



REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 6.9

(Draft was issued as DG-6007, dated July 2009)

ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR THE MANUFACTURE AND DISTRIBUTION OF SEALED SOURCES AND DEVICES CONTAINING BYPRODUCT MATERIAL

A. INTRODUCTION

This regulatory guide directs the reader to the type of quality assurance (QA) and quality control (QC) program acceptable to the staff of the U.S. Nuclear Regulatory Commission (NRC) during the review of an application to manufacture or distribute sealed sources and devices containing byproduct materials.

Title 10 of the *Code of Federal Regulations* (10 CFR) Part 32, “Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material” (Ref. 1), regulates the manufacture and distribution of sealed sources or devices containing byproduct material. Regulations in 10 CFR 32.51(a)(2) and 10 CFR 32.210(c) require the applicant or registrant to submit information about the QA program in sufficient detail to allow the NRC reviewers to ensure that the product is manufactured and distributed in a manner that is adequate to protect health and minimize danger to life and property.

This regulatory guide endorses the methods and procedures for a QA/QC program described in Section 10.7, “Quality Assurance and Quality Control” of NUREG 1556, Volume 3, “Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration,” Revision 1, issued April 2004 (Ref. 2), as a process that the NRC finds acceptable. As described in Revision 1 of Volume 3 of NUREG 1556, the applicant must provide details of the QA program that ensure that the product is manufactured and distributed in accordance with the representations made in the application and the statements contained in the registration certificate for the

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. ML100490731.

product. QA/QC programs for the manufacture and distribution of sealed sources or devices containing byproduct material should be structured to verify that the byproduct material will not breach its containment and contaminate the environment or unnecessarily expose individuals to radiation. The QA/QC program proposed by the applicant should demonstrate that the design fully conforms to the statements and commitments submitted in support of the application (including materials, dimensions within stated tolerances, manufacturing methods, assembly methods, and labeling), using sampling methods that meet the provisions of 10 CFR 32.110, "Acceptance Sampling Procedures Under Certain Specific Licenses," or the equivalent.

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 32 that the Office of Management and Budget (OMB) approved under OMB control number 3150 0001. 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 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.

Revision 1 of volume 3 of NUREG 1556 provides guidance to applicants who request a sealed source or device safety evaluation and registration. It also gives reviewers of such requests the information and materials necessary to determine that the products are acceptable for licensing purposes. It provides the applicants and reviewers with information on how to file a request, a list of the applicable regulations and industry standards, policies affecting evaluation and registration, administrative procedures to be followed, information on how to perform the evaluation and write a registration certificate, and the responsibilities of the registration certificate holder.

Many of the volumes of NUREG 1556 also 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 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 meets the regulatory requirements. By supplying examples, the NRC seeks to meet the needs of applicants for licenses, without being prescriptive. Guidance in the NUREG represents one means of complying with NRC regulations but is not intended to be the only one.

C. REGULATORY POSITION

This regulatory guide endorses the method described in Volume 3 of NUREG 1556 as a process the NRC has found to be acceptable for QA/QC programs to verify that the design, manufacture, and distribution of sealed sources and devices containing byproduct material meet the QA/QC requirements of 10 CFR Part 32.

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. 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.

REFERENCES¹

1. 10 CFR Part 32, "Specific Domestic Licenses To Manufacture or Transfer Certain Items Containing Byproduct Material," U.S. Nuclear Regulatory Commission, Washington, DC.
2. NUREG 1556, Volume 3, "Consolidated Guidance about Materials Licenses Applications for Sealed Source and Device Evaluation and Registration," Revision 1, U.S. Nuclear Regulatory Commission, Washington, DC, April 2004.

¹ Publicly available NRC published documents such as Regulations, Regulatory Guides, NUREGs, and Generic Letters 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/>. 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.Resource@nrc.gov.