

Makhijani to prepare the contention and he was not available during the winter holidays. The contention was filed on January 18, 1993. The time taken from when the document became available to the time of filing was not unreasonable. We find that it was a prompt submittal.

(ii) We weigh factor (ii) in CANT's favor. There are no assured other means whereby Intervenor's interest will be protected. Commenting on the DEIS is an alternative but the determination of the matters raised would be in the hands of another party to this proceeding.

(iii) Petitioner's participation may reasonably be expected to assist in developing a sound record. CANT will rely on a witness it considers to have expertise on the issue it has raised on the DEIS. Intervenor has acted knowledgeably and responsibly in the time that this proceeding has been under way and it is expected that it will continue to do so on the subject issue.

(iv) This factor must also be weighed in favor of CANT. CANT is the only intervenor in opposition to the application and there is no other party that will represent its interest.

(v) Petitioner's participation may somewhat broaden the issues and delay the proceeding but not in any material way. Staff asserts that it will respond to CANT's concerns in the FEIS and if that satisfies the Intervenor there will be a negligible effect on the proceeding.

There is an area common to Contention W where CANT questions the basis for NRC's cost estimate for tails disposal and admitted Contention B where CANT's objection is that LES provides no details on how its decommissioning costs were determined. The data developed to respond to Contention B might also apply to Contention W and that would limit the broadening effect of admitting Contention W.

Contention W does raise the issue of the environmental impacts of the conversion of DUF₆ to U₃O₈ which has a broadening effect. However, the hearing on environmental issues is not due to start until December 27, 1994. The issue should not delay the start of the hearing nor should it significantly extend the hearing itself. Factor (v) does not present any real negative to accepting the contention for consideration.

The weight of the five factors requires entertaining the contention as provided under 10 C.F.R. § 2.714(a)(1).

We find that Contention W satisfies the requirements of 10 C.F.R. 2.714(b)(2) except to the extent that the contention asserts that "the NRC, in consultation with the Department of Energy, should be required to evaluate those impacts [of adding to the national inventory of DUF₆ tails] before LES can be licensed to produce more DUF₆,"

As its basis for the foregoing, CANT asserts that the LES proposal would add 10,000 tonnes of DUF₆ tails to an existing inventory of 500,000 tonnes.
CANT submits that the issue should be addressed in a generic environmental impact statement by the NRC and the DOE.

In its answer, LES asserts that the effect will be nil. CANT does not respond to this in its response.

While the environmental effects of adding 10,000 tonnes of DUF$_6$ to the national inventory are a legitimate area of concern, our mandate in hearing this license application is not to solve any problem that the national inventory of DUF$_6$ tails may present. The request for a generic environmental impact statement is without merit and will not be considered. What is required is an environmental impact statement that is specific to CEC. It is the responsibility of the NRC to prepare the statement. The Licensing Board knows of no requirement that it prepare its statement with any other governmental entity. It is expected that Staff will have complied with 10 C.F.R. §§ 51.26 and 51.74 for exchanging comments with other federal agencies.

III. ORDER

Based upon the foregoing, it is hereby Ordered that Contention W be admitted to the extent described.

THE ATOMIC SAFETY AND LICENSING BOARD

Morton B. Margulies, Chairman
CHIEF ADMINISTRATIVE LAW JUDGE

Richard F. Cole
ADMINISTRATIVE JUDGE

Frederick J. Shon
ADMINISTRATIVE JUDGE

Bethesda, Maryland
April 5, 1994
MEMORANDUM AND ORDER
(Granting Request for Hearing)

I. BACKGROUND

Babcock and Wilcox Company (B&W or Applicant) has applied for the renewal of its special nuclear material license issued to the Pennsylvania Nuclear Service Operation facility located in Parks Township, Armstrong County, Pennsylvania (Parks Township facility).¹

On January 5, 1994, Citizens Action for a Safe Environment (CASE), by Patricia J. Ameno, and Kiski Valley Coalition to Save Our Children (the Coalition), by John Bologna, filed a joint request for a hearing on the application. Both the NRC Staff and B&W initially opposed the hearing requests on the grounds that the Requestors had not established their right or “standing” to

intervene in an NRC proceeding and that they had failed to allege an area of concern within the scope of the application.\footnote{\textit{NRC Staff Notice of Participation and Response to Petitioners' Request for Hearing, January 24, 1994}. Letter of January 13, 1994, from B L. Haertens, B&W Environmental Services, to Chief Administrative Judge B Paul Cotter.}

In a Memorandum and Order of February 2, 1994, 1 B.P. 94-4, 39 NRC 47, I granted the Requestors an opportunity to establish that their members have standing to intervene and that such members have authorized the Requestors to represent them in this proceeding.

On February 25, 1994, the Requestors submitted an amendment to their request styled “Illustration of Standing to Intervene.” Forwarded with the “Illustration” were certificates and letters from residents of the Kiski Valley region, the essence of which was to authorize CASE and the Coalition to represent them in this proceeding.

However, because Ms. Ameno and Mr. Bologna refused to permit the public use of the letters, the letters could not be used to establish standing to intervene.\footnote{Transcribed prehearing conference of March 8, 1994, Tr 1-79} Without objection from Staff or B&W, I afforded a second opportunity for the Requestors to show that they have standing to intervene derived from the standing of their members. \textit{E.g.}, Tr. 30. Subsequently, the Requestors served on the public record information from their members.

II. STANDING TO INTERVENE

The Requestors’ second amendment to their request for hearing, served on March 12, 1994, contains permission slips and letters from residents, most of whom demonstrate that they have standing to intervene, all of whom are members of either CASE, the Coalition, or both, and have authorized both organizations to represent them. B&W\footnote{Response of Licensee to Request for Hearing and “Illustration of Standing to Intervene” (Mar. 25, 1994) and the NRC Staff\footnote{NRC Staff Response to Petitioners’ Supplemented Request for Hearing (Mar 31, 1994) concede that the Requestors have established standing to intervene in this proceeding. I agree.}

III. STATED AREAS OF CONCERN

A. Legal Standards

Requests for a hearing must describe in detail the requestor’s areas of concern about the licensing activity subject to the hearing. 10 C.F.R. § 2.1205(d)(3). However, requestors need not set forth all of their concerns until the request for a hearing has been granted and the NRC Staff creates and serves a hearing

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Under the formal procedures of Subpart G, an intervention petitioner must explain the basis for any contention it seeks to litigate and demonstrate that a genuine dispute exists with the applicant on a material issue. 10 C.F.R. § 2.714(b)(2). In this informal Subpart I proceeding, however, there is no such requirement. The test is simple — persons or organizations with standing to intervene need only identify their "areas of concern germane to the proceeding" to have those areas addressed in a hearing. Of course, to be germane to a proceeding, an area of concern must also be rational.

B&W argues that the Requestors have not alleged any area of concern that constitutes a litigable issue in this proceeding, and the request for a hearing should be denied. B&W Response at 7–20.

The NRC Staff concludes that the Requestors have established one litigable area of concern, the so-called "sloppy housekeeping and experiments" issue discussed below, and that the request for a hearing should be granted on that issue alone. March 31 Staff Response at 14.

For convenience, in the following discussion, I shall follow the framework previously used by the Staff and B&W in responding to the areas of concern arguably stated in the request for hearing and supplements to the request.

B. Critical and Sensitive Population

Requestors allege that over 75% of the population are critical or sensitive persons, such as elderly and invalids, and are thus "more vulnerable to dangerous situations than the general population." The allegation is too inconclusive to be litigable. Also, I infer that the Requestors' concern is that special evacuation or emergency measures would be needed for this special population. But, as noted in the following section, there is no regulatory requirement for such measures with respect to this type of facility.

C. One Road to Kiskimere

The Requestors are concerned that there is only one road to and from Kiskimere with no alternative emergency evacuation exits. Request at 1; Illustration at 9. B&W and the Staff explain that, unlike nuclear power facilities licensed under 10 C.F.R. Part 50, and for the amount of radioactive materials

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involved in the Parks Township facility, as provided by 10 C.F.R. § 70.22(t), there is no regulatory requirement for an evacuation plan. I agree that there is no regulatory basis upon which the need for a Kiskimere evacuation route can be litigated.

