



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0017 (Proposed Revision 2 of Regulatory Guide 10.7, dated August 1979)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES FOR LABORATORY AND INDUSTRIAL USE OF SMALL QUANTITIES OF BYPRODUCT MATERIAL

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 specific license for laboratories and industries to use megabecquerel (MBq) (millicurie (mCi)) quantities of byproduct material (reactor-produced radionuclides).

The regulatory framework that the NRC has established for laboratory and industrial use of small quantities of byproduct material is in Title 10, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 30).

This regulatory guide endorses the methods and procedures for applying for a license for laboratory and industrial use of small quantities of byproduct material contained in the current revisions of NUREG-1556, Volume 7, Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope" and NUREG-1556, Volume 12, "Consolidated Guidance about Material Licenses: Program-Specific Guidance About Possession and Licenses for Manufacturing and Distribution," as a process that the NRC staff finds acceptable.

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 collection requirements covered by 10 CFR Part 30 and approved by the Office of Management and Budget (OMB) under OMB control numbers 3150-0017 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.

Volumes 7 and 12 of NUREG-1556 identify the information needed to complete NRC Form 313, "Application for Materials License," for laboratory and industrial use of small quantities of byproduct material. They contain 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, which 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 method 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 guidance on how to prepare a license application for laboratory and industrial use of small quantities of byproduct material described in the current revisions of NUREG-1556, Volumes 7 and 12, 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 10.7 in August 1979 to provide licensees with agency-approved guidance for complying with the then-current version of 10 CFR Part 30. 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 a license application for laboratories and industries using small quantities of byproduct material.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 10.7.
- Withdraw Regulatory Guide 10.7.
- Revise Regulatory Guide 10.7 to match or replace Volumes 7 and 12 of NUREG-1556.
- Revise Regulatory Guide 10.7 to endorse Volumes 7 and 12 of NUREG-1556.

3.1 Alternative 1: Do Not Revise Regulatory Guide 10.7

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/impact considerations.

3.2 Alternative 2: Withdraw Regulatory Guide 10.7

Withdrawing this regulatory guide would eliminate the problem of the inclusion of duplicate and occasionally contradictory information in NUREG 1556 and this guide.

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 and provide no quick means for laboratories or industrial sites to identify the requirements necessary to prepare an acceptable license application for the use of small quantities of byproduct material. 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 10.7 to Match or Replace Volumes 7 and 12 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 10.7 contains specific guidance about only one of the many areas covered in Volumes 7 and 12 of NUREG-1556. Revising the regulatory guide to match the information in Volumes 7 and 12 of 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 Volumes 7 and 12 of 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 inefficient use of staff resources.

3.4 Alternative 4: Revise Regulatory Guide 10.7 to Endorse Volumes 7 and 12 of NUREG-1556

The August 1979 version of the regulatory guide no longer represents a method that is acceptable to the NRC for satisfying the requirements for licensing laboratory and industrial use of small quantities of byproduct material under 10 CFR Part 30. Failure to revise the regulatory guide would 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 Volumes 7 and 12 of NUREG-1556.

4. Conclusion

Based on this regulatory analysis, the staff recommends that the NRC revise Regulatory Guide 10.7 to endorse the guidance on how to prepare a license application for laboratory and industrial use of small quantities of byproduct material described in the current revisions of NUREG-1556, Volumes 7 and 12. 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.