

January 30, 1998

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL

PURPOSE:

To obtain Commission approval to terminate proposed rulemaking revising 10 CFR Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," and to proceed with finalizing draft guidance in a NUREG.

BACKGROUND:

The staff submitted a Commission Paper, SECY-96-167, dated July 30, 1996, requesting approval of an Advance Notice of Proposed Rulemaking (ANPR) for Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material." The Commission approved the ANPR, in a Staff Requirements Memorandum (SRM) dated September 18, 1996 (Attachment 1). The Commission directed the staff to add a detailed definition of the term "broad scope," to include a question regarding the separation of contamination risk versus external radiation risk, and to include a discussion, and request for comments, on the balance between performance-based and a prescriptive approach for regulating broad scope licensees. The Commission also recommended that the staff address the issue of whether non-Federal licensees may obtain master materials licenses (MMLs). Additionally, the Commission indicated that the staff should consider finalizing any guidance on broad scope licensees' radiation safety officer training and experience contained in draft guides. These issues were addressed in the ANPR.

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DISCUSSION:

The ANPR was noticed in the Federal Register on November 14, 1996 (61 FR 58346). The comment period closed February 12, 1997. The staff received 22 comments on the ANPR (there are 371 broad scope licensees, 145 of which are academic facilities or medical institutions). An analysis of the comments is included in Attachment 2. Generally, the commenters did not see a valid reason to amend the regulation for broad scope licensees, and indicated that the proposals discussed in the ANPR were overly prescriptive. One commenter agreed with the background section of the ANPR which stated that, "The current program governing the regulation of specific licenses of broad scope for byproduct material has worked well to provide for public health and safety from these licensed activities." This commenter went on to say that the Nuclear Regulatory Commission should examine the 38 specific incidents during 1993-1996 and evaluate their significance in terms of risks to employees and the public. The commenter did not believe that the small incremental increase in risk that these incidents posed justified overhauling the broad scope regulatory framework which has proven effective for many years. Many commenters indicated that the specific responsibilities of licensee management should not be included in the Federal regulations; that the role of management varies for different types of programs. Additionally, many commenters stated that the overall objectives of the radiation safety officer (RSO) and the radiation safety committee (RSC) should be provided in Part 33, while examples of qualifications, duties, and responsibilities should be discussed in regulatory guidance. The rationale for this position is that the qualifications needed vary greatly, depending on the scope of the program.

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) discussed the ANPR during its meeting in May 1996. The Committee commented that the draft ANPR and background material had many references to the recent contamination incidents at the National Institutes of Health and Massachusetts Institute of Technology. There was concern that the ANPR was based on these incidents and that the staff was reacting to events that the licensees may not have been able to prevent. The staff indicated that there were discussions regarding revisions of Part 33 before these events. The ACMUI recommended that the staff reconsider the emphasis in the background information presented in the ANPR to avoid the appearance that NRC was reacting to these events. Overall, the ACMUI believed the draft language in the ANPR to be too prescriptive and that broad scope licensees, by definition, are trying to achieve a maximum level of flexibility. The ACMUI, during its April 1997 meeting, recommended retention of the current regulatory approach for Part 33. A copy of the minutes for this meeting is provided in Attachment 3.

Because of the negative response to the ANPR, including the recommendation of the ACMUI, the staff is proposing to terminate the rulemaking effort for Part 33. In lieu of rulemaking, the staff is proposing to finalize draft guidance currently contained in Draft Regulatory Guide DG-0005, "Applications for Licenses of Broad Scope, Revision 2." This guidance will be finalized as a NUREG as part of the ongoing guidance updating and consolidation project.

The guidance discusses the role and responsibilities of licensee management, emphasizing that strong management controls and oversight are needed to ensure that licensed activities are conducted properly. The guidance also stresses the importance of devoting sufficient resources to support the radiation protection program. The roles of the RSO and the RSC, their respective duties and responsibilities, as well as the qualifications needed for the RSO, are also addressed in the guidance.

Broad scope licensees currently have the flexibility to make changes in their program, such as naming authorized users; having broad authorization for radionuclides with atomic numbers 3-83; changing locations of use within the facility; and decommissioning of previously use areas. Broad scope licensees generally submit detailed information about their proposed operating procedures and radiation safety program in their initial application for a broad scope license. This information is included in the license under a "tie-down" condition. As part of this project, the staff plans to evaluate the

licensing process and license conditions for ways to provide greater flexibility for broad scope licensees to modify their programs without seeking a license amendment.

The Commission, in an SRM dated September 18, 1996, directed the staff to include a question of separation of contamination risk versus external radiation risk. The staff received 15 comment letters on this question, all of which opposed addressing this issue in rulemaking. The commenters believe that there is no need for special considerations for internal exposure to include a separate or different internal or external dose limit. A detailed summary of the comments on this question may be found in the comment analysis provided in Attachment 2, question 5, on page 5.