D. Property Values and Public Health and Safety

Requestors and some of the members they represent are concerned about a decline in property values should the facility license be renewed. Request at 1; Illustration at 3. The NRC Staff opposes the admission of this issue on the ground that economic interests are not within the scope of the Atomic Energy Act, citing, e.g., Portland General Electric Co. (Pebble Springs Nuclear Plant, Units 1 and 2), CLI-76-27, 4 NRC 610, 614 (1976). B&W states that there is no linkage between property values and the renewal of the license.

The economic interests at stake in the Pebble Springs proceeding, cited by the Staff, pertained to the potential for increased electric power rates — patently a matter beyond the zone of interests of the Atomic Energy Act. Property values, however, should be considered in a different context.

The Staff failed to mention the provisions of 10 C.F.R. § 2.1205(g)(2), which require the presiding officer to consider “the nature and extent of the requestor’s property . . . interest in the proceeding” when ruling on a request for a hearing.

The Requestors are not specific about this allegation, stating only, “we are also concerned about the property values.” Request at 1. Their concern is expressed by the statement of Mildred E. Chelko, who is a licensed realtor and a member of both requesting organizations. Ms. Chelko states that the market value of property in the Parks Township area is “way below other areas.” In another statement, Ms. Chelko alludes to a potential buyer who decided not to proceed with building a house because “he would never be able to sell it.”

Nowhere do the Requestors state in so many words that the depressed property values are directly attributable to the Parks Township facility or the renewal of its license, but, solely for the purpose of this ruling, I shall assume that such is the case.

Even so, I have no basis whatever to infer that the Requestors or their members are concerned about property values that are depressed because of direct radiological contamination from the Parks facility. To the contrary, the best inference is that potential buyers simply don’t want to purchase property in the vicinity of the facility because of attitude, concern about resale values, and perhaps fear of living in the vicinity of the plant — in other words, psychological concerns.

The Commission addressed the issue of psychological stress attributed to the fear of releases of radioactivity in a proceeding following the accident at Three Mile Island, and decided that, as a matter of public policy, NRC’s administration
of the Atomic Energy Act will not include psychological effects from the fear of radiation. Therefore, I cannot accept as an issue to be heard a concern that property values may be depressed where such effect is attributable solely to public and buyer attitude.

F. Opportunity to Be Heard

Requestors wish a "level playing field" for the general population of the region to be heard on the license renewal. Request at 1. This is a standing-to-intervene issue and is mooted by today's order granting the hearing request.

F. The Part 50 Issue

The Requestors complain that certain provisions of 10 C.F.R. Part 50 pertaining to the solicitation of public comments were not complied with. This is a Part 70 proceeding and the Part 50 allegation is irrelevant.

G. Report to Pennsylvania Department of Environmental Resources

In the joint request for hearing, Requestors assert that "according to the Licensee's own report to the Pa. D.E.R. we have chemical contamination as well as radiological." Request at 1. The report was provided by the Requestors with their February 25, 1994 Illustration. Contrary to Requestors' statement, the document does not report radiological contamination. Moreover, Requestors discuss the report again in their February 25 Illustration, but they did not then allege radiological contamination in the water supply within the context of the report. I conclude that the Requestors were mistaken in the initial allegation. This proceeding does not encompass purely chemical contamination.

H. Shot-Blasting Process

Requestors express concern about the shot-blasting process approved by the NRC and the Commonwealth of Pennsylvania for use at the facility. B&W responded by submitting the affidavit of Mr. B.L. Haertjens, Technical Control Manager at the Parks Township facility. He reports that the process was

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7 Metropolitan Edison Co. (Three Mile Island Nuclear Station, Unit 1) CL1-82-6, 15 NRC 407 (1982). With respect to the National Environmental Policy Act, the Supreme Court held that the NRC need not consider psychological effects in a related case Metropolitan Edison Co. v. People Against Nuclear Energy, 460 U.S. 756 (1983). See also supra note 11.

employed only for a 9-day period early in 1992; that the system was dismantled in February 1994; and that B&W will file an amendment to renewal application to remove authorization for its use.

Normally in NRC proceedings, the factual merits of an issue or contention are not addressed until the issue is accepted for litigation. In this case, however, the shot-blast concern is so clearly mooted by the circumstances explained in Mr. Haertjen's affidavit that I reject it as a separate issue. However, within 10 days following the service of this order, Requestors may move for a reconsideration of this ruling, explaining why, if such be the case, the shot-blast issue should be heard despite the affidavit.

I. Decommissioning

Decommissioning the Parks Township facility, as urged in the Request for Hearing, is not within the scope of this proceeding. Therefore, I have no authority to consider or grant that relief, even though decommissioning might logically follow from a denial of the application for renewal.

J. Housekeeping and Experiments

The Requestors made the blanket allegation that for over 35 years the company has performed "sloppy housekeeping" and experiments "along with a keen eye for 'loop-hole' in the system." The charge was augmented by specifics in the February 25 Illustration and by an accompanying video cassette.9

The video cassette recording, as explained in the Illustration (at 8-9), supports a litigable area of concern. It depicts the Parks Township facility in close proximity to residences and a restaurant. Within the radiation area, marked by radiation warning symbols, one can see many drums and industrial containers sitting directly on the ground and close to the facility perimeter. Not knowing the context and contents of the containers, I stop short of calling the housekeeping "sloppy," but there is an aura of casualness about the housekeeping. Overall the video cassettes raise a reasonable area of concern. The NRC Staff agrees that the "sloppy housekeeping" area of concern is acceptable for hearing. Staff Response at 12. The allegation and area of concern regarding housekeeping is accepted as a subissue for hearing, specifically included in a broader area of concern discussed below.

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9 In their Illustration, Requestors refer to a June 1993 document entitled "Notations of Deficiencies in the NRC Oversight of Decommissioning Activities in the Babcock and Wilcox, Pennsylvania Facility." Contrary to the Requestors' assertion, the document is not "typical," nor is it "self-explanatory." Among other deficiencies, it is (1) anonymous, (2) without context, (3) nonspecific, and (4) it contains no explanation of the relevance to this proceeding.
K. Soil Testing of Residential Properties

The Requestors urge that the Parks Township facility license not be renewed until the residences neighboring the facility have had soil testing for radiological, and, presumably, mixed wastes contamination. Request at 2.

The Applicant and NRC Staff oppose the soil-testing issue on the grounds that NRC regulations do not require such testing. Applicant explains that it will be required to meet the applicable provisions 10 C.F.R. Parts 20 and 70, and that offsite soil testing is not a prerequisite to license renewal. B&W Response at 19.

I find three discrete issues involved in this subject matter: (1) soil testing as a part of a broader area of concern, (2) regulatory and procedural authority to require soil testing, and (3) the acceptable purposes for soil testing.

1. Soil Testing as a Part of a Broader Issue

This area of concern is not about soil testing alone. It is inextricably intertwined with the overall concern about offsite radiological contamination.

The Apollo facility plays a major role in raising areas of concern to the Requestors. They argue that Apollo is relevant because:

(1) it is the same company; (2) they have the same manager; (3) both sites operated during the same time span; (4) waste was transported between the two facilities; and (5) the plant sites are approximately 3 miles apart.

Illustration at 6. They allude to a recent finding of offsite contamination of enriched uranium within a 500-foot radius of Apollo. Id.

Mr. Bologna also expresses concern about newspaper reports that the Parks dump site, grown to 40 acres, is the "Number 1 Contaminated Site —." Illustration at 7. The Requestors are also concerned that the entire Parks Township facility is located over a mined-out area.10 The request that nearby residences undergo soil testing is simply a tag to the basic area of concern about offsite contamination, an issue that I accept in the order below.

2. Regulatory or Procedural Authority for Soil Testing

I can find no regulation that requires soil testing as a condition for renewing that Parks Township facility license. In that respect, I agree with B&W and the Staff. However, I do not now reject categorically the possibility that soil testing

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10 This statement is contained in a "Response to N.R.C. Staff" (at 2) attached to the Illustration.
may be required as a condition of authorizing the license renewal because of evidence adduced in this proceeding.

