

**Revisions to Transportation Safety Requirements and Harmonization with
International Atomic Energy Agency Transportation Requirements; Including Corrections**

10 CFR Part 71

(80 FR 33987, Published June 12, 2015 and 80 FR 48683, Published August 14, 2015)

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 71.0(d)(1) Revised	Purpose and Scope	.0316	D	In § 71.0, paragraph (d)(1), remove the reference “§§ 71.20 through 71.23” and add, in its place, the reference “§§ 71.21 through 71.23”.			
§ 71.4 New	Definition: Contamination	.0316	[B]	In § 71.4, add the definition of “contamination” to read as follows: <i>Contamination</i> means the presence of a radioactive substance on a surface in quantities in excess of 0.4 Bq/cm ² (1x10 ⁻⁵ µCi/cm ²) for beta and gamma emitters and low toxicity alpha emitters, or 0.04 Bq/cm ² (1x10 ⁻⁶ µCi/cm ²) for all other alpha emitters. <i>(1) Fixed contamination</i> means contamination that cannot be removed from a surface during normal conditions of transport.			

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				(2) <i>Non-fixed contamination</i> means contamination that can be removed from a surface during normal conditions of transport.			
§ 71.4 Revised	Definition: Criticality Safety Index (CSI)	.0316	[B]	<p>In § 71.4, revise the definition of “Criticality Safety Index (CSI)” to read as follows:</p> <p><i>Criticality Safety Index (CSI)</i> means the dimensionless number (rounded up to the next tenth) assigned to and placed on the label of a fissile material package, to designate the degree of control of accumulation of packages, overpacks or freight containers containing fissile material during transportation. Determination of the criticality safety index is described in §§ 71.22, 71.23, and 71.59. The criticality safety index for an overpack, freight container, consignment or conveyance containing fissile material packages is the arithmetic sum of the criticality safety indices of all the fissile material packages contained within the overpack, freight container, consignment or conveyance.</p>			

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§ 71.4 Revised	Definition: Low Specific Activity (LSA) material	.0316	[B]	<p>In § 71.4, revise the definition of “Low Specific Activity (LSA) material” to read as follows:</p> <p><i>Low Specific Activity (LSA) material</i> means radioactive material with limited specific activity which is nonfissile or is excepted under § 71.15, and which satisfies the descriptions and limits set forth in the following section. Shielding materials surrounding the LSA material may not be considered in determining the estimated average specific activity of the package contents. The LSA material must be in one of three groups:</p> <p>(1) LSA-I.</p> <p>(i) Uranium and thorium ores, concentrates of uranium and thorium ores, and other ores containing naturally occurring radionuclides that are intended to be processed for the use of these radionuclides;</p> <p>(ii) Natural uranium, depleted uranium, natural thorium or their compounds or mixtures, provided they are unirradiated and in solid or liquid form;</p>			

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				<p>(iii) Radioactive material other than fissile material, for which the A_2 value is unlimited; or</p> <p>(iv) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed 30 times the value for exempt material activity concentration determined in accordance with appendix A.</p> <p>(2) LSA-II.</p> <p>(i) Water with tritium concentration up to 0.8 TBq/liter (20.0 Ci/liter); or</p> <p>(ii) Other radioactive material in which the activity is distributed throughout and the estimated average specific activity does not exceed $10^{-4} A_2/g$ for solids and gases, and $10^{-5} A_2/g$ for liquids.</p> <p>(3) LSA-III. Solids (e.g., consolidated wastes, activated materials), excluding powders, that satisfy the requirements of § 71.77, in which:</p> <p>(i) The radioactive material is distributed throughout a solid or a collection of solid objects, or is essentially uniformly distributed in a solid compact binding agent</p>			

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				<p>(such as concrete, bitumen, ceramic, etc.);</p> <p>(ii) The radioactive material is relatively insoluble, or it is intrinsically contained in a relatively insoluble material, so that even under loss of packaging, the loss of radioactive material per package by leaching when placed in water for 7 days will not exceed 0.1 A₂; and</p> <p>(iii) The estimated average specific activity of the solid, excluding any shielding material, does not exceed 2 × 10⁻³ A₂/g.</p>			
§ 71.4 Revised	Definition: Special form radioactive material	.0316	[B]	<p>In § 71.4, revise the definition of “Special form radioactive material” to read as follows:</p> <p><i>Special form radioactive material</i> means radioactive material that satisfies the following conditions:</p> <p>(1) It is either a single solid piece or is contained in a sealed capsule that can be opened only by destroying the capsule;</p> <p>(2) The piece or capsule has at least one dimension not less than 5 mm (0.2 in); and</p> <p>(3) It satisfies the requirements of §71.75. A special form</p>			

