

### Harmonization of NRC Transportation Safety Requirements with IAEA Standards

Council on Radionuclides and Radiopharmaceuticals, Inc. Transportation Committee

#### James Firth, Project Manager

Division of Rulemaking, Environmental, and Financial Support Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission

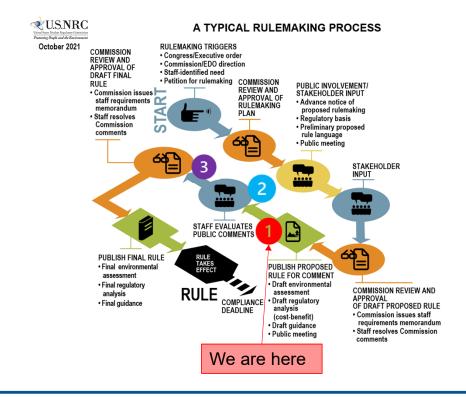
#### **Bernard White, Senior Project Manager**

Division of Fuel Management Office of Nuclear Material Safety and Safeguards U.S. Nuclear Regulatory Commission

November 15, 2022

ADAMS Accession No.: ML22286A071

# **Rulemaking Process and Current Status**



- Proposed rule published in the *Federal Register* on September 12, 2022
  - 75-day comment period
  - Comment period closes on November 28, 2022
- We are currently within the public comment period 1
- Public comment period ends: November 28, 2022
- Staff will respond to comments and develop a final rule
- Final rule currently due to the Commission: February 2024 3



# Status of Harmonization and Compatibility with DOT Regulations

- The NRC is proposing changes to Regulatory Guide 7.9 and has published draft regulatory guide 7011, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material," for public comment.
- The proposed rule was published in the Federal Register on September 12, 2022 (87 FR 55708) with a 75-day comment period.
  - The comment period ends November 28, 2022.
- The U.S. Department of Transportation (DOT) published a related proposed rule on September 12, 2022 (87 FR 55743) with a 90-day public comment period.



### Proposed Rule and Related Documents

### Regulations.gov Docket: NRC-2016-0179

<u>https://www.regulations.gov/docket/NRC-2016-0179</u>

### Proposed Rule

- Citation: 87 FR 55708 (September 12, 2022)
- <u>https://www.govinfo.gov/content/pkg/FR-2022-09-12/pdf/2022-</u> 18520.pdf

### Supporting & Related Material

- Draft Regulatory Analysis (<u>ML22209A039</u>)
- Draft Environmental Assessment (ML22209A045)
- Draft Supporting Statement for Information Collections (ML22209A052)



### Proposed Rule and Related Documents

### Correction notice

• Citation: <u>87 FR 65177</u> (October 28, 2022)

### Corrections and Changes

- Corrected information collection
  - Changed the number of responses from 7.5 to 100 and the number of respondents from 6.5 to 99
  - The overall burden does not change (rounded to a total of 1,377 hours)
  - Comment period for the information collection extended until November 28, 2022
- Republished Draft Regulatory Analysis (correcting a publication error)
- Clarified the units for the mass limit (changed "140 g" to "140 grams")



### Proposed Rule and Related Documents

#### Guidance Document

- Draft Regulatory Guide DG-7011, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material" (<u>ML22223A085</u>)
- Unofficial redline/strikeout comparison between DG-7011 and Regulatory Guide 7.9, (Revision 2), "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material" (ML22280A061)



### International Atomic Energy Agency Harmonization

- Fissile material exemptions
- Revise insolation requirements for package evaluations
  - Revise units for insolation for normal conditions
     of transport
  - Include insolation for Hypothetical Accident Conditions
- Include Definition for Radiation Level
- Delete Low Specific Activity-III Leaching Test\*
- Include New Definition for Surface Contaminated Object\*

- Revise Uranium Hexafluoride Package Requirements
- Include Evaluation of Aging Mechanisms and a Maintenance Program
- Revise Transitional Arrangements\*
- Include Head Space for Liquid Expansion\*
- Revise Tables Containing A<sub>1</sub> and A<sub>2</sub> Values and Exempt Material Activity and Consignment Limits\*
  - \* Changes to harmonize with U.S. Department of Transportation and International Atomic Energy Agency Specific Safety Requirements (SSR) No. 6