3. Acceptable Purposes of Soil Testing

However, I can already rule out soil testing for the sole purpose of alleviating unfounded fears of offsite radiation. In the Three Mile Island proceeding, cited above, an issue was whether an Atomic Safety and Licensing Board, under the National Environmental Policy Act, could impose a condition designed to improve the quality of life around the Three Mile Island Station by ordering radiation monitoring. The purpose would have been to mitigate community fears about the possibility of offsite radiation releases even though there was no factual basis to expect releases. The Commission would not permit consideration of psychological stress contentions solely directed to mitigating community fears.\(^{11}\)

IV. ORDER

A. Areas of Concern Accepted for Hearing

I have found in the papers filed by the Requestors the following broad area of concern and related subareas of concern which I accept as issues for hearing:

*Broad area of concern:*

Whether there has been, and under a license renewal whether there will be, offsite radiation from the Parks Township facility which threatens the health and safety of the nearby population and threatens radiological contamination of nearby residential, agricultural, and business property.

*Included subareas of concern:*

1. Whether the housekeeping practices (drums, containers, etc.) at the Parks Township facility threaten the offsite release of radiation through water, dust, and air pathways.
2. Whether B&W management practices as manifested by the management of the Apollo facility threaten offsite releases of radiation from the Parks Township facility.
3. Whether transportation of wastes between Parks and Apollo has radiologically contaminated offsite properties.

\(^{11}\) *Metropolitan Edison Co.* (Three Mile Island Nuclear Station, Unit 1), LBP-80-8, 11 NRC 297, 308 (1980) (Certification to the Commission), CLI-80-39, 12 NRC 607 (1980) (Order regarding Certification). See also *Three Mile Island*, CLI-82-6, supra note 7.
4. Whether the location of the Parks Township facility waste dump over a mined-out area threatens, through subsidence, the integrity of the dump, and whether the mined-out area creates a threat of offsite release of radiation through a water-migration pathway.

B. Requestors Admitted as Intervenors

The Joint Requestors, Citizens Action for a Safe Environment and Kiski Valley Coalition to Save Our Children have demonstrated their standing to intervene and have stated areas of concern germane to the proceeding. Therefore, I admit them as Intervenors and as parties to this proceeding. Their interests in the proceeding appear to be identical or at least very closely related. Therefore, I grant B&W's motion to consolidate their intervention. I shall henceforth usually refer to them as “Intervenors.” Unless informed to the contrary I will assume that Ms. Ameno and Mr. Bologna each has the authority to speak for and to commit the Intervenors.\(^\text{12}\)

The NRC Staff and the Applicant, Babcock & Wilcox Company, are also parties to the proceeding.

C. Request for Hearing Granted

The Joint Request for a hearing is \textit{GRANTED}. A hearing based upon an official NRC hearing file and written presentations, as provided by 10 C.F.R. §§ 2.1231 and 2.1233, is \textit{COMMENCED}.

B&W’s motion to adopt a schedule is granted as follows:

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<tr>
<th>Action</th>
<th>Schedule</th>
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<tr>
<td>• The NRC Staff makes the hearing file available to Intervenors and Applicant pursuant to section 2.1231.</td>
<td>Within 30 days of the Presiding Officer’s entry of an order granting in part Intervenors’ Request for Hearing.</td>
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<tr>
<td>• Intervenors submit a written presentation of their arguments and documentary data,</td>
<td>Within 45 days after the NRC Staff either serves the hearing file on Intervenors and</td>
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\(^{12}\) B&W’s motion to serve a single copy of pleadings and documents on the Intervenors is denied even though they share the same mailing address. Both Ms. Ameno and Mr. Bologna have contributed to the hearing requests and I assume that each will work on the Intervenors’ positions in the hearing. On the other hand, the Intervenors may agree to a single service, and they should cooperate when requested to share large documents. If practicable, both Ms. Ameno and Mr. Bologna will be included in any prehearing conference.
informational material, and other supporting written evidence pursuant to section 2.1233.

• Applicant submits a written presentation pursuant to section 2.1233.

V. APPEALABILITY

Pursuant to the provisions 10 C.F.R. § 2.1205(n), within 10 days following the service of this order, the Applicant, Babcock and Wilcox Company, may appeal this order on the grounds that the request for hearing should have been denied in its entirety. An appeal may be taken by filing a succinct statement of alleged errors with supporting argument. Any other party may oppose or support any appeal by the Applicant by filing a counterstatement within 15 days of the service of the appeal documents.

It is so ORDERED.

Ivan W. Smith, Presiding Officer
ADMINISTRATIVE JUDGE

Bethesda, Maryland
April 22, 1994
Denials of Petitions for Rulemaking
UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

COMMISSIONERS:

Ivan Selin, Chairman
Kenneth C. Rogers
Forrest J. Remick
E. Gail de Planque

In the Matter of Docket No. PRM 170-3

AMERICAN COLLEGE OF NUCLEAR PHYSICIANS, et al.

March 11, 1994

The Nuclear Regulatory Commission ("NRC" or "Commission") received a petition for rulemaking submitted by the American College of Nuclear Physicians ("ACNP") and the Society of Nuclear Medicine ("SNM") ("Petitioners"). The Petitioners requested that the Commission amend its regulations governing the user and annual fees charged to their members because of increases in those fees. Among the specific requests contained in the petition were to establish a generic exemption for medical licensees who provide services in nonprofit institutions and to allow NRC licensees a greater voice in the development of new regulations by the NRC. After careful consideration, the Commission has decided not to adopt the proposals made in the petition.

REGULATIONS: INTERPRETATION (10 C.F.R. § 171.11)

Both exemption procedures (power reactor and materials licensee) contained in section 171.11 allow the requester to inform the Commission of "[a]ny . . . relevant matter that the licensee believes" should impact on the exemption decision. This allows the Commission flexibility to consider each situation on its own merits. Were the Commission to attempt to establish specific criteria for each type of materials licensee, itself a daunting task, it might then be prevented from considering factors that did not fall precisely within those enumerated.
REGULATIONS: INTERPRETATION (10 C.F.R. § 171.11)

The Commission explained in the first 100% fee recovery rule, in FY 1991, that because it was statutorily required to collect 100%, it could not easily exempt licensees from fees. If one licensee or class of licensees is exempted, those fees must then be placed on other licensees, increasing their fee burden. It is for that reason that the Commission only grants exemptions in exceptional circumstances.

DENIAL OF PETITION FOR RULEMAKING

I. THE PETITION

On February 18, 1992, the NRC received a petition for rulemaking submitted by Petitioners American College of Nuclear Physicians (ACNP) and Society of Nuclear Medicine (SNM). The Petitioners requested that the NRC amend 10 C.F.R. Parts 170 and 171 which govern the annual and user fees imposed on most NRC materials licensees by the Commission since the advent of 100% fee recovery in FY 1991. The Petitioners requested these amendments because of the substantial adverse impacts experienced by their members following increases in the NRC’s user and annual fees.

On May 12, 1992 (57 Fed. Reg. 20,211), the NRC published a notice in the Federal Register announcing receipt of the petition. In that notice, the NRC stated that it would consider the issues raised by Petitioners within the context of the review and evaluation of the fee program for FY 1993 conducted as part of the NRC’s continued implementation of Pub. L. No. 101-508, the Omnibus Budget Reconciliation Act of 1990, as amended (OBRA-90). On October 13, 1992 (57 Fed. Reg. 46,818), the NRC published a notice requesting public comment on the issues raised in the petition.

The NRC received nearly 100 comments in response to this request, with the vast majority in favor of granting the petition. After careful consideration of the comments, the Commission has decided to deny the petition for rulemaking, for reasons stated below.

II. RESPONSES TO COMMENTS AND REASON FOR DENIAL

1. Comment

The majority of commenters simply restated their support for some or all of the requested changes in NRC policy detailed in the petition. In their petition,
ACNP and SNM stated that NRC fee increases under the 100% recovery regime were adversely affecting their members' practice of nuclear medicine, in the process harming the societal benefits that stem from that field of medicine. The Petitioners claimed that they could not recoup the costs of NRC fees because Medicare reimbursement levels are inadequate and because competing nuclear medicine alternatives are not regulated (or charged fees) by the NRC. Petitioners then compared their treatment under the NRC's fee rules to that of nonprofit educational institutions, power reactors, and small entities, all of whom Petitioners claimed receive special treatment by the NRC, and argued that, for exemption purposes, medical licensees should not be lumped together with all other materials licensees.

