

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

RIN 3150-A111

[NRC-2013-0082; NRC-2008-0198]

**Establishing Quality Assurance Programs for Packaging Used in Transport of
Radioactive Material**

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its regulations for the packaging and transportation of radioactive material. The NRC is issuing for public comment draft regulatory guide (DG), DG-7009, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material." This draft regulatory guide describes a proposed method that the NRC staff considers acceptable for use in complying with the NRC's proposed amendments to its regulations on quality assurance programs related to transport of radioactive materials.

DATES: Submit comments by July, 30, 2013. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0082. Address questions about NRC dockets to Carol Gallagher; telephone: 301-492-3668; e-mail: Carol.Gallagher@nrc.gov. For technical questions, contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

- **Mail comments to:** Cindy Bladey, Chief, Rules, Announcements, and Directives Branch (RADB), Office of Administration, Mail Stop: TWB-05-B01M, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

- **Fax comments to:** RADB at 301-492-3446.

For additional direction on accessing information and submitting comments, see “Accessing Information and Submitting Comments” in the SUPPLEMENTARY INFORMATION section of this document.

FOR FURTHER INFORMATION CONTACT: Jessica Glenny, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-492-3285, e-mail: Jessica.Glenny@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Accessing Information

Please refer to Docket ID NRC-2013-0082 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, by the following methods:

- **Federal Rulemaking Web Site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0082.

- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may access publicly available documents online in the NRC Library at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "[ADAMS Public Documents](#)" and then select "[Begin Web-based ADAMS Search](#)." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by e-mail to pdr.resource@nrc.gov. The draft regulatory guide is available in ADAMS under Accession No. ML13079A004. The draft regulatory analysis for the proposed rule may be found in ADAMS under Accession No. ML13079A005. Because this draft regulatory analysis explains the reasons for revising the rule and its implementing guidance, a separate regulatory analysis was not prepared for this draft regulatory guide.

- **NRC's PDR:** You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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B. Submitting Comments

Please include Docket ID NRC-2013-0082 in the subject line of your comment submission, in order to ensure that the NRC is able to make your comment submission available to the public in this docket.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at <http://www.regulations.gov> as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

II. Proposed Rule

In the Proposed Rules section of this issue of the *Federal Register*, the NRC published a proposed rule, “Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements” (RIN 3150-A111; NRC-2008-0198), that would amend its regulations for the packaging and transportation of radioactive material in Part 71 of Title 10 of the *Code of Federal Regulations* (10 CFR). These amendments would make the NRC’s regulations compatible with the 2009 edition of the

International Atomic Energy Agency's (IAEA) transportation standards, "Regulations for the Safe Transport of Radioactive Material" (TS-R-1); maintain consistency with changes in the U.S. Department of Transportation's regulations; and make other changes to the requirements for the packaging and transportation of radioactive material.

III. Draft Regulatory Guide

The NRC is issuing for public comment a draft regulatory guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public such information as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

In conjunction with the proposed rule, the NRC is issuing DG-7009, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material." The draft regulatory guide is temporarily identified by its task number, DG-7009. The DG-7009 is proposed Revision 3 of Regulatory Guide 7.10, with the same title, dated March 2005, available in ADAMS under Accession No. ML050540330.

This draft regulatory guide describes a proposed method that the NRC staff considers acceptable for use in complying with the NRC's proposed regulations on quality assurance (QA) programs related to transport of radioactive materials.

This draft regulatory guide is being revised to address changes to the regulation of QA programs issued under 10 CFR Part 71. These changes include: (1) establishing requirements to allow some changes to be made to a previously approved QA program without obtaining NRC approval, and (2) removing the requirements for renewal of QA program approvals.

If adopted in final form, DG-7009 would supersede Regulatory Guide 7.10 , Revision 2, and would represent the NRC staff's guidance for future users, including licensees, certificate holders, and applicants.

IV. Backfitting and Issue Finality

This draft regulatory guide contains proposed NRC guidance on one acceptable means of addressing NRC requirements in 10 CFR Part 71 on QA programs related to transport of radioactive materials. The NRC proposes to determine that the draft regulatory guide may be adopted in final form without preparation of a backfit analysis or further documentation of backfitting and issue finality. There are two bases for the NRC's proposed determination, which are addressed separately in the following paragraphs.

Lack of Backfitting or Issue Finality Provisions Applicable to Entities with Respect to Requirements in 10 CFR Part 71

Part 71 of 10 CFR does not contain any backfitting or issue finality provisions protecting persons and entities subject to its provisions. The NRC recognizes that persons and entities required to comply with the 10 CFR Part 71 QA requirements, such as nuclear power plant licensees, may also be protected by backfitting and issue finality protection under other parts of 10 CFR Chapter I. Nonetheless, it is the NRC's position that those backfitting and issue finality protections are limited to activities directly regulated under those parts, and do not apply to

activities regulated under other parts without backfitting or issue finality protections. The exception to this general principle is where the activity regulated under other parts without backfitting or issue finality protections is an inextricable part of the regulated activity subject to backfitting or issue finality.

However, the exception to this principle is not applicable to the issuance of this regulatory guide, which addresses QA for transportation of radioactive materials. Nuclear power plant licensees, for example, are protected by backfitting requirements in 10 CFR 50.109, and (depending upon the circumstance) issue finality requirements in 10 CFR Part 52. Nonetheless, quality assurance governing transportation of certain radioactive materials is not an inextricable part of the licensed activity in 10 CFR Parts 50 and 52, viz. the design, construction and operation of a nuclear power plant. Analogous arguments also apply with respect to entities protected by backfitting requirements in 10 CFR Parts 70, 72, and 76.

First Issuance of Guidance on a New or Amended Regulation

This draft regulatory guide addresses proposed changes to the regulation of QA programs issued under 10 CFR Part 71, which are being published in a companion notice in this issue of the Federal Register. These changes include: (1) establishing requirements to allow some changes to be made to a previously approved QA program without obtaining NRC approval, and (2) removing the requirements for renewal of QA program approvals. The first issuance of guidance on a newly-changed or newly-added rule provision does not constitute backfitting or raise issue finality concerns, inasmuch as the guidance must be consistent with the regulatory requirements in the newly-changed or newly-added rule provisions and the backfitting and issue finality considerations applicable to the newly-changed or newly-added rule

provisions must logically apply to this guidance. Therefore, issuance of guidance addressing the newly-changed and newly-added provisions of the amended rule does not constitute issuance of “changed” or “new” guidance within the meaning of the definition of “backfitting” in 10 CFR 50.109(a)(1). Similarly, the issuance of the guidance addressing the newly-changed or newly-added provisions of the amended rule, by itself, does not constitute an action inconsistent with any of the issue finality provisions in 10 CFR Part 52.

Accordingly, no further consideration of backfitting or issue finality is needed in order to issue this draft regulatory guide in final form.

Dated at Rockville, Maryland, this ____30th____ day of ____April____, 2013.

For the Nuclear Regulatory Commission.

/RA/

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