### Part 71: NRC-Initiated Changes

- Biennial quality assurance reporting (§ 71.106)
- Remove Type A limits from general license requirements (§§ 71.22, 71.23)
- Revise the determination of the mass limits containing mixed quantities of fissile material when uranium-233 is present (§ 71.22)
- Revise compatibility category designations for quality assurance requirements (Subpart H)
- Remove duplicative reporting (§ 71.95)
- Revise the definition of *Low Specific Activity (LSA) Material* (§ 71.4)
- Remove references to irradiated reactor fuel in the advance notification requirements (§ 71.97)



Revision of Tables Containing A<sub>1</sub> and A<sub>2</sub> Values and Exempt Material Activity and Consignment Limits

- Summary:
  - NRC proposes revising 10 CFR 71, Appendix A, Tables A-1 and A-2

#### Additional information:

- Seven radionuclides would be added
- Footnote c for Thorium-natural would be revised
- Alphabetical listing of radionuclides would be revised
- Would align with DOT



Conform to DOT



Inclusion of Evaluation of Aging Mechanisms and a Maintenance Program

Where is this discussed in the FRN?• Section III.C. (Issue Number 9) (pages 55714–55715)Which sections of the CFR would be amended?• 10 CFR 71.35(d) 10 CFR 71.43(d)What are the current and proposed compatibility categories?• [--]  $\rightarrow$  NRC and NRC  $\rightarrow$  NRC

- Summary:
  - Would add a requirement in § 71.35(d) for the application for package approval to include a description of the package maintenance program
  - Would revise § 71.43(d) to include the evaluation of the effects of aging

#### Additional information:

- IAEA added requirement for applications for package approval include a maintenance program and evaluation of the effects of aging
- No burden on NRC certificate holders since applications for NRC package approval already include both

**IAEA Harmonization** 



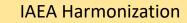
Revision of Transitional Arrangements

Where is this discussed in the FRN?• Section III.C. (Issue Number 10) (pages 55715–55716)Which sections of the CFR would be amended?• 10 CFR 71.19What are the current and proposed compatibility categories?• NRC  $\rightarrow$  NRC

- Summary:
  - Phase out older packages without a "–85" or "–96" in the package identification number
  - Limit use of packages with a "–96" in the package identification number to those whose fabrication has been completed by December 31, 2028
  - Limit fabrication of special form sources

#### Additional information:

 Proposing to revise § 71.19 to allow existing packages be recertified to show compliance with the revised regulations and remove restrictions on package use and fabrication



Conform to DOT



Inclusion of Head Space for Liquid Expansion

Where is this discussed in the FRN?• Section III.C. (Issue Number 11) (pages 55716–55717)Which sections of the CFR would be amended?• 10 CFR 71.43(i)What are the current and proposed compatibility categories?•  $[--] \rightarrow NRC$ 

- Summary:
  - Would add a design requirement in § 71.43(i) for packages containing liquids to ensure adequate space for liquid expansion during evaluation of the normal conditions of transport and hypothetical accident conditions
- Additional information:
  - Ensure consistency with § 71.87(d)



Conform to DOT



Deletion of Duplicative Reporting Requirements Where is this discussed in the FRN?• Section III.C. (Issue Number 15.1) (page 55719)Which sections of the CFR would be amended?• 10 CFR 71.95(a)(3)What are the current and proposed compatibility categories?•  $D \rightarrow [--]$ 

- Summary:
  - Proposes to remove reporting requirement in § 71.95(a)(3), which is duplicative of paragraph (b)
- Additional information:
  - None

NRC-Initiated



Quality Assurance Program (QAP) Biennial Report Issue

- Summary:
  - Clarification of requirements for biennial reports for QAP changes

#### Additional information:

- Proposed change modifies language in § 71.106 to clarify that biennia reports are required even when no changes have been made to an NRCapproved QAP in the previous 24-month period
- Consistent with 10 CFR 50 reporting requirements [§§ 50.54(a)(3) and 50.71(e)(2)]
- Would match guidance currently provided in RG 7.10
- Would remove regulatory uncertainty



### Revision to Agreement State Compatibility Categories

Where is this discussed in the FRN?

