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DRAFT REGULATORY GUIDE

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DRAFT REGULATORY GUIDE DG-6007

(Proposed Revision 1 to Regulatory Guide 6.9, dated February 1995)

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 32.210(c) require the applicant or registrant to submit information about the QC 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," issued April 2004 (Ref. 2), as a process that the NRC finds acceptable. As described in 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 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

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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 and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; submitted through the NRC's interactive rulemaking Web page at http://www.nrc.gov; or faxed to (301) 492-3446. 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 21, 2009.

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. ML091670485.

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.

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.

REGULATORY ANALYSIS

Statement of the Problem

The NRC published Regulatory Guide 6.9, "Establishing Quality Assurance Programs for the Manufacture and Distribution of Sealed Sources and Devices Containing Byproduct Material," in February 1995, to provide licensees with agency-approved guidance for complying with the QA/QC program requirements of 10 CFR Part 32. 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.

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—the multivolume NUREG-1556. Each volume of the NUREG 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 about materials licenses, in general, and leak-testing radioactive brachytherapy sources in particular.

Alternative Approaches

The NRC staff considered the following alternative approaches:

- Do not revise Regulatory Guide 6.9.
- Withdraw Regulatory Guide 6.9.
- Revise Regulatory Guide 6.9 to match or replace NUREG-1556.
- Revise Regulatory Guide 6.9 to endorse NUREG-1556.

Alternative 1: Do Not Revise Regulatory Guide 6.9

Under this alternative, the NRC would not revise this document and the original version of this regulatory guide would remain active. This alternative would continue the current conflict with the guidance in Volume 3 of NUREG-1556 and could cause unnecessary confusion. This alternative is considered the baseline or "no action" alternative and, as such, involves no value/impact considerations.

Alternative 2: Withdraw Regulatory Guide 6.9

Withdrawing this regulatory guide would eliminate the duplicative and somewhat contradictory information that currently exists in NUREG-1556 and the current version of Regulatory Guide 6.9. However, this action would leave a void in the regulatory guide system and provide no quick means for interested parties to identify the general safety standards that the NRC finds to be acceptable for installations using nonmedical sealed gamma-ray sources. Although this would be a relatively low-cost alternative, it does not comply with the NRC's goal of enhancing the public's accessibility to the most current information.

Alternative 3: Revise Regulatory Guide 6.9 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 6.9 contains specific guidance about only one of the many areas covered in NUREG-1556. Revising the regulatory guide to match the information in the existing NUREG would create duplicate sources of information and would require continuing staff resources to ensure that the separate documents continued to contain duplicate information. Revising this regulatory guide to replace the NUREG 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.

Alternative 4: Revise Regulatory Guide 6.9 to Endorse NUREG-1556

The February 1995 version of the regulatory guide no longer represents a method that is acceptable to the NRC for satisfying the requirements of 10 CFR Part 32. Failure to revise the regulatory guide will result in conflicting guidance documents and possible confusion to interested parties. Therefore, the staff has opted to revise the regulatory guide to direct any interested parties to the most current guidance, which is provided in Volume 3 of NUREG-1556.

Based on this regulatory analysis, the staff recommends that the NRC revise Regulatory Guide 6.9 to endorse NUREG-1556, Volume 3, and thereby provide guidance for installations using nonmedical sealed gamma-ray sources. The staff has concluded 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.

REFERENCES [1]

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," 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.