For these reasons, ACNP and SNM requested that the Commission take the following policy actions:

1. Grant a generic exemption for medical services provided in nonprofit institutions, such as hospitals, similar to that granted to nonprofit educational institutions;
2. Provide individualized exemption criteria for medical licensees, by means of a "simple template for structuring exemption requests";
3. Adopt a sliding scale of minimum fees that grants nuclear physicians more relief than the current small entity classification (which grants relief to physicians in private practice with less than $1,000,000 in gross receipts); and
4. Give NRC licensees a greater voice in the NRC's decisionmaking process for developing new regulatory programs.

In that regard, Petitioners suggested that the criteria contained in the NRC's backfit rule be applied to the development of all new regulatory programs. That is, if a regulation is not necessary for the adequate protection of the public health and safety, the NRC would be required to show that the rule would substantially increase safety and that its benefits outweigh its costs.

Response

The Commission does not believe that the analogy between colleges and universities and medical services provided in a nonprofit institution is a valid one. The Commission recently decided to reinstate a longstanding (but temporarily withdrawn) fee exemption for nonprofit educational institutions. The key to educational institutions' singular treatment, however, is not their nonprofit status, or the fact that they provide valuable social benefits; rather, it is the existence of certain structural market failures in educational institutions' production of new knowledge. In other words, colleges and universities produce new knowledge primarily through basic research, and disseminate it (essentially for free) to
all who want it, without receiving compensation from those benefitting. In economic terms, this new knowledge is often termed a “public good.”

Two defining characteristics of a public good are its nondepletability and nonexcludability. That is, one person’s acquisition of knowledge does not reduce the amount available to others; further, it is not efficient — and often is impossible, as a practical matter — to prevent others from acquiring it at a zero price. These characteristics make it difficult to recoup the costs of producing new knowledge. Because the value of a public good may be very great, but the costs of producing it impossible to recapture, public subsidies may be necessary for production to occur at all. The Commission has decided to exempt nonprofit educational institutions from annual fees to advance continued production of new knowledge.

By contrast, medical practitioners have the capability of obtaining compensation for the benefits they provide. Unlike new knowledge, medical services are both depletable and excludable. The benefits of medicine, while unquestionably significant, are therefore a private rather than a public good, in economic terms. The Commission believes, in sum, that the market failure considerations that apply to educational institutions’ attempts to produce new knowledge simply do not apply to medical practitioners. There is no structural barrier to the recovery of costs incurred in producing the benefits of medicine. The situation of the medical practitioners is not fundamentally different from that of the for-profit licensees whose claims for exemption on grounds of inability to pass through costs the Commission has rejected in the past. (See 58 Fed. Reg. 38,666-68 (July 20, 1993).)

In this regard, the Commission notes Petitioners’ claim that Medicare may not account for NRC fees when reimbursing physicians and hospitals. The Commission is also aware of pricing pressures caused by competing nuclear medicine modalities not regulated (or charged fees) by the NRC. However, as the Commission explained in its FY 1993 fee rule, it is impracticable for this agency to evaluate the merits of such empirical claims regarding the ability of licensees to pass through fee costs to their customers. (See 58 Fed. Reg. at 38,667-68.) The Commission “does not believe it has the expertise or information needed to undertake the subtle and complex inquiry whether in a market economy particular licensees can or cannot easily recapture the costs of annual fees from their customers.” (Id. at 38,667.) This statement applies equally to medical licensees as it does to all others whose products cannot be characterized as a “public good.”

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1 The Commission’s analysis of this aspect of the petition is based in part on a memorandum prepared by an NRC consultant on the topic of externalized benefits and public goods. This memorandum has been placed in the NRC Public Document Room for examination by any interested persons. See Memorandum to NRC Staff from Stephen J.K. Walters, Professor of Economics, Loyola College (Maryland), dated January 4, 1994.
Addressing the petition’s second major point, the Commission disagrees with those commenters who call for new individualized exemption criteria for medical licensees. The Commission believes that the current exemption process for materials licensees, as codified in 10 C.F.R. § 171.11(d), provides medical licensees with the opportunity to request an exemption by means of detailing their particularized circumstances.

Both exemption procedures (power reactor and materials licensee) contained in section 171.11 allow the requester to inform the Commission of “[a]ny . . . relevant matter that the licensee believes” should impact on the exemption decision. This allows the Commission flexibility to consider each situation on its own merits. Were the Commission to attempt to establish specific criteria for each type of materials licensee, itself a daunting task, it might then be prevented from considering factors that did not fall precisely within those enumerated. And if the Commission retained the open-ended provision quoted above, it would have expended considerable time and resources to little purpose, as licensees could make the same claims under new criteria that they can at this time.

Petitioners also complained that the NRC had established a high threshold for granting materials exemption requests. In this regard, the Commission explained in the first 100% fee recovery rule, in FY 1991, that because it was statutorily required to collect 100%, it could not easily exempt licensees from fees. If one licensee or class of licensees is exempted, those fees must then be placed on other licensees, increasing their fee burden. It is for that reason that the Commission only grants exemptions in exceptional circumstances. (See 56 Fed. Reg. 31,472, 31,485 (July 10, 1991).)

Petitioners’ third request, that the Commission establish a sliding scale of minimum fees based on the size of the licensee, which “reflects the unique constraints on physicians,” also is denied. In its FY 1991 fee rule, the Commission explained in great detail why it devised its fee schedules in the manner it did, basing fees on classes of licensees rather than licensee-by-licensee. (See FY 1991 Final Rule, 56 Fed. Reg. 31,472, and Appendix A to the Final Rule (July 10, 1991).) There is no information contained in either the petition or comments on the petition that would lead the Commission to reconsider this approach, and therefore the Commission must deny this aspect of the petition as well.

However, the Commission intends to reexamine the size standards it uses to define small entities within the context of compliance with the Regulatory Flexibility Act. The Commission will conduct this review within the context of revision of the small business size standards proposed by the Small Business Administration (“SBA”) (58 Fed. Reg. 46,573 (Sept. 2, 1993)). The Commission will not complete this review until the SBA promulgates its final rule on this matter. These activities may result in a revised definition of “small entity” more favorable to Petitioners.
Finally, the Commission denies Petitioners' request that licensees be provided more power over the development of NRC regulations, and that a new backfit rule incorporating cost-benefit analysis be instituted to evaluate the agency's regulatory programs. The Commission denied similar requests in its FY 1991 fee rule, explaining that the NRC is not exempt "from the normal Government review and budgetmaking process." The Commission at that time pointed out that "the Government is not subject to audit by outside parties," and that "[a]udits are performed by the General Accounting Office or the agency's Inspector General, as appropriate." (56 Fed. Reg. at 31,482 (July 10, 1991)). Additionally, the NRC complies with federal regulations such as the Paperwork Reduction Act of 1980 (44 U.S.C. §§ 3501 et seq.) and the Regulatory Flexibility Act of 1980 (5 U.S.C. §§ 601 et seq.) that require agency analysis of the economic effects of new regulations on licensees. The NRC Staff also prepares detailed cost-benefit analyses to justify any new regulatory requirements; these analyses are carefully reviewed by the Commission. The Commission has seen nothing either in the petition or comments on the petition that would lead it to change its approach in this area. The Commission would like to emphasize, however, that licensees are always welcome and expected to comment on proposed rulemakings, including the accompanying cost-benefit analyses, and that such comments, along with petitions such as the present one, workshops, meetings of the Advisory Committee on the Medical Use of Isotopes, and the day-to-day interaction between licensees and the agency, in the Commission's view provide an adequate and successful method of keeping each group apprised of the other's concerns.

