U.S. NUCLEAR REGULATORY COMMISSION
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Division 10

DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0015

(Proposed Revision 2 of Regulatory Guide 10.5, dated December 1980)

APPLICATIONS FOR A TYPE A LICENSE OF BROAD SCOPE

A. INTRODUCTION

This guide directs the reader to the type of information needed by the U.S. Nuclear Regulatory Commission (NRC) staff to evaluate an application for a Type A specific license of broad scope for byproduct material (reactor-produced radionuclides). This type of license is regulated by Title 10, Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 33).

This regulatory guide endorses the methods and procedures contained in the current revision of NUREG-1556, Volume 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses of Broad Scope," as a process that the NRC staff finds acceptable for meeting the regulatory requirements of 10 CFR Part 33.

Volume 11 of NUREG 1556 is not intended to be used alone. Because broad-scope licensees may be involved in many different program areas (e.g., medicine, research and development, manufacturing and distribution), Volume 11 frequently refers the user to other more program-specific guidance documents in the NUREG-1556 series. A single document containing all of the guidance that might be required by a broad-scope licensee or an applicant for a broad-scope license would be unwieldy and may become obsolete as guidance in the individual program areas is revised. Volume 11 of NUREG-1556 takes a more risk-informed, performance-based approach to the information needed to support an application for a specific license of broad scope. Applicants should consider the entire NUREG-1556 series when preparing broad-scope license applications. NRC staff will use applicable portions of the complete NUREG-1556 series when reviewing applications.

This regulatory guide is being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. It has not received final staff review or approval and does not represent an official NRC final staff position.

Public comments are being solicited on this draft guide (including any implementation schedule) and its associated regulatory analysis or value/impact statement. Comments should be accompanied by appropriate supporting data. Written comments may be submitted to the Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; e-mailed to NRCREP@nrc.gov; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov; faxed to (301) 415-5144; or hand delivered to the Rulemaking, Directives, and Editing Branch, Office of Administration, U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, MD 20852, between 7:30 a.m. and 4:15 p.m. on Federal workdays. Copies of comments received may be examined at the NRC's Public Document Room, 11555 Rockville Pike, Rockville, MD. Comments will be most helpful if received by April 18, 2008.

Electronic copies of this draft regulatory guide are available through the NRC's interactive rulemaking Web page (see above); the NRC's public Web site under Draft Regulatory Guides in the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/; and the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML073331052.

The NRC issues regulatory guides to describe to the public methods that the staff considers acceptable for use in implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations and compliance with them is not required.

This regulatory guide contains information collections that are covered by the requirements of 10 CFR Part 33 and NRC Form 313 which the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0015 and 3150-0120, respectively. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

As part of its redesign of the materials licensing program, the NRC consolidated and updated numerous guidance documents for material licenses into the multivolume NUREG-1556. Various volumes in the NUREG-1556 series provide current, program-specific guidance on testing, licensing, decommissioning, and terminating materials licenses.

Volume 11 of NUREG-1556 identifies information needed to complete NRC Form 313, "Application for Materials License," for broad-scope licenses. It contains appendices that include (1) copies of necessary forms, (2) sample applications and completed examples for different types of applications, and (3) examples of the types of supporting information, such as implementing procedures that the applicant may need to prepare. The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. This approach is intended to be less prescriptive and to allow licensees the flexibility to implement the agency's regulations in a manner that is more specific to their needs yet still meets the regulatory requirements. By supplying examples, the NRC seeks to provide information to meet the needs of applicants for licensure without being prescriptive. Guidance in NUREG-1556 represents one means of complying with NRC regulations and is not intended to be the only means of satisfying the regulatory requirements.

NUREG-1556 is available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556. Copies are also available for inspection or copying for a fee from the NRC's Public Document Room (PDR) at 11555 Rockville Pike, Rockville, MD. The mailing address for the PDR is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and email PDR@nrc.gov. In addition, copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, DC 20402-9328, telephone (202) 512-1800; or from the National Technical Information Service (NTIS), at 5285 Port Royal Road, Springfield, VA 22161, online at http://www.ntis.gov, by telephone at (800) 553-NTIS (6847) or (703) 605-6000, or by fax to (703) 605-6900.