Section III.C.(Issue Number 15.4) (pages 55719–55720)
Which sections of the CFR would be amended?
N/A
What are the current and proposed compatibility categories?
NRC → B, §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125
D → C, §§ 71.95

#### • Summary:

- Regulations that contain QAP review criteria would be revised from Compatibility Category NRC to Compatibility Category B so Agreement States can approve, inspect, and enforce their licensees' QAPs
- Reporting requirements in § 71.95 would change from Compatibility Category D to Compatibility Category C, so State licensees would report to:
  - NRC for instances of package defects or a reduction in effectiveness
  - State regulator for instances where the CoC was not followed in making a shipment

#### Additional information:

- §§ 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 would be revised from Compatibility Category NRC to Compatibility Category B
- § 71.95 would be revised from Compatibility Category D to Compatibility Category C

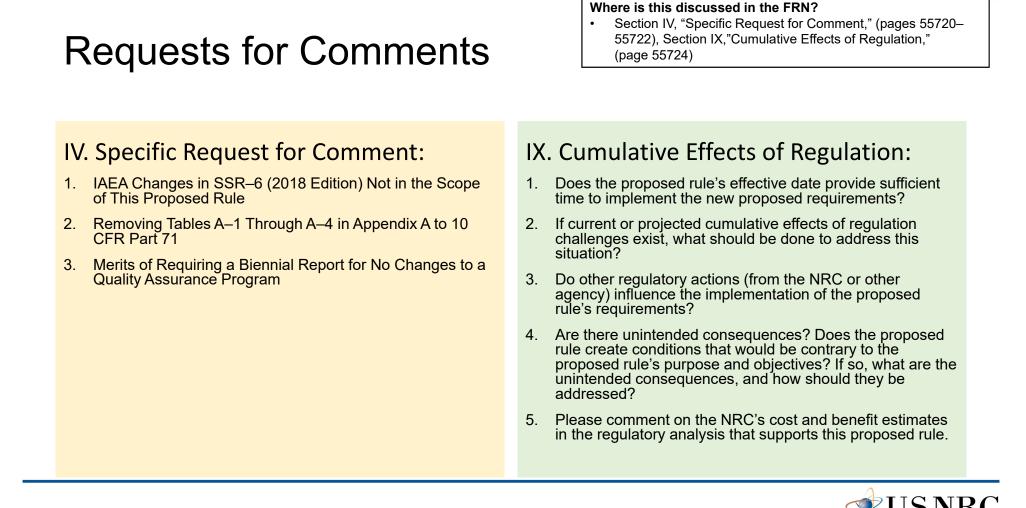


### Draft Regulatory Guide

Where is this discussed in the FRN?
Section XVII (pages 55727–55728)
Which sections of the CFR would be amended?
N/A
What are the current and proposed compatibility categories?
N/A

- Draft Regulatory Guide DG-7011, "Standard Format and Content of Part 71 Applications for Approval of Packages for Radioactive Material" (<u>ML22223A085</u>)
  - Added detail on air transport requirements in structural and thermal chapters
  - Moved information on materials evaluations to Chapter 7
  - Added Chapter 10 on Quality Assurance
- Unofficial Redline/Strikeout Version of draft guidance (ML22280A061)





17

United States Nuclear Regulatory Commissio

Protecting People and the Environment

# **Questions and Discussion**



Contacts:

James Firth James.Firth@nrc.gov 301-415-6628 Bernard White Bernard.White@nrc.gov 301-415-6577



## Acronyms

- CFR Code of Federal Regulations
- CoC Certificate of Compliance
- DG Draft regulatory guide
- DOT U.S. Department of Transportation
- FAQs Frequently Asked Questions
- FR Federal Register
- H&S Health and safety
- IAEA International Atomic Energy Agency
- LSA Low Specific Activity
- NRC U.S. Nuclear Regulatory Commission
- QAP Quality Assurance Program

RGregulatory guideSSRSpecific Safety Requirements



## Background



## Compatibility



# Compatibility Categories A and B

Where is this discussed in the FRN?
Section XV. (pages 55725–55727)
Which sections of the CFR would be amended?
N/A
What are the current and proposed compatibility categories?
See Compatibility Table

#### Compatibility Category A

- Basic radiation protection standards and scientific terms and definitions that are necessary to understand radiation protection concepts.
- Should be essentially identical to those of the NRC to provide uniformity in the regulation of agreement material on a nationwide basis.

#### Compatibility Category B

- Activities that cross jurisdictional boundaries.
- Need to be adopted in an essentially identical manner in order to ensure uniformity of a regulation on a national basis.



