

NUCLEAR REGULATORY COMMISSION

10 CFR Part 71

[NRC-2016-0179]

RIN 3150-AJ85

Harmonization of Transportation Safety Requirements with IAEA Standards

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory basis; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting comments on a draft regulatory basis to support a proposed rule that would harmonize the NRC's regulations with the safety requirements of the International Atomic Energy Agency (IAEA) for the transport of radioactive material and the regulations of the U.S. Department of Transportation (DOT). In addition, the proposed rule would make administrative, editorial, or clarification changes to the NRC's regulations. The NRC plans to hold a public meeting to discuss the draft regulatory basis and facilitate public participation.

DATES: Submit comments by May 28, 2019. Comments received after this date will be considered if it is practical to do so; however, the NRC is only able to ensure consideration of comments received on or before this date.

ADDRESSES: You may submit comments by any of the following methods:

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID **NRC-2016-0179**. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; e-mail: Carol.Gallagher@nrc.gov. For technical questions contact the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.
- **E-mail comments to:** Rulemaking.Comments@nrc.gov. If you do not receive an automatic e-mail reply confirming receipt, then contact us at 301-415-1677.
- **Fax comments to:** Secretary, U.S. Nuclear Regulatory Commission at 301-415-1101.
- **Mail comments to:** Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff.
- **Hand deliver comments to:** 11555 Rockville Pike, Rockville, Maryland 20852, between 7:30 a.m. and 4:15 p.m. (Eastern Time) Federal workdays; telephone: 301-415-1677.

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

FOR FURTHER INFORMATION CONTACT: Latif Hamdan, telephone: 301-415-6639, e-mail: Latif.Hamdan@nrc.gov; or Solomon Sahle, telephone: 301-415-3781, e-mail: Solomon.Sahle@nrc.gov. Both are staff of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC-2016-0179 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- **Federal Rulemaking Web site:** Go to <http://www.regulations.gov> and search for Docket ID NRC-2016-0179.
- **NRC's Agencywide Documents Access and Management System (ADAMS):** You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, 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 basis document is available in ADAMS under Accession No. ML18262A185.
- **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.

B. Submitting Comments

Please include Docket ID NRC-2016-0179 in your comment submission. If you cannot submit your comments on the Federal Rulemaking Web site, www.regulations.gov, then contact one of the individuals listed in the FOR FURTHER INFORMATION CONTACT section of this document.

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 to not 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 into ADAMS.

Please note that the NRC will not provide formal written responses to each of the comments received on the draft regulatory basis. However, the NRC will consider all comments received in the development of the final regulatory basis.

II. Discussion

In SECY-16-0093, “Rulemaking Plan for Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements,” dated July 28, 2016, the staff requested Commission approval to initiate a rulemaking to harmonize part 71 of title 10 of the *Code of Federal Regulations* (10 CFR), “Packaging and Transportation of Radioactive Material,” with the IAEA’s safety requirements and the DOT’s regulations. The proposed rule would revise 10 CFR part 71 to be in harmony with the IAEA’s requirements and compatible with the DOT’s regulations. In addition, the proposed rule would include staff-initiated administrative, editorial, or clarification changes. The Commission approved the staff’s recommendation in the staff requirements memorandum (SRM) associated with SECY-16-0093, dated August 19, 2016.

The NRC reviewed the updated IAEA requirements in Specific Safety Requirements No. 6 (SSR-6), 2012 and 2018 editions, and initially identified 14 regulatory issues to be analyzed during the rulemaking process. These issues were documented in an issues paper that was published in the *Federal Register* for public comment on November 21, 2016 (81 FR 83171). The NRC subsequently held a public meeting on December 5 - 6, 2016, to discuss the issues with stakeholders. After the public meeting, the NRC received 49 comment letters on the issues paper.

The DOT participated in the public meeting held in December 2016 to discuss the issues paper, and the staff has engaged with the DOT staff in the current rulemaking to identify and evaluate gaps between 10 CFR part 71 regulations and the updated IAEA requirements in SSR-6, 2012 and 2018 editions. The DOT also plans to undertake a similar action to harmonize its regulations for the transportation of radioactive material in 49 CFR parts 107 and 171 through 180 with SSR-6, 2012 and 2018 editions.

After the publication of the issues paper, the staff identified several additional items that were grouped under a new issue, designated as Issue 15. The draft regulatory basis documents the basis for the NRC's recommendation to revise the existing regulations in 10 CFR part 71. The draft regulatory basis includes a main document and two appendices. Appendix A provides a summary of cost estimates and uncertainty analysis. Appendix B provides detailed assessments of the regulatory issues identified and analyzed by the NRC and used to scope and provide justification for the proposed revisions to 10 CFR part 71.

In the draft regulatory basis, the NRC describes its evaluation of four alternative actions to achieve the objectives of the harmonization initiative. These are: no-action option that would maintain the status quo (Alternative 1); issue generic communications and regulatory guidance (Alternative 2); issue license specific conditions and exemptions (Alternative 3); and initiate a rulemaking to revise 10 CFR part 71 (Alternative 4).

The NRC evaluated these alternatives in terms of their viability to address the regulatory issues of concern and their cost estimates and determined that a combination of rulemaking (Alternative 4) and the no-action alternative (Alternative 1) is the preferred approach. Specifically, the NRC recommends no action for Issues 3 and 5 and rulemaking for the remaining issues.

The recommended rulemaking action is consistent with the NRC's response to previous revisions and updates of the international requirements by the IAEA and would not impose broad programmatic requirements on the NRC, nor would it have any significant negative effects on the NRC's licensees or certificate holders. In addition, the rulemaking action can be expected to reduce regulatory burden on licensees by maintaining consistency between the NRC's and DOT's regulations and aligning the U.S. domestic regulations with the IAEA's requirements, thereby eliminating potential conflicts or duplication across requirements.