2. Comment

The Commission received a potpourri of comments on other aspects of the petition. A number of commenters disagreed with the petition, arguing that medical licensees should not receive an exemption, as the costs of such an exemption would be borne by other licensees to whom the additional fees would have no relation, and that every licensee should pay its fair share. Other commenters stated that the fees should be abolished entirely, which would remove the dilemma over granting exemptions. One commenter argued for basing an exemption on the function for which the license is utilized, not the function of the licensed organization. Some commenters argued that fees should be based on factors such as the amount of radioactive sources possessed, the number of procedures performed or the size of the nuclear department within a hospital. Certain commenters suggested expanding the number of exemptions to include government agencies, along with those licensees that provide products and services to medical and educational entities. One commenter requested that the NRC take Agreement State schedules into account when setting its own
fee schedule. Another commenter raised concerns as to the expense of NRC contractors and the quality of NRC regulation. And a few commenters urged the NRC to reevaluate or abolish its then recently instituted Quality Management (QM) Program.

Response

As the Commission stated above, it is denying this petition for rulemaking, and therefore not exempting medical licensees for services provided in a nonprofit institution. The Commission cannot abolish its fees unilaterally, as the requirement to collect 100% of the agency’s annual budget authority through user and annual fees is statutorily mandated by Congress, see section 6101 of OBRA-90.

The Commission has explained in the past why it did not believe that basing fees on factors such as number of sources or the size of the facility would result in a fairer allocation of the 100% recovery requirement. (See FY 1991 Final Rule, 56 Fed. Reg. 31,472 (July 10, 1991), and Appendix A to that Final Rule; and Limited Revision of Fee Schedules, 57 Fed. Reg. 13,625 (Apr. 17, 1992).) The Commission has seen no evidence in the petition or comments on the petition that would lead it to change its current approach of charging fees by class of licensee. For reasons similar to those stated in the earlier rules cited above, the Commission does not believe it would be feasible to base an exemption on the function for which a license is utilized rather than on the function of the licensed organization.

The Commission has also explained in prior rulemakings why it has decided to charge federal agencies annual fees, and has seen nothing in comments on the petition that would cause it to change its position on this policy matter. (See FY 1991 Final Rule, 56 Fed. Reg. at 31,474-45 (July 10, 1991).) The Commission also does not believe that the exemption for nonprofit educational institutions should be expanded to cover those private companies supplying services and products to medical or educational licensees. The fact that the cost of these services and products impacts upon exempt licensees is not sufficient reason to exempt private for-profit licensees. By exempting nonprofit educational institutions from fees, the Commission has addressed the direct impact of its fees on those institutions. Additionally, the Commission has discussed in both prior and current rulemakings the necessity of a high threshold for exemption requests and the overarching requirement to collect as close to 100% of its annual budget authority as possible; these factors remain valid here.

While the Commission acknowledges that in many cases Agreement States base their fee schedules in some measure on the NRC’s fee schedule, the NRC cannot do the reverse. The NRC must conform its fees to the 100%
recovery requirements mandated by OBRA-90, independent of Agreement State fee schedules over which the agency has no control.

Finally, the Commission believes that comments on the agency's QM program, NRC contracting practices and the overall quality of NRC regulation are beyond the scope of this notice. However, the Commission notes that the agency's regulation codifying its QM program was challenged and ultimately upheld in court. See American College of Nuclear Physicians and Society of Nuclear Medicine v. United States Nuclear Regulatory Commission and United States of America, No. 91-1431, slip op. at 2 (D.C. Cir. May 22, 1992) (per curiam).

Because each of the issues raised in the petition has been substantively resolved, the NRC has denied this petition.

FOR THE NUCLEAR REGULATORY COMMISSION

SAMUEL J. CHILK
Secretary of the Commission

Dated at Rockville, Maryland, this 11th day of March 1994.
The Nuclear Regulatory Commission (NRC) is denying a petition for rule-making submitted by the New England Coalition on Nuclear Pollution, Inc. (PRM 61-2). The Petitioner requested that the NRC amend its regulations regarding waste classification of low-level radioactive waste (LLW) to restrict the number and types of waste streams that can be disposed of in near-surface disposal facilities and prepare a supplemental Environmental Impact Statement (EIS). The NRC is denying the petition because the "new information" as presented by the Petitioner is not sufficient to invalidate the existing classification system or justify that NRC prepare a supplemental EIS.

REGULATIONS: INTERPRETATION (10 C.F.R. PART 61)

The final rule for 10 C.F.R. Part 61 did not include a dose limit for inadvertent intrusion. However, provisions, including waste classification, were included in the final rule to reduce the likelihood and magnitude of exposures to potential intruders. The existence of multiple controls in the final rule to reduce the likelihood of exposures to postulated inadvertent intruders at closed LLW sites was, and continues to be, wholly consistent with the ICRP perspective. These multiple controls are specifically identified or included in sections 61.7, 61.12, 61.14, 61.42, 61.52, and 61.59 and are intended to prevent inadvertent intrusion and to reduce potential exposure if intrusion were to occur.
REGULATIONS: INTERPRETATION (10 C.F.R. PART 61)

The NRC believes that to protect against deliberate intrusion would be unnecessarily conservative and unwarranted. The NRC regulations currently include provisions to protect against intrusion by, for example, requiring government land ownership, records, and the use of markers. In order to deliberately intrude into the LLW site, an individual will have to break the law and overlook the hazard. In the development of 10 C.F.R. Part 61, the NRC stated, "it would appear to be difficult to establish regulations designed to protect a future individual who recognizes a hazard but then chooses to ignore the hazard."

DENIAL OF PETITION FOR RULEMAKING

I. THE PETITION

On July 23, 1992 (57 Fed. Reg. 32,743), the Nuclear Regulatory Commission published a notice of receipt of a petition for rulemaking filed by the New England Coalition on Nuclear Pollution, Inc. The Petitioner requested that the NRC amend 10 C.F.R. Part 61 concerning the classification of low-level radioactive waste for near-surface disposal to restrict the number and types of waste streams that may be disposed of in these disposal facilities. The Petitioner believes that the requested changes are necessary because of significant new information concerning intrusion into LLW disposal facilities that was not available at the time the original EIS was developed. Because of the new information, the Petitioner argues that the NRC must prepare a supplemental EIS since the premises leading to the conclusions reached in the original EIS have substantially changed.

The petition is based on three purported changes that the Petitioner believes have occurred since the rule was promulgated. The Petitioner asserts that these changes affect the basis used to promulgate 10 C.F.R. Part 61.

1. The Petitioner argues that the original EIS was based on a 500-millirem per year (mrem/yr) dose to "inadvertent intruders." Revised guidance by international organizations has reduced dose limits for individual members of the public to 100 mrem/yr and this new criterion has been incorporated into 10 C.F.R. Part 20. The Petitioner presumes that the intruder and public dose limits are integrally linked. The Petitioner asserts that this revised dose limit should also be incorporated into the waste classification system and that this would impact waste streams allowed to be disposed of in LLW facilities.

2. The Petitioner states that the three intrusion scenarios that the NRC considered in the development of Part 61 do not define a broad enough
spectrum of possible events. Of particular concern is that the NRC used regulatory discretion, rather than scientific data, to exclude deliberate intrusion. The Petitioner states that recent studies conducted at the behest of the State of Vermont show that, when intrusion is deliberate, the ability of near-surface facilities to properly provide isolation for all of the currently classified LLW streams is questionable.

3. The Petitioner states that because most currently planned LLW facilities are using an engineered structure to isolate the waste, the cost differential between shallow-land burial facilities, assumed in the EIS, and a geologic repository (for high-level waste) has significantly changed since promulgation of Part 61. Because cost considerations were a factor in the development of the waste classification system, a supplemental EIS is needed.

II. PUBLIC COMMENTS ON THE PETITION

The notice of receipt of petition for rulemaking invited interested persons to submit written comments concerning the petition. The NRC received fourteen comment letters. Three comment letters were received from states (two from Vermont), three from private organizations, three from associated industries (including one disposal site operator), three from private individuals, one from a university, and one from the Department of Energy. The comments generally focused on the main elements of the petition — revision of the Part 61 waste classification system and the Petitioner’s rationale for this change. In addition, the Commission received responses from the Petitioner on many of the points raised by the commenters. The comments and responses were reviewed and considered in the development of NRC’s decision on this petition. These comments and responses are available in the NRC Public Document Room. Following is a summary of the significant comments.