### Compatibility Category C

Where is this discussed in the FRN?
Section XV. (pages 55725–55727)
Which sections of the CFR would be amended?
N/A
What are the current and proposed compatibility categories?
See Compatibility Table

#### Compatibility Category C

- Program elements that are important for an Agreement State to have in order to avoid conflict, duplication, gaps, or other conditions that would jeopardize an orderly pattern in the regulation of agreement material on a nationwide basis.
- Agreement State program elements must embody the essential objectives of these NRC program elements.
- May be more restrictive than the NRC program elements provided that the essential objective is met, and the State requirements do not jeopardize an orderly pattern of regulation of agreement material on a nationwide basis.



### **Compatibility Category D**

Where is this discussed in the FRN?
Section XV. (pages 55725–55727)
Which sections of the CFR would be amended?
N/A
What are the current and proposed compatibility categories?
See Compatibility Table

#### Compatibility Category D

- Program elements that do not meet any of the criteria of Compatibility Categories A, B, or C, or have a particular health and safety role.
- Do not need to be adopted by Agreement States for purposes of compatibility.
- An Agreement State may adopt and implement these program elements that fall within its jurisdiction.
- If adopted, the program element should be adopted in a manner such that:
- They are comparable with those of the NRC,
- They do not preclude, or effectively preclude a practice in the national interest without adequate protection of public health and safety, security, or environmental basis related to radiation protection, and
- They do not preclude, or effectively preclude the ability of the NRC to evaluate the effectiveness of the Agreement State program with respect to the protection of public health and safety.



# Compatibility Categories NRC and H&S

Where is this discussed in the FRN?
Section XV. (pages 55725–55727)
Which sections of the CFR would be amended?
N/A
What are the current and proposed compatibility categories?
See Compatibility Table

#### Compatibility Category NRC

- Program elements that address areas of regulation that cannot be discontinued when a State enters into an Agreement with the NRC pursuant to the Atomic Energy Act or provisions of Title 10 of the Code of Federal Regulations (CFR).
- The NRC maintains regulatory authority over these program elements.
- Agreement States must not adopt these NRC program elements.

#### Compatibility Category H&S

- Program elements that embody the basic health and safety aspects of the NRC's program elements because of particular health and safety considerations.
- Must be adopted by Agreement States.
- Not required for compatibility.



### Compatibility Table: Compatibility Categories and Changes

Section	Change	Subject	Compatibility	
		and an and a second s	Existing	New
71.0(d)(1)	Revised	Purpose and Scope	D	D
71.4	New	Definition: Radiation Level	34 <u>-</u> 31	[A]
71.4	Revised	Definition: Low Specific Activity (LSA) material [Deletion of Low Specific Activity-III Leaching Test]	[B]	[B]
71.4	Revised	Definition: Special form radioactive material	[B]	[B]
71.4	Revised	Definition: Surface Contaminated Object (SCO)	[B]	[B]
71.15(a) and (d)	Revised	Exemption from classification as fissile material	[B]	[B]
71.15(g)	New	Exemption from classification as fissile material	-	[B]
71.17(e)	Revised	General license: NRC-approved package.	В	В
71.19	Revised	Previously approved package	NRC	NRC
71.22(a), (c), and (e)(3) through (5)	Revised	General license: Fissile material	[B]	[B]
71.22(f) through (h)	New	General license: Fissile material		[B]
71.23(a) and (c)	Revised	General license: Plutonium-beryllium special form material	[B]	[B]
71.23(f) through (h)	New	General license: Plutonium-beryllium special form material	0.2220	[B]
71.31(a)	Revised	Contents of application	NRC	NRC
71.35(b) and (c)	Revised	Package evaluation	NRC	NRC
71.35(d)	New	Package evaluation	-	NRC
71.43(d)	Revised	General standards for all packages	NRC	NRC
71.43(i)	New	General standards for all packages	( ) (	NRC
71.55(g)	Revised	General requirements for fissile material packages	NRC	NRC
71.71(c)(1)	Revised	Normal conditions of transport	NRC	NRC
71.73(b)	Revised	Hypothetical accident conditions	NRC	NRC
71.77	Removed	Qualification of LSA-III Material	NRC	
71.95	Revised compatibility category	Reports	D	C**
71.95(a)(3)	Removed	Reports	D	*
71.97	Revised	Advance notification of shipment of irradiated reactor fuel and nuclear waste	В	В
71.100	Revised	Criminal penalties	D	D
71.101(b)	Revised compatibility category	Quality assurance requirements	C***	B***
71.101(c)(1)	Revised compatibility category	Quality assurance requirements	C***	B**

#### Where is this discussed in the FRN?

Section XV. (pages 55726–55727)

Which sections of the CFR would be amended?

