



# REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

## REGULATORY GUIDE 10.4

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# 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.

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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.

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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.

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
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

<b>NUREG-1556 Volume No.</b>	<b>Volume Titles for NUREG-1556, Consolidated Guidance about Material Licenses</b>
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. 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(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 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.