The staff received 11 comments on the question of MMLs in the ANPR. Eight of the 11 commenters opposed incorporating these requirements within Part 33. An MML is not a true broad scope license. An MML is a license which authorizes a single entity, such as a Federal agency or military organization, to issue permits for new facilities of use, conduct enforcement, and perform oversight inspections or audits for facilities at multiple sites in multiple regions. All permit reviewers and inspectors must be fully qualified according to the guidelines in Manual Chapter 1246, "Formal Qualification Programs in the Nuclear Material Safety and Safeguards Programs Area," identical to NRC staff. NRC does not review or approve new users or locations, and does not inspect the permitted facilities under the routine inspection frequency for that type of facility. NRC does conduct an annual inspection of the MML to review the management, inspection permitting, and enforcement activities performed under the license. Additionally, NRC inspectors accompany MML inspectors on certain inspections as part of our review of the MML. While broad scope licensees approve their own users, they differ from an MML in that a broad scope licensee must apply for an amendment when adding new facilities of use and they cannot conduct their own inspection and enforcement program. Therefore, the staff has decided that the MML process should not be codified within Part 33.

The Commission, in an SRM dated September 18, 1996, recommended that the staff address the issue of whether non-Federal licensees may obtain an MML. The staff discussed this issue in a memorandum to the Commission, dated June 4, 1997 (Attachment 4). To summarize, although there is no prohibition in the Atomic Energy Act against private entities obtaining an MML, there are State and Federal legal and policy implications involving the role of the Agreement States. Agreement States have jurisdiction over the types of materials that would be covered by an MML for a private entity. This creates a jurisdictional problem in establishing an MML for a licensee having facilities within NRC and Agreement State jurisdiction. On September 25, 1997, the staff distributed Revision 1 to Policy and Guidance Directive (PGD) 6-02, "Guidelines for Evaluating Programs for Master Material License Applications," which is an extensive standard review plan on the MML process, and is available to licensees (Attachment 5) The revision to PGD 6-02 specifies that MMLs will only be issued to Federal facilities, which addresses the jurisdictional issue staff raised in the June 4, 1997, memorandum to the Commission. The staff will continue to review applications for an MML on a case-by-case basis, using PGD 6-02, Revision 1.

SCHEDULE and RESOURCES:

If the Commission approves this plan, the staff plans to begin finalizing the draft guidance in April 1998. A draft NUREG will be published August 1998, for a 90-day comment period. Any comments received will be resolved and incorporated into the final NUREG. The staff plans to publish the final NUREG in April 1999. A Gantt Chart outlining this schedule is provided in Attachment 6.

The guidance will be finalized as part of the guidance consolidation project, following the approach developed during the business process re-engineering effort. The proposed project will require a combined total of less than 2.5 FTEs from Headquarters and the regions. These resources are available within the current budget.

RECOMMENDATIONS:

The staff recommends that the Commission approve termination of the proposed rulemaking for Part 33, and approve the finalization of draft guidance in a NUREG. The staff will publish the appropriate notice of termination of rulemaking in the Federal Register, informing the public that NRC is not going forward with a proposed rulemaking for Part 33 and that the staff plans to finalize draft guidance in a NUREG. Any comments received in response to the notice will be considered in the development of the final guidance.

COORDINATION:

The Office of the General Counsel has no legal objection to this paper. The Office of the Chief Financial Officer has reviewed this Commission Paper for resource implications and has no objections.

L. Joseph Callan
Executive Director for Operations

Attachments: 1. SRM dtd 9/18/96
 2. Comment analysis
 3. Minutes - 4/97 ACMUI mtg
 4. Memo dtd. 6/4/97
 5. PGD 6-02
 6. Gantt chart

September 18, 1996

TO: Executive Director for Operations
FROM: John C. Hoyle, Secretary /s/
SUBJECT: STAFF REQUIREMENTS - SECY-96-167 - SPECIFIC DOMESTIC LICENSES OF BROAD SCOPE FOR BYPRODUCT MATERIAL - ADVANCE NOTICE OF PROPOSED RULEMAKING

The Commission has approved publication of the Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register subject to incorporation of the following comments.

1. A detailed definition of the term "broad scope" should be added to the rule language.
2. The question of separation of contamination risk versus external radiation risk should be posed to the public.
3. A discussion and request for comments on what balance the NRC should strike between a performance-based and a prescriptive approach to regulating broad scope licensees should be included in the ANPR. In the specific context of regulating such licensees, the discussion should state what NRC means by performance-based regulation and prescriptive regulation and should identify the principal issues associated with each of these regulatory approaches.

(EDO)

(SECY Suspense: 11/1/96)

The staff should consider, while not delaying publication of the ANPR, directly addressing the issue of whether non-Federal licensees may obtain master materials licenses. This is an important policy issue in that only federal agencies already have master materials licenses.

(EDO)

(SECY Suspense: 4/25/97)

Concurrent with the development of 10 CFR Part 33, the staff should also consider finalizing any guidance on broad scope licensee Radiation Safety Officer (RSO) training and experience contained in draft regulatory guides. By finalizing the guidance, licensees will know what type of "specific training in radiation health sciences" and what type of experience is appropriate for broad scope licensee RSOs. This should be provided for Commission review with the proposed rule.

(EDO)

(SECY Suspense: 12/31/97)

cc: Chairman Jackson
Commissioner Rogers
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
OGC
OCA
OIG
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)

SECY NOTE: THIS SRM, SECY-96-167, AND THE VOTE SHEETS OF ALL COMMISSIONERS WILL BE MADE PUBLICLY AVAILABLE 5 WORKING DAYS FROM THE DATE OF THIS SRM.