C. REGULATORY POSITION

This regulatory guide endorses the method for preparation of a type A license of broad scope for byproduct material described in the current revision of NUREG-1556, Volume 11, as a process that the NRC has found to be acceptable.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants and licensees regarding the NRC's plans for using this draft regulatory guide. No imposition or backfit is intended or approved in connection with its issuance.

The NRC has issued this draft guide to encourage public participation in its development. The NRC will consider all public comments received in development of the final guidance document. Except in those cases in which an applicant or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in the active guide will be used in evaluating compliance with the regulations as discussed in this guide for license applications, license amendment applications, and exemption requests.

REGULATORY ANALYSIS

1. Statement of the Problem

The NRC published Revision 1 of Regulatory Guide 10.5 in December 1980 to provide licensees with agency-approved guidance for complying with the then-current version of 10 CFR Part 33. The NRC's implementation of a risk-informed, performance-based approach, combined with multiple updates and revisions to the regulations, makes the current regulatory guide outdated.

2. Objective

As part of its redesign of the materials licensing process, the NRC consolidated and updated numerous materials license guidance documents into a single comprehensive repository. This comprehensive repository is the multivolume NUREG-1556. Each volume of NUREG-1556 contains program-specific guidance for various materials licenses and licensee activities. The NRC developed and issued the multiple volumes of NUREG-1556 to provide both the licensee and NRC staff with current guidance.

The objective of this action is to provide clear and up-to-date information to support consolidated guidance for the preparation of an application for a Type A license of broad scope for byproduct material.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 10.5.
- Withdraw Regulatory Guide 10.5.
- Revise Regulatory Guide 10.5 to match or replace Volume 11 of NUREG-1556.
- Revise Regulatory Guide 10.5 to endorse Volume 11 of NUREG-1556.

3.1 <u>Alternative 1: Do Not Revise Regulatory Guide 10.5</u>

Under this alternative, the NRC would not revise this document, and applicants would continue to use the original version of this regulatory guide. However, this alternative would leave conflicting guidance in place and could cause unnecessary confusion. This alternative is considered the baseline or "no action" alternative and, as such, involves no value/impact considerations.

3.2 Alternative 2: Withdraw Regulatory Guide 10.5

Withdrawing this regulatory guide would eliminate the problem of NUREG-1556 and this regulatory guide containing duplicate and occasionally contradictory information. However, this action would leave a void in the regulatory guide system and provide no quick means for interested parties to identify the requirements necessary to prepare an application for a Type A license of broad scope for byproduct material that the NRC finds acceptable. Although this alternative would cost relatively little, it may impede the public's access to the most current information.

3.3 Alternative 3: Revise Regulatory Guide 10.5 to Match or Replace Vol. 11 of NUREG-1556

NUREG-1556 is a multivolume document first published in May 1997 to provide consolidated guidance about materials licenses in accordance with the most current regulatory requirements. Regulatory Guide 10.5 contains specific guidance about only one of the many areas covered in NUREG-1556. Revising the regulatory guide to match the information in NUREG-1556 would create duplicate sources of information and would require continuing staff resources to ensure that the separate documents continued to contain duplicate information. Revising this regulatory guide to replace NUREG-1556 would require substantial expansion of the current guide and a large expenditure of labor without a noticeable enhancement in performance or efficiency for the NRC or its licensees. This alternative is considered to be an unnecessary use of staff resources.

3.4 Alternative 4: Revise Regulatory Guide 10.5 to Endorse Vol. 11 of NUREG-1556

The December 1980 version of the regulatory guide no longer represents a method that is acceptable to the NRC for satisfying the requirements of 10 CFR Part 33. Failure to revise the regulatory guide will result in conflicting guidance documents and possible confusion to interested parties. Therefore, the staff has chosen to revise the regulatory guide to direct any interested parties to the most current guidance provided in Volume 11 of NUREG-1556.

4. Conclusion

Based on this regulatory analysis, the staff recommends that the NRC revise Regulatory Guide 10.5 to endorse the methods and procedures in NUREG-1556, Volume 11, as a process acceptable for meeting the requirements in 10 CFR Part 33 and thereby provide applicants with guidance on how to prepare an application for special Type A licenses of broad scope. The staff has concluded that the proposed action will reduce unnecessary burden on both the NRC and its licensees and will result in an improved and more uniform process. Moreover, the staff sees no adverse effects associated with issuing this regulatory guide.