



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 10.7

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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 sought by the U.S. Nuclear Regulatory Commission (NRC) staff in an application for a specific license for laboratories and industries to use megabecquerel (MBq) (millicurie (mCi)) quantities of byproduct material (reactor- or accelerator-produced radionuclides). Title 10, Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 30) (Ref. 1) contains the licensing requirements for laboratory and industrial use of small quantities of byproduct material.

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" (Ref. 2), and NUREG-1556, Volume 12, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession and Licenses for Manufacturing and Distribution" (Ref. 3), as a process that the NRC staff finds acceptable.

This regulatory guide contains information collection requirements covered by 10 CFR Part 30 that the Office of Management and Budget (OMB) approved under OMB control number 3150-0017. 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.

The NRC issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions—1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Electronic copies of this guide and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC's Electronic Reading Room at <http://www.nrc.gov/reading-rm/doc-collections/> and through the NRC's Agencywide Documents Access and Management System (ADAMS) at <http://www.nrc.gov/reading-rm/adams.html>, under Accession No. ML081960533.

B. DISCUSSION

As part of its redesign of the materials licensing program, the NRC consolidated and updated numerous guidance documents for materials 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.

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 regulatory guide. The NRC does not intend or approve any imposition or backfit in connection with its issuance.

In some cases, applicants or licensees may propose or use a previously established acceptable alternative method for complying with specified portions of the NRC’s regulations. Otherwise, the methods described in this guide will be used in evaluating compliance with the applicable regulations for license applications, license amendment applications, and amendment requests.

REFERENCES

1. 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.¹
2. NUREG-1556, Volume 7, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Academic, Research, and Development, and Other Licenses of Limited Scope," U.S. Nuclear Regulatory Commission, Washington DC, most current date and revision.² (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>).
3. NUREG-1556, Volume 12, "Consolidated Guidance about Material Licenses: Program-Specific Guidance about Possession and Licenses for Manufacturing and Distribution," U.S. Nuclear Regulatory Commission, Washington DC, most current date and revision. (<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/>)

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/cfr/>. 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 All NUREG-series report listed herein are published by the U.S. Nuclear Regulatory Commission. Most are available electronically through the Electronic Reading Room on the NRC's public Web site, at <http://www.nrc.gov/reading-rm/doc-collections/nuregs/>. 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. 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 at (703) 605-6900.