U.S. NUCLEAR REGULATORY COMMISSION
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Division 10

DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0018

(Proposed Revision 3 of Regulatory Guide 10.8, dated August 1987)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR MEDICAL USE PROGRAMS

A. INTRODUCTION

This regulatory guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for review of an application for a medical use license. Title 10, Part 35, "Medical Use of Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 35) (Ref. 1) regulates the medical use of byproduct material. In addition to the requirements of 10 CFR Part 35, medical use licensees may be subject to those portions of 10 CFR Part 20, "Standards for Protection Against Radiation," (Ref. 2) that relate to radiation safety and the sections of 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," (Ref. 3) that relate to licensing and the noncommercial transfer of specific radioactive drugs to medical use licensees within a consortium.

This regulatory guide endorses the methods and procedures for medical licensing applications contained in the current revision of NUREG–1556, Volume 9, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Medical Use Licenses," (Ref. 4) as a process that the NRC staff finds acceptable for meeting the regulatory requirements.

Volume 9 of NUREG–1556 addresses the issues that an applicant must respond to when preparing a license application on NRC Form 313, "Application for Materials License," and the NRC Form 313A series of forms. The NUREG also includes (for clarification purposes) descriptions of certain key elements of a medical use program that do not require a response on NRC Form 313.

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; emailed 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 Rulemaking, Directives, and Editing Branch, Office of Administration, US NRC, 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 June 30, 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. ML080450166.

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 covered by 10 CFR Parts 20, 30, and 35 and NRC Form 313 and that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0014, 3150-0017, 3150-0010, and 3150-0044, 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 9 of NUREG–1556 provides program-specific guidance about medical use licenses. It identifies the information needed to complete NRC Form 313 and the NRC Form 313A series of forms. NUREG–1556 provides an overview of the types of licenses issued by the NRC, the commitments and responsibilities that a licensee must undertake, applicable regulations, the process for filing a license application, and the contents of applications for different medical uses of byproduct material. In particular, Volume 9 of NUREG–1556 gives an item-by-item description of the information the applicant should provide. Because of the wide variety in the types of medical use programs, NUREG–1556 contains indicators to alert applicants for particular types of medical use licenses to information that pertains to those types of uses. The NRC is placing added emphasis on conducting its regulatory activities in a risk-informed and performance-based manner. The agency intends for this approach 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. It is not 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(s) of preparing a medical use program license application or revision request described in the current revision of NUREG–1556, Volume 9, as a process that the NRC has found to be acceptable for meeting the regulatory requirements.

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 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 NRC staff will use the methods described in the active guide 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 2 of Regulatory Guide 10.8, "Guide for the Preparation of Applications for Medical Use Programs," in August 1987 to provide licensees and applicants with agency-approved guidance for complying with the then-current version of 10 CFR Part 35. The agency published Appendix X, "Guidance on Complying with New Part 20 Requirements," to Regulatory Guide 10.8 in June 1992 to address revisions to 10 CFR Part 20. The NRC also issued a proposed supplement, titled "Proposed Supplement to Regulatory Guide 10.8, Revision 2," for public comment as Draft Regulatory Guide DG–0009 in March 1997 but never finalized it. Consequently, the current version of Regulatory Guide 10.8 is outdated because it does not reference the correct sections of the regulations and does not reflect the NRC's implementation of a risk-informed, performance-based approach to licensing.

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 medical use license.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 10.8.
- Withdraw Regulatory Guide 10.8.
- Revise Regulatory Guide 10.8 to match or replace Volume 9 of NUREG–1556.
- Revise Regulatory Guide 10.8 to endorse Volume 9 of NUREG–1556.

3.1 Alternative 1: Do Not Revise Regulatory Guide 10.8

Under this alternative, the NRC would not revise this guidance, 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 or impact considerations.

3.2 Alternative 2: Withdraw Regulatory Guide 10.8

Withdrawing this regulatory guide would eliminate the problem of the inclusion of duplicate and occasionally contradictory information in NUREG–1556 and this guide. However, this action would leave a void in the regulatory guide system. It also provides no quick means for interested parties to identify the methods and procedures for applying for a license for medical use of byproduct material that the NRC finds acceptable. Although this alternative would cost relatively little, it could impede the public's access to the most current information.

3.3 Alternative 3: Revise Regulatory Guide 10.8 to Match or Replace Volume 9 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 10.8 contains specific guidance about only one of the many areas covered in Volume 9 of NUREG–1556. Revising the regulatory guide to match the information in Volume 9 of NUREG–1556 would create duplicate sources of information and would require ongoing staff resources to ensure that the separate documents continued to contain duplicate information. Revising this regulatory guide to replace Volume 9 of NUREG–1556 would require substantial expansion of the current guide. It would also require 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 10.8 to Endorse Volume 9 of NUREG–1556

The August 1987 version of the regulatory guide no longer represents a method that is acceptable to the NRC for satisfying the requirements of 10 CFR Part 35. Failure to revise the regulatory guide will result in conflicting guidance documents and the possible confusion of 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 9 of NUREG–1556.

4. Conclusion

Based on this regulatory analysis, the staff recommends that the NRC revise Regulatory Guide 10.8 to endorse the guidance on applying for a medical use license described in the current revision of NUREG–1556, Volume 9. The staff concludes 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.

REFERENCES

1. 10 CFR Part 35, "Medical Use of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.[1]
2. 10 CFR Part 20, "Standards for Protection Against Radiation," U.S. Nuclear Regulatory Commission, Washington, DC.[1]
3. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.[1]
4. NUREG-1556, Volume 9, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance About Medical Use Licenses." U.S. Nuclear Regulatory Commission, Washington, DC.[2]

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1 All NRC regulations listed herein are available electronically through the Electronic Reading Room on the NRC's public Web site, at http://www.nrc.gov/reading-rm/doc-collections/ . 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 is USNRC PDR, Washington, DC 20555; telephone (301) 415-4737 or (800) 397-4209; fax (301) 415-3548; and e-mail PDR@nrc.gov.

2 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.