• N/A

•

#### What are the current and proposed compatibility categories?

• See Compatibility Table

Section	Change	Subject	Compatibility	
			Existing	New
71.103 (a) and (b)	Revised compatibility category	Quality assurance organization	C***	B**
71.103 (c), (d), (e) and (f)	Revised compatibility category	Quality assurance organization	D	B**
71.105	Revised compatibility category	Quality assurance program	С	B**
71.106	Revised compatibility category	Changes to quality assurance program	С	B**
71.109	Revised compatibility category	Procurement document control	NRC	B**
71.111	Revised compatibility category	Instructions, procedures and drawings	NRC	B**
71.113	Revised compatibility category	Document control	NRC	B**
71.115	Revised compatibility category	Control of purchased material, equipment, and services	NRC	B**
71.117	Revised compatibility category	Identification and control of materials, parts and components	NRC	B**
71.119	Revised compatibility category	Control of special processes	NRC	B**
71.121	Revised compatibility category	Internal inspection	NRC	B**
71.123	Revised compatibility category	Test control	NRC	B**
71.125	Revised compatibility category	Control of measuring and test equipment	NRC	B**
71.127	Revised compatibility category	Handling, storage, and shipping control	[C]	B**
71.129	Revised compatibility category	Inspection, test, and operating status	[C]	B**
71.131	Revised compatibility category	Nonconforming materials, parts, or components	[C]	B**
71.133	Revised compatibility category	Corrective action	С	B**
71.135	Revised compatibility category	Quality assurance records	C***	C**
71.137	Revised compatibility category	Audits	С	C**
Table A-1 in Appendix A to 10 CFR Part 71	Revised	A <sub>1</sub> and A <sub>2</sub> Values for Radionuclides [B]		[B]
Table A-2 in Appendix A to 10 CFR Part 71	Revised	Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides	[B]	[B]

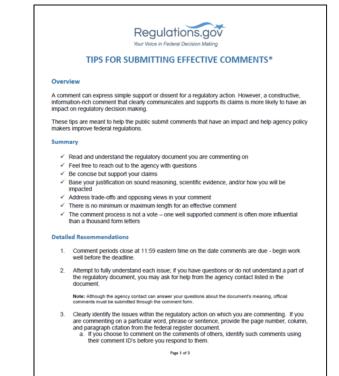


# Resources for Preparing and Submitting Comments



### Commenter's Checklist on Regulations.gov

- Available from <u>Regulations.gov</u> at: <u>https://downloads.regulations.gov/F</u> <u>S-2018-0053-0007/content.pdf</u>
- This information is also available from the page for submitting comments on the proposed rule: <u>https://www.regulations.gov/comme</u> <u>nton/NRC-2016-0179-0072</u>





# Submitting a comment

- Frequently Asked Questions (FAQs) on commenting are available at: <u>https://www.regulations.gov/faq</u>
- Ways You Can Submit Comments:
  - **Regulations.gov**: <u>comment form</u> for the proposed rule on docket NRC–2016–0179

#### or

• Email: Rulemaking.Comments@nrc.gov

#### or

 Mail: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, ATTN: Rulemakings and Adjudications Staff