Four of the commenters supported this petition for rulemaking. They supported the concept of changing the classification system to restrict the more hazardous components of currently defined LLW, although not necessarily in the same way as proposed in the petition.

One commenter stated that the definitions of LLW and high-level radioactive waste should be changed to essentially require that waste that presents a potential hazard after 100 years be defined as high-level radioactive waste. Disposal of such newly defined high-level radioactive waste would be the responsibility of the federal government.

A second commenter believes that the bases for developing the Part 61 classification system are not conservative, and therefore, the petition should
be accepted to protect the public from disposal of waste containing long-lived radionuclides.

A third commenter believes that restricting the longevity hazard (long-lived radionuclides) would increase public acceptance of LLW disposal facilities and eliminate program delays.

The fourth commenter, the Vermont Department of Public Service, believes that the classification system should be revised to reclassify nonfuel reactor components as greater than Class C. It is stated that these components, in Vermont, produce 99% of the activity, while comprising less than one-half of 1% of the volume. These components are easily segregated and can be stored in spent fuel pools. The commenter believes that the reclassification "could assist the State processes established by the Low-Level Radioactive Waste Policy Amendments Act of 1985."

The other ten commenters believe that granting the petition would not only be unwarranted, as the Petitioner has not made a justifiable case for changing the waste classification system, but would also cause significant and unnecessary problems for the disposal of LLW. Problems cited include major uncertainty and delay while the NRC was developing a new rule, the creation of "orphan" wastes that would not be acceptable at LLW sites, and the inaccurate use of existing information. For example, the Petitioner refers to a study by Rogers and Associates Engineering Corporation (RAE) prepared for the Vermont Low-Level Radioactive Waste Authority. Several commenters, including RAE and the Vermont Low-Level Radioactive Waste Authority, commented that the Petitioner has incorrectly used the results of this study to assess facility performance and that this study does not support the Petitioner's request.

The commenters argued that Part 61, and supporting documentation, provide a sound regulatory basis for protection of public health and safety and that the Petitioner has not provided any new significant information to justify changing the current rules. These commenters further argued that the Petitioner is inappropriately applying requirements in 10 C.F.R. Part 20 to potential intruder exposures at a closed disposal site. They noted that Part 20 limits, and the international recommendations upon which they are based, are regulatory dose limits for routine exposures and are not uniquely pertinent to accidents, inadvertent intrusion, or other hypothetical events.

Some commenters also took exception to the Petitioner's goal of protecting against willful, purposeful, or intentional intrusion instead of the inadvertent intruder. They stated that to protect against deliberate misuse of disposed waste would be unnecessarily conservative and unwarranted. One commenter noted that mining activities on a previously closed LLW disposal site (an activity postulated by the Petitioner) would constitute possession of source, byproduct, or special nuclear material and would be regulated under the statutory basis of the Atomic Energy Act of 1954, as amended.
Several commenters were concerned that a revised classification system would generate an “orphan” class of waste. These wastes would not be accepted at an LLW site and would have to be stored, pending disposal at a high-level waste or other appropriate facility, resulting in additional radiation exposure due to the extra handling and storage required. These commenters stated that the current classification system provides an adequate level of protection of public health and safety.

Other commenters believe that revising the classification system unnecessarily would be extremely disruptive until new regulations were finalized.

Finally, several commenters did not see a need to develop a supplemental EIS because in their view no significant new information has been provided.

III. REASONS FOR DENIAL

The NRC is denying the petition for the following reasons:

1. The NRC believes that the Petitioner is incorrect in asserting that recommendations by international and national standards organizations (the International Committee on Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP)) on public dose limits applicable to licensee operations should also be applied to hypothetical inadvertent intrusion at a closed LLW facility. In fact, the ICRP distinguishes between limits for the conduct of operations where exposures might be expected and the approach to be taken for “potential exposures,” which are hypothetical or postulated. The new Part 20 limit was adopted to impose restrictions on the releases from currently operating licensed facilities or on the ways that current licensees conduct operations. In contrast to this, the LLW classification system specifically addressed limiting potential exposures to an inadvertent intruder who might hypothetically pursue activities at a closed LLW disposal facility following loss of institutional control. Inadvertent intrusion is a hypothetical exposure scenario evaluated in the EIS to support the concentration limits for classifying radioactive wastes. It is a separate and different evaluation from the evaluation performed under 10 C.F.R. § 61.41 to demonstrate protection of the general population from releases of radioactivity. The NRC’s calculations, based on conservative assumptions about intrusion activities, demonstrated that if inadvertent intrusion were to occur, the one or few individuals involved might receive radiation exposure of the order of 200 millirems, well below the 500-mrem/yr goal selected as the dose rate limitation guideline.

In its final EIS, as noted by the Petitioner, the NRC summarized the rationale for retaining the 500-millirem limitation guideline as follows:

NRC's selection of the 500 mrem limit was based on (1) public opinion gained through the four regional workshops held on the preliminary draft of Part 61; (2) its acceptance by national and international standards organizations (e.g., ICRP) as an acceptable exposure limit for members of the public; and (3) the results of analyses presented in Chapter 4 of the draft EIS.²

However, a fuller explanation for having selected this dose limitation guideline can be found in the Draft Environmental Impact Statement (DEIS) on 10 C.F.R. Part 61 (NUREG-0782, Vol. 1).³ At that time, three candidate values of different orders of magnitude were under consideration; 25 mrem/yr, 500 mrem/yr, and 5000 mrem/yr. While noting the similarity of the selected value to the then-current effective public dose limit in 10 C.F.R. Part 20, the DEIS went on to explain the considerations for selection. Selection of the 25-mrem/yr value would likely have resulted in considerably more costs, more changes in existing practices and greater reduction in disposal efficiency than the other two candidates. This was cited as "especially important considering the hypothetical nature of the intrusion event." The 5000-mrem/yr alternative was seen to involve approximately the same costs and impacts as the 500-mrem/yr alternative. The higher value was considered to potentially result in allowing disposal of larger quantities of long-lived isotopes, which could result in moderately higher intruder hazards extending for long time periods. Therefore, 500 mrem/yr was selected as a general dose rate limitation guideline for the inadvertent intruder.

In the final EIS, the NRC noted that the EPA, in commenting on the DEIS and the proposed Part 61, stated that it was not appropriate to include a dose limit for intrusion in the regulations because the licensee would not be able to monitor or demonstrate compliance with a dose limit related to an event that might occur hundreds of years in the future. Consequently, the final rule for Part 61 did not include a dose limit for inadvertent intrusion. However, provisions, including waste classification, were included in the final rule to reduce the likelihood and magnitude of exposures to potential intruders.

Finally, as noted above, ICRP distinguishes between limits for the conduct of operations where exposures might be expected and the approach to be taken for "potential exposures," which are hypothetical or postulated. In the former case, the ICRP proposed imposition of dose limits, but in the latter case recommended

³ Copies of NUREGs may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Mail Stop SSOP, Washington, DC 20402-9328. Copies are also available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161. A copy is also available for inspection and/or copying at the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington, DC.
that the probability of postulated events or scenarios be considered along with their consequences. The ICRP noted that the initial focus in controlling the consequences of potential or postulated events should be "prevention," that is, by incorporating provisions to reduce the probability of the postulated events that may lead to radiation exposures. The existence of multiple controls in the final rule to reduce the likelihood of exposures to postulated inadvertent intruders at closed LLW sites was, and continues to be, wholly consistent with the ICRP perspective. These multiple controls are specifically identified or included in sections 61.7, 61.12, 61.14, 61.42, 61.52, and 61.59 and are intended to prevent inadvertent intrusion and to reduce potential exposure if intrusion were to occur.

For these reasons, the NRC does not believe that the current ICRP or NCRP recommendation that the public dose limit be 100 mrem/yr constitutes new information that would warrant modifying these regulations. The NRC believes that the provisions of Part 61 provide an acceptable level of protection to the public and the inadvertent intruder.

