



DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-0020

(Proposed Revision 3 of Regulatory Guide 10.4, dated December 1987)

GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES TO PROCESS SOURCE MATERIAL

A. INTRODUCTION

This guide directs the reader to the type of information acceptable to the U.S. Nuclear Regulatory Commission (NRC) staff for the review of an application for new licenses, license amendments, and license renewals for the processing and use of source material in such activities as research and development; shielding; manufacturing depleted uranium and thorium-magnesium alloy products; manufacturing glass containing uranium; manufacturing and distributing other products containing source material; or shaping, grinding, and polishing lenses containing thorium. This guide does not apply to (1) activities related to the reactor fuel cycle such as uranium and thorium mill operation and uranium hexafluoride production or (2) large-scale processing of source material for extraction of metallic compounds such as zirconium or hafnium.

Title 10, Part 40, "Domestic Licensing of Source Material," of the *Code of Federal Regulations* (10 CFR Part 40) contains the NRC regulations on licensing source material. Source material is material that contains either the element thorium or the element uranium, provided that the uranium has not been enriched in the isotope uranium-235. Source material also includes any combination of thorium and uranium, in any physical or chemical form, or ores that contain by weight one-twentieth of 1 percent (0.05 percent) or more of uranium, thorium, or any combination thereof. Depleted uranium (left over from uranium enrichment) is considered source material.

This regulatory guide endorses the application and review procedure for a license to process source material contained in the current revision of the multivolume NUREG-1556, "Consolidated Guidance about Material Licenses," 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 nrcprep_resource@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 November 10, 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. ML081130210.

In addition to 10 CFR Part 40, other regulations pertaining to a license to process source material appear in 10 CFR Part 20, “Standards for Protection Against Radiation”; 10 CFR Part 71, “Packaging and Transportation of Radioactive Material”; 10 CFR Part 75, “Safeguards on Nuclear Material—Implementation of US/IAEA Agreement”; and 10 CFR Part 76, “Certification of Gaseous Diffusion Plants.” It is the responsibility of each applicant and licensee to have copies of and to abide by the applicable regulations. Licensees are subject to all applicable provisions of the regulations that pertain to the use of source material.

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 may contain information collection requests covered by the requirements of 10 CFR Parts 20, 40, 71, and 75 and NRC Form 313 that the Office of Management and Budget (OMB) approved under OMB control numbers 3150-0014, 3150-0020, 3150-0008, 3150-0055, 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 licensing, testing, processing, decommissioning, and terminating source material licenses. Each volume of NUREG-1556 provides specific guidance about different types of materials licenses. The following table identifies the volumes of NUREG-1556 that may be applicable to preparing an application for a new license, license amendment, and license renewal for the processing and use of source material.

Table 1. List of Volume Titles for NUREG-1556

NUREG-1556 Volume No.	Volume Titles for NUREG-1556, Consolidated Guidance about Material Licenses
Volume 1	Program-Specific Guidance About Portable Gauge Licenses
Volume 2	Program-Specific Guidance About Industrial Radiography Licenses
Volume 3	Applications for Sealed Source and Device Evaluation and Registration
Volume 4	Program-Specific Guidance About Fixed Gauge Licenses
Volume 5	Program-Specific Guidance About Self-Shielded Irradiator Licenses
Volume 6	Program-Specific Guidance About 10 CFR Part 36 Irradiator Licenses
Volume 7	Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers
Volume 8	Program-Specific Guidance About Exempt Distribution Licenses
Volume 9	Program-Specific Guidance About Medical Use Licenses

NUREG-1556 Volume No.	Volume Titles for NUREG-1556, Consolidated Guidance about Material Licenses
Volume 10	Program-Specific Guidance About Master Materials Licenses
Volume 11	Program-Specific Guidance About Licenses of Broad Scope
Volume 12	Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution
Volume 13	Program-Specific Guidance About Commercial Radiopharmacy Licenses
Volume 14	Program-Specific Guidance About Well Logging, Tracer, and Field Flood Study Licenses
Volume 15	Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses
Volume 16	Program-Specific Guidance About Licenses Authorizing Distribution to General Licensees
Volume 17	Program-Specific Guidance About Licenses for Special Nuclear Material of Less than Critical Mass
Volume 18	Program-Specific Guidance About Service Provider Licenses
Volume 19	Guidance for Agreement State Licensees About NRC Form 241 Report of Proposed Activities in Non-Agreement States, Areas of Exclusive Federal Jurisdiction, or Offshore Waters and Guidance for NRC Licensees Proposing To Work in Agreement State Jurisdiction (Reciprocity)
Volume 20	Guidance About Administrative Licensing Procedures
Volume 21	Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator

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 in NUREG-1556, 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(s) of applying for a license to process source material, or requesting a revision to a source material processing license, as described in the current version of NUREG-1556, 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. The NRC does not intend or approve any imposition or backfit 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. In some cases, applicants or licensees may propose an alternative 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.

REGULATORY ANALYSIS

1. Statement of the Problem

The NRC published Revision 2 of Regulatory Guide 10.4 in December 1987 to provide licensees with agency-approved guidance for complying with the NRC regulations on licensing the processing of source material. The NRC's implementation of a risk-informed, performance-based approach, combined with 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 license to process source material.

3. Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 10.4.
- Withdraw Regulatory Guide 10.4.
- Revise Regulatory Guide 10.4 to match or replace NUREG-1556.

- Revise Regulatory Guide 10.4 to endorse NUREG-1556.

3.1 Alternative 1: Do Not Revise Regulatory Guide 10.4

Under this alternative, the NRC would not revise (or issue additional) guidance, and the current version of this regulatory guide would be retained as the most recent staff guidance on the subject matter. 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 10.4

Withdrawing this regulatory guide would eliminate the problem of the 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 interested parties to identify the requirements necessary to prepare an application for a license to process source 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 10.4 To Match or Replace 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 10.4 contains specific guidance about only one of the many areas covered in NUREG-1556. Revising the regulatory guide to match the licensing information in NUREG-1556 would create duplicate sources of information and would require ongoing staff resources to ensure that the separate documents continued to duplicate each other. Revising this regulatory guide to replace all 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 unnecessary use of staff resources.

3.4 Alternative 4: Revise Regulatory Guide 10.4 To Endorse NUREG-1556

The December 1987 version of the regulatory guide no longer represents a method that is acceptable to the NRC for satisfying the requirements for licensing the processing of source material in accordance with the regulations in 10 CFR Part 40. 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 NUREG-1556.

4. Conclusion

Based on this regulatory analysis, the staff recommends that the NRC revise Regulatory Guide 10.4 to endorse the guidance on applying for a license to process source material described in the current version of NUREG-1556. 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.