Proposed Rules		Federal Register
		Vol. 87, No. 175
		Monday, September 12, 2022
This section of the FEDERAL REGISTER contains notices to the public of the proposed	Forder; telephone: 301-415-3407; email: Dawn.Forder@nrc.gov. For	I. Obtaining Information and Submitting Comments
Issuance of rules and regulations. The purpose of these notices is to give interested	technical questions contact the individual or individuals listed in the	A. Obtaining Information
persons an opportunity to participate in the	FOR FURTHER INFORMATION CONTACT	Please refer to Docket ID NRC-
rule making prior to the adoption of the final rules.	section of this document.	0179 when contacting the NRC al
	Email comments to:	the availability of information for action. You may obtain publicly-
NUCLEAR REGULATORY COMMISSION	Rulemaking.Comments@nrc.gov. If you do not receive an automatic email reply confirming receipt, then contact us at	available information related to t action by any of the following me • Federal Rulemaking Website
10 CFR Part 71	301-415-1677.	https://www.regulations.gov and
[NRC-2016-0179]	<ul> <li>Mail comments to: Secretary, U.S. Nuclear Regulatory Commission,</li> </ul>	<ul> <li>for Docket ID NRC-2016-0179.</li> <li>NRC's Agencywide Document</li> </ul>
RIN 3150-AJ85	Washington, DC 20555-0001, ATTN:	Access and Management System
	Rulemakings and Adjudications Staff.	(ADAMS): You may obtain public available documents online in the
Harmonization of Transportation Safety Requirements With IAEA	For additional direction on obtaining information and submitting comments,	ADAMS Public Documents colleg
Standards	see "Obtaining Information and	https://www.nrc.gov/reading-rm/
AGENCY: Nuclear Regulatory	Submitting Comments" in the	adams.html. To begin the search "Begin Web-based ADAMS Search
Commission.	SUPPLEMENTARY INFORMATION section of this document.	problems with ADAMS, please c
ACTION: Proposed rule and guidance;	FOR FURTHER INFORMATION CONTACT:	the NRC's Public Document Root reference staff at 1-800-397-420
request for comment.	James Firth, 301-415-6628, email:	415-4737, or by email to
SUMMARY: The U.S. Nuclear Regulatory	James.Firth@nrc.gov; or Bernard White,	PDR.Resource@nrc.gov. For the convenience of the reader, instru
Commission (NRC), in consultation with the U.S. Department of Transportation,	301-415-6577, email: Bernard. White@ nrc.gov. Both are staff of the Office of	about obtaining materials referen
is proposing to amend its regulations for	Nuclear Material Safety and Safeguards,	this document are provided in th
the packaging and transportation of radioactive material. The NRC has	U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.	"Availability of Documents" sec • NRC's PDR: You may examine
historically revised its transportation		purchase copies of public docum
safety regulations to ensure	SUPPLEMENTARY INFORMATION:	by appointment, at the PDR, Roo
harmonization with the International Atomic Energy Agency standards. These	Table of Contents	B35, One White Flint North, 115 Rockville Pike, Rockville, Maryla
changes are necessary to maintain a	I. Obtaining Information and Submitting Comments	20852. To make an appointment
consistent regulatory framework with the U.S. Department of Transportation	A. Obtaining Information	the PDR, please send an email to PDR.Resource@nrc.gov or call 1-
for the domestic packaging and	B. Submitting Comments II. Background	397-4209 or 301-415-4737, betv
transportation of radioactive material	III. Discussion	8:00 a.m. and 4:00 p.m. eastern t
and to ensure general accord with International Atomic Energy Agency	A. Action the NRC is Proposing To Take B. Applicability of the Proposed Action	(ET), Monday through Friday, ex Federal holidays.
standards. Concurrently, the NRC is	C. Discussion of Issues Specific Request for	B. Submitting Comments
issuing for public comment Draft	Comment IV. Specific Request for Comment	Please include Docket ID NRC
Regulatory Guide DG-7011, which would become Revision 3 to Regulatory	V. Section-by-Section Analysis	0179 in your comment submission
Guide 7.9, "Standard Format and	VI. Regulatory Flexibility Certification VII. Regulatory Analysis	The NRC cautions you not to i identifying or contact informatio
Content of Part 71 Applications for Approval of Packages for Radioactive	VIII. Backfitting and Issue Finality	you do not want to be publicly
Material "	IX. Cumulative Effects of Regulation X. Plain Writing	disclosed in your comment subn
DATES: Submit comments by November	XL Environmental Assessment and Proposed	The NRC will post all comment submissions at https://
28, 2022. Comments received after this	Finding of No Significant Environmental Impact	www.regulations.gov as well as e
date will be considered if it is practical to do so, but the NRC is able to ensure	XII. Paperwork Reduction Act	comment submissions into ADA
consideration only for comments	XIII. Criminal Penalties	The NRC does not routinely edit comment submissions to remove
received on or before this date.	XIV. Coordination with NRC Agreement States	identifying or contact informatio
ADDRESSES: You may submit comments by any of the following methods:	XV. Compatibility of Agreement State	If you are requesting or aggreg comments from other persons for
<ul> <li>Federal rulemaking website: Go to</li> </ul>	Regulations XVI. Voluntary Consensus Standards	submission to the NRC, then you
https://www.regulations.gov and search	XVII. Availability of Guidance	inform those persons not to inclu
for Docket ID NRC-2016-0179. Address	XVIII. Public Meeting	identifying or contact informatio