2. The NRC believes that the Petitioner has not provided adequate information to justify considering "deliberate" intrusion scenarios. The NRC believes that to protect against deliberate intrusion would be unnecessarily conservative and unwarranted. The NRC regulations currently include provisions to protect against intrusion by, for example, requiring government land ownership, records, and the use of markers. In order to deliberately intrude into the LLW site, an individual will have to break the law and overlook the hazard. In the development of Part 61, the NRC stated, "it would appear to be difficult to establish regulations designed to protect a future individual who recognizes a hazard but then chooses to ignore the hazard."

The NRC also believes that the likelihood of deliberate intrusion is very small. Deliberate intruders would have to ignore the hazard information on markers. The future value of LLW as a material cannot be accurately assessed, but the NRC believes that its value would be unlikely to warrant illegal actions that in themselves would be hazardous, and would require a significant amount of time and effort. If the value of LLW were to become significant, then it is likely that responsible institutions would assess risks and would make rational decisions regarding use or control of the site. Although the NRC is not relying on institutional controls beyond 100 years, the NRC believes that relevant records will be preserved and remain accessible for hundreds of years after closure. This would reduce the likelihood and level of exposure of inadvertent or deliberate intrusion. For example, if intrusion did not occur until 500 years after closure, the exposure would be limited to a few millirems as calculated in the EIS. The NRC, therefore, believes that its current treatment of intrusion continues to

\footnote{NUREG-0782, Draft Environmental Impact Statement on 10 C.F.R Part 61 "Licensing Requirements for Land Disposal of Radioactive Waste" (September 1981), Vol. 2, at 4-3.}
reflect a rational and acceptable approach. The NRC current regulations provide reasonable assurance of protection against an inadvertent intruder. And while not directly protecting against the deliberate intruder, the NRC believes that such an intrusion is unlikely to happen; therefore, the risk is very small.

3. The NRC believes that the Petitioner’s request for a supplemental EIS, due to increased costs of current disposal plans (including engineered structures), is not valid for several reasons. First, the NRC considered a range of different disposal options and costs, including the use of engineered barriers and structures, in the development of Part 61. Shallow-land burial, as had been practiced at commercial disposal sites, was considered as the base case for analysis. Two improved shallow-land disposal alternatives were also considered. The use of engineered barriers was anticipated and included in cost impact analyses as the upper-bound alternative. Second, although the Petitioner is correct in stating that LLW disposal costs for new facilities have significantly increased since promulgation of the rule, so have the expected costs for other potential methods of waste disposal, including geologic disposal, referred to by the Petitioner. Third, as noted by one of the commenters, much of the increased cost for new LLW disposal facilities is independent of the disposal technology used. That is, the increased costs for site characterization, licensing, public involvement, and administration for all disposal sites would tend to minimize long-term cost differentials between shallow-land burial with and without engineered structures. The Petitioner is erroneously asserting that costs were a prime consideration in the selection of the waste classification system. Although costs were considered in the EIS, the NRC principally looked to identify and implement improvements in the disposal of LLW, such as the development of the waste classification system, to help ensure adequate protection of the public health and safety and the environment. The costs of developing and constructing a facility were not the prime considerations.

In addition to the three reasons above, the NRC has also qualitatively considered the effect of imposing a classification system as indicated in the petition. The benefit would be to reduce the potential radiation exposure of a very small number of individuals after the end of the institutional control period. A realistic estimate of the benefit, as shown in the EIS, would be a 100-millirem reduction in dose (from 200 mrem/yr to 100 mrem/yr) to one or a few individuals per site, 100 years after closure. To maximize the benefit, the intrusion would need to occur relatively shortly after the end of the institutional control period, since the 100-millirem difference between the existing classification system and that suggested by the Petitioner becomes smaller with time. As discussed earlier, as the time period increases beyond 100 years to 500 years, potential exposures reduce to only a few millirems for the existing classification system.

Not only are the perceived benefits exceedingly small, but if a revised classification system were imposed, the NRC believes that it would result in
significant negative impacts. First, it would take years to revise the waste classification regulations. During this time, current efforts by the states and compact organizations to develop LLW facilities could be severely impacted as they would not know what waste would be acceptable in an LLW facility. Second, as provided in the Low-Level Radioactive Waste Policy Amendments Act of 1985, states will continue to be responsible to provide for disposal of waste that is classified A, B, and C under the existing classification system in Part 61. If a new classification system were developed that resulted in some currently acceptable waste being unacceptable for a LLW facility, either congressional action would be necessary to change the Act to make the federal government responsible for the waste or the states would be forced to develop alternative methods to dispose of this new class of waste. And third, additional operational exposures could be expected to occur as specific waste would need to be segregated, handled, treated, stored, and transported while awaiting alternative disposal facilities.

In sum, no new significant information has been provided by the Petitioner that would call into question the basis for, or conclusion of, the final EIS. On the other hand, in a qualitative analysis, it is clear that granting the petition would result in significant negative impacts relative to the small potential reduction in intruder exposures. Therefore, a supplemental EIS is not needed. For reasons cited in this document, the NRC denies the petition.

FOR THE NUCLEAR REGULATORY COMMISSION

James M. Taylor
Executive Director for Operations

Dated at Rockville, Maryland, this 29th day of March 1994.
The Nuclear Regulatory Commission (NRC) is denying a petition for rule-making (PRM-32-3) from Advanced Medical Systems, Inc. The Petitioner requested that the NRC amend its regulations because it believed that the requirements of Part 32, which are applicable to original manufacturers and suppliers, were not equally applicable to manufacturers and suppliers of replacement parts. The petition is being denied because current regulations apply equally to manufacturers and suppliers of both original and replacement parts, ensuring the integrity of these parts; therefore, no additional requirements addressing the regulation of manufacturers and suppliers of replacement parts are necessary. Further, current regulations address service and maintenance of sources and devices possessed and used under an NRC license, including replacement parts, whether manufactured or supplied by the original manufacturer or supplier or some other manufacturer or supplier. Therefore, the amendments suggested by the Petitioner are not necessary.

REGULATIONS: INTERPRETATION (10 C.F.R. PARTS 30, 32, 35)

Under current NRC regulations, persons authorized under a specific license to use devices containing byproduct material (e.g., use of teletherapy equipment under a Part 35 specific license) ultimately are responsible for the safe use of these devices, and for ensuring that such devices are properly maintained. Suppliers of sources or devices containing byproduct material, whether they are an original manufacturer or a manufacturer of replacement sources or devices, must be licensed under Parts 30 or 32 or an appropriate Agreement State license,
and also have responsibility for the safety of the sources or devices that they supply or replace.

REGULATIONS: INTERPRETATION (10 C.F.R. PART 21)

Under the provisions of Part 21, the supplier of any basic component, whether or not a licensee of NRC or an Agreement State, is also responsible for the quality of the component, whether it is original or replacement.

DENIAL OF PETITION FOR RULEMAKING

I. THE PETITION

In a letter dated June 28, 1991, Advanced Medical Systems, Inc. (AMS) filed a petition for rulemaking with the NRC. The petition was docketed by the Commission on July 19, 1991, and was assigned Docket No. PRM 32-3. The Petitioner requested that the NRC amend its regulations because it believed that the requirements of 10 C.F.R. Part 32, which are applicable to original manufacturers and suppliers, were not equally applicable to manufacturers and suppliers of replacement parts. The Petitioner has suggested two alternatives for accomplishing this objective. The first alternative is to insert the necessary language regarding manufacturers and suppliers of replacement parts into each appropriate section of Part 32. The second alternative would revise the purpose and scope provisions of 10 C.F.R. §32.1 to include manufacturers and suppliers of replacement parts.

II. BASIS FOR REQUEST

The Petitioner identified itself as an original teletherapy equipment manufacturer. As such, it has a definite and direct interest in the health and safety of the public who may use or be treated by equipment it manufactures.

According to the Petitioner, it appears that the requirements of Part 32 are being interpreted as applying only to manufacturers and suppliers of original equipment and not to manufacturers and suppliers of replacement parts, devices, products, or sources designated for units originally manufactured or transferred by others. In the Petitioner’s view, lack of specific requirements applicable to manufacturers and suppliers of replacement parts, devices, products, or sources, can lead to use of inferior-quality replacement parts which, in turn, can cause malfunction or failure of devices, in particular teletherapy equipment, and
thereby risk of overexposure. Advanced Medical Systems cited two incidents as examples of this problem: Access No. M49250, Anderson Memorial Hospital, Anderson, South Carolina; and Access No. M49324, St. Mary’s Medical Center, Saginaw, Michigan.

