



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 10.5

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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 license of broad scope for byproduct material. Title 10, Part 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," of the *Code of Federal Regulations* (10 CFR Part 33) (Ref. 1) regulates this type of license.

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" (Ref. 2), 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.

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. ML081140591.

This regulatory guide contains information collection requirements covered by 10 CFR Part 33 and NRC Form 313 that 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.

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 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 33, "Specific Domestic Licenses of Broad Scope for Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.¹
2. NUREG-1556, Volume 11, "Consolidated Guidance about Materials Licenses: Program-Specific Guidance about Licenses of Broad 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/>)

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 email PDR@nrc.gov.

² The multivolume NUREG-series report listed herein was published by the U.S. Nuclear Regulatory Commission. These volumes 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 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.