III. Specific Request for Comment

The NRC is requesting public comment on the draft regulatory basis and its supporting appendices. In preparing comments, consider the following questions:

1) Regulatory issues: The NRC has identified and analyzed 15 regulatory issues to be considered in a proposed rule. Do you have comments on the regulatory issues or the scope of analysis performed by the NRC? Are there any other issues or areas of concern that ought to be considered in a proposed rule?

2) Impacts: Does the draft regulatory basis, including supporting documentation, address all potential impacts of a proposed rule? Are there any additional regulatory or other impacts that should be addressed before or during development of a proposed rule?

3) Evaluation of options: The draft regulatory basis provides a discussion of alternatives and options for harmonizing the regulations in 10 CR part 71 with the IAEA regulations. Are there any additional alternatives or options that the NRC should consider before development of a proposed rule?

4) Proposed revisions to the existing regulations: Do you have comments on the proposed revisions to the existing regulations as discussed in the draft regulatory basis?

5) Other comments: Are there any other concerns that you think should be addressed before or during development of a proposed rule?

IV. Cumulative Effects of Regulation

The cumulative effects of regulation (CER) describe the challenges that licensees or other affected entities (such as Agreement State regulatory partners) may face while implementing new regulatory positions, programs, and requirements (e.g., rules, generic letters, backfits, inspections). The CER is an organizational effectiveness challenge that results from a licensee or affected entity implementing a number of complex positions, programs, or requirements within a limited implementation period and with available resources (which may include limited available expertise to address specific issues). The NRC has implemented CER enhancements to the rulemaking process to facilitate public involvement throughout the rulemaking process. Therefore, the NRC is specifically requesting comment on the cumulative effects that may result from a proposed rule. In developing comments on the draft regulatory basis, consider the following questions:

1) In light of any current or projected CER challenges, what should be a reasonable effective date, compliance date, or submittal date(s) from the time the

final rule is published to the actual implementation of any new proposed requirements, including changes to programs, procedures, or the facility?

2) If current or projected CER challenges exist, what should be done to address this situation (e.g., if more time is required to implement the new requirements, what time period would be sufficient, and why such a time frame is necessary)?

3) Do other regulatory actions (e.g., orders, generic communications, license amendment requests, and inspection findings of a generic nature) by the NRC or other agencies influence the implementation of the potential proposed requirements?

4) Are there unintended consequences? Does a proposed rulemaking action create conditions that would be contrary to the purpose and objectives of the 10 CFR part 71 harmonization initiative? If so, what are the consequences and how should they be addressed?

5) Please consider providing information on the estimates of the costs and benefits of a proposed rulemaking action, which can be used to support any additional regulatory analysis by the NRC.

V. Public Meeting

The NRC will conduct a public meeting to describe the draft regulatory basis and to give the public an opportunity to ask questions.

The NRC will publish a notice of the location, time, and agenda for the meeting on the NRC's public meeting Web site at least 10 calendar days before the meeting. Stakeholders should monitor the NRC's public meeting Web site for information about the public meeting at: <http://www.nrc.gov/public-involve/public-meetings/index.cfm>. The meeting notice will also be added to the Federal Rulemaking Web site at <http://www.regulations.gov> under Docket ID NRC-2016-0179. See the "Availability of

Documents” section of this document for instructions on how to subscribe to receive e-mail notifications when documents are added to the docket folder on the Federal Rulemaking Web site.

VI. Availability of Documents

The NRC may post additional materials related to this rulemaking activity to the Federal Rulemaking Web site at www.regulations.gov under NRC-2016-0179. These documents will inform the public of the status of this activity and/or provide additional material for use at future public meetings.

The Federal Rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: 1) navigate to the docket folder (NRC-2016-0179); 2) click the “Sign up for E-mail Alerts” link; and 3) enter your e-mail address and select how frequently you would like to receive e-mails (daily, weekly, or monthly).

The documents identified in the following table are available to interested persons through one or more of the methods listed in the ADDRESSES section of this document.

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK
Draft Regulatory Basis — Harmonization of Transportation Safety Requirements with IAEA Standards	ML18262A185
“Revisions to Transportation Safety Requirements and Compatibility with International Atomic Energy Agency Transportation Standards,” published November 21, 2016	https://www.govinfo.gov/content/pkg/FR-2016-11-21/pdf/2016-27944.pdf
SECY-16-0093, “Rulemaking Plan for Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy	ML16158A164

Agency Transportation Requirements,” dated July 28, 2016	
SRM-SECY-16-0093, “Rulemaking Plan for Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements,” dated August 19, 2016	ML16235A182
“Regulations for the Safe Transport of Radioactive Material, 2012 Edition,” Specific Safety Requirements No. SSR-6 (draft Rev.1); published October 2012	https://www-pub.iaea.org/MTCD/publications/PDF/Pub1570_web.pdf
“Regulations for the Safe Transport of Radioactive Material, 2018 Edition,” Specific Safety Requirements No. SSR-6 (Rev. 1); published June 2018	https://www-pub.iaea.org/MTCD/Publications/PDF/PUB1798_web.pdf

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111-274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, “Plain Language in Government Writing,” published in the *Federal Register* on June 10, 1998 (63 FR 31883). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

Dated at Rockville, Maryland, this 9th day of April, 2019.

For the Nuclear Regulatory Commission.

/RA/

Theresa Clark, Deputy Director,
 Division of Rulemaking,
 Office of Nuclear Material Safety and Safeguards.