III. PUBLIC COMMENTS ON THE PETITION

A notice of receipt of the petition for rulemaking was published in the Federal Register on October 10, 1991 (56 Fed. Reg. 51,182). Interested persons were invited to submit written comments concerning the petition. The comment period closed December 9, 1991. The NRC received comments from the State of Illinois, Department of Nuclear Safety, and the Department of the Air Force, Headquarters Air Force Office of Medical Support.

The State of Illinois, Department of Nuclear Safety, stated that the Department fully supports development of the rule proposed in the petition. The Department further stated that the integrity of NRC-evaluated devices (NRC or an Agreement State evaluates for safety any devices containing radioactive materials) may be compromised significantly if nonstandard replacement parts are used during the life of the device. While the Department agreed that the issue of replacement components needs to be addressed, it was concerned with the use of the term “replacement sources and devices” in the wording of 10 C.F.R. §§ 32.74, 32.110, and 32.210 as suggested by the Petitioner. The Department believed that all sources and devices must be evaluated by the NRC or an Agreement State, whether or not they are considered “original” or “replacement” equipment. Therefore, the Department did not believe that it is necessary to distinguish between original or replacement sources or devices. The Department was in favor of the Petitioner’s suggested alternative to modify section 32.1, Purpose and Scope.

The Headquarters Air Force Office of Medical Support, Department of the Air Force, opposed the rule language proposed by the Petitioner, as written, although it agreed with the Petitioner’s intent to ensure that the safety and effectiveness of devices not be compromised because original parts are replaced by inferior ones. They did not agree that all replacement parts should be subject to the requirements of 10 C.F.R. Part 32. They stated that NRC review and approval should apply to replacements of parts or components that are essential to the proper and safe operations of a device. The Air Force gave examples of parts (such as panel screws and covers) that conform to industry standards. These, the Air Force stated, should not be subject to the proposed requirements. The Air Force voiced concern that the petition, as written, may serve to restrict competition and would lead to greater expense which would have to be recouped.

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through higher medical costs from patients, or, in the case of the Air Force, from taxpayers.

IV. NRC ACTION ON THE PETITION

The NRC reviewed the petition, the public comments, and the two cases (incidents) cited by the Petitioner as supporting evidence for filing this petition. The NRC also reviewed its regulations pertinent to the petition.

Shortly after the NRC received correspondence\(^1\) from AMS about the two cases, the NRC advised\(^2\) AMS of its intention to investigate these incidents, especially with regard to the quality of service and replacement parts used in servicing the teletherapy units. From October to December 1989, the NRC conducted a thorough investigation which included three onsite inspections: Atom Mechanical Company, Cleveland, Ohio (the servicing company that conducted the maintenance and replacement of parts in the two cases), St. Mary's Medical Center, Saginaw, Michigan, and Picker International, Highland Heights, Ohio (the company that manufactured the teletherapy units at Anderson Memorial Hospital and at St. Mary's Medical Center). The NRC also referred the case of Anderson Memorial to the State of Maryland, because the company that serviced the teletherapy unit there, Atom Mechanical Company, is an authorized user on the Neutron Products, Inc., license, and Neutron Products is located in the State of Maryland, an Agreement State.

The incident at Anderson Memorial Hospital was caused by a broken spring in a teletherapy unit which failed to retract the source into the OFF position following a cobalt-60 cancer treatment. The hospital technologist promptly retracted the source manually. According to the hospital report, the technologist received very little additional exposure over expected monthly exposure, as evidenced by the individual's radiation film badge reading. Moreover, according to the same report, the delivered daily dose to the patient was less than the prescribed daily dose, i.e., no patient overexposure for that treatment, because the technologist acted promptly. In its communication with NRC (prior to filing the petition), AMS stated that it was concerned about the quality of the replacement springs used in the teletherapy machine.

The incident at St. Mary's Medical Center was caused by the failure of a microswitch. The failure of the switch prevented a timing device from operating properly, to automatically terminate the treatment. No misadministration

\(^1\) Three letters dated June 20, August 8, and August 25, 1989, to Hugh L. Thompson, Jr., Deputy Executive for Nuclear Materials Safety and Safeguards & Operations Support, NRC, from Sherry Stein, Director, Regulatory Affairs, Advanced Medical Systems, Inc.

\(^2\) By a letter dated September 15, 1989, from Robert M. Bernero, Director, Office of Nuclear Material Safety and Safeguards, NRC, to Sherry Stein, Director, Regulatory Affairs, Advanced Medical Systems, Inc.
occurred because the subsequent treatment times were adjusted and the total delivered dose did not differ from the prescribed dose. Neutron Products, Inc., was called to repair the machine.

The NRC investigation and subsequent inspections revealed several violations. Enforcement action was taken by the NRC against Atom Mechanical for violation of Part 21 requirements, and against St. Mary's Hospital and Picker International for violations of Part 35 and Part 30 requirements, respectively. Furthermore, the State of Maryland determined from its own investigation that the incident at Anderson Memorial Hospital resulted from a failure of the part, i.e., breakage of the return spring. No enforcement action was taken by the State of Maryland.

Under current NRC regulations, persons authorized under a specific license to use devices containing byproduct material (e.g., use of teletherapy equipment under a Part 35 specific license) ultimately are responsible for the safe use of these devices, and for ensuring that such devices are properly maintained. Suppliers of sources or devices containing byproduct material, whether they are an original manufacturer or a manufacturer of replacement sources or devices, must be licensed under Part 30 or 32 or an appropriate Agreement State license, and also have responsibility for the safety of the sources or devices that they supply or replace. Service or repair, which would include the replacement of parts or components of medical or industrial sources or devices that present a risk of radiation exposure from the failure of certain parts, such as the teletherapy devices discussed as examples in this petition, may be performed only by qualified persons authorized under an NRC or Agreement State license (cf. 10 C.F.R. §§ 35.605, 39.43(e)). Some generally licensed devices may be serviced by general licensees who are authorized to perform limited service work if sufficient information about the service work (e.g., procedures, training, expected dose) is submitted by the manufacturer or initial distributor and accepted by the NRC. However, these devices typically are not mechanically complex and do not present the same risk of significant radiation exposure. Moreover, the NRC has no record of failure of these devices leading to a radiation exposure attributable to defective replacement parts or improper servicing. Finally, under the provisions of Part 21, the supplier of any basic component, whether or not a licensee of NRC or an Agreement State, is also responsible for the quality of the component, whether it is original or replacement.

3 Specifically, Atom Mechanical Company was found to be in violation of 10 C.F.R. § 21.21 (Oct. 16, 1989), St. Mary Medical Center was found to be in violation of 10 C.F.R. §§ 35.59(g), 35.605, 35.630(a), 35.615(d)(4), 35.632(a), and 35.634(a) (Oct. 17 and 26, 1989), and Picker International, Inc., was found to be in violation of 10 C.F.R. § 30.3 (subsequent to inspections that occurred on Oct. 26 and Nov. 9, 1989). Inspection reports are available for review in the NRC Public Document Room.

4 A “basic component” is defined in Part 21 as one, “in which a defect could create a substantial safety hazard.”
V. REASONS FOR DENIAL

The NRC has examined the petition (1) in light of its regulations and policies for both general and specific licensees, and (2) in view of the cases cited by the Petitioner in support of the petition. The NRC is denying the petition because current regulations apply equally to manufacturers and suppliers of both original and replacement parts, ensuring the integrity of these parts; therefore, no additional requirements addressing the regulation of manufacturers and suppliers of replacement parts are necessary. Further, current regulations address service and maintenance of sources and devices possessed and used under an NRC license, including replacement parts, whether manufactured or supplied by the original manufacturer or supplier or some other manufacturer or supplier. Accordingly, the petition for rulemaking is denied.

FOR THE NUCLEAR REGULATORY COMMISSION

James M. Taylor
Executive Director for Operations

Dated at Rockville, Maryland,
this 28th day of March 1994.
DATE
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