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				<p>encapsulation designed in accordance with the requirements of § 71.4 in effect on June 30, 1983 (see 10 CFR part 71, revised as of January 1, 1983), and constructed before July 1, 1985; a special form encapsulation designed in accordance with the requirements of § 71.4 in effect on March 31, 1996 (see 10 CFR part 71, revised as of January 1, 1996), and constructed before April 1, 1998; and special form material that was successfully tested before September 10, 2015 in accordance with the requirements of § 71.75(d) of this section in effect before September 10, 2015 may continue to be used. Any other special form encapsulation must meet the specifications of this definition.</p>			
§ 71.4 Revised	Definition: Uranium – natural, depleted, enriched	.0316	[B]	<p>In § 71.4, revise the definition of “Uranium—natural, depleted, enriched” to read as follows: <i>Uranium – natural, depleted, enriched.</i> (1) Natural uranium means uranium (which may be chemically</p>			

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				<p>separated) with the naturally occurring distribution of uranium isotopes (approximately 0.711 weight percent uranium-235 and the remainder by weight essentially uranium-238).</p> <p>(2) Depleted uranium means uranium containing less uranium-235 than the naturally occurring distribution of uranium isotopes.</p> <p>(3) Enriched uranium means uranium containing more uranium-235 than the naturally occurring distribution of uranium isotopes.</p>			
§ 71.6 Revised	Information Collection Requirements: OMB Approval	N/A	D	<p>In § 71.6, revise paragraph (b) to read as follows:</p> <p>(b) The approved information collection requirements contained in this part appear in §§ 71.5, 71.7, 71.9, 71.12, 71.17, 71.19, 71.22, 71.23, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.47, 71.85, 71.87, 71.89, 71.91, 71.93, 71.95, 71.97, 71.101, 71.103, 71.105, 71.106, 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, 71.125, 71.127, 71.129, 71.131, 71.133, 71.135, 71.137, and appendix A, paragraph II.</p>			

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§ 71.14(a)(1) – (a)(3) Revised, New	Exemption for low-level materials	.0316	[B]	<p>In § 71.14, revise paragraphs (a)(1) and (2), and add paragraph (a)(3) to read as follows:</p> <p>(a) * * *</p> <p>(1) Natural material and ores containing naturally occurring radionuclides that are either in their natural state, or have only been processed for purposes other than for the extraction of the radionuclides, and which are not intended to be processed for the use of these radionuclides, provided the activity concentration of the material does not exceed 10 times the applicable radionuclide activity concentration values specified in appendix A, Table A-2, or Table A-3 of this part.</p> <p>(2) Materials for which the activity concentration is not greater than the activity concentration values specified in appendix A, Table A-2, or Table A-3 of this part, or for which the consignment activity is not greater than the limit for an exempt consignment found in appendix A, Table A-2, or Table A-3 of this part.</p>			

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				(3) Non-radioactive solid objects with radioactive substances present on any surfaces in quantities not in excess of the levels cited in the definition of contamination in § 71.4.			
§ 71.15(d) Revised	Exemption from classification as fissile material	.0316	[B]	In § 71.15, revise paragraph (d) to read as follows: (d) Uranium enriched in uranium-235 to a maximum of 1 percent by weight, and with total plutonium and uranium-233 content of up to 1 percent of the mass of uranium-235, provided that the mass of any beryllium, graphite, and hydrogenous material enriched in deuterium constitutes less than 5 percent of the uranium mass, and that the fissile material is distributed homogeneously and does not form a lattice arrangement within the package.			
§ 71.17 Revised, Removal of Brackets on Compatibility Category.	General license: NRC approved package	.0316	B Note: The Compatibility Category for §71.17 has	The Compatibility Category for all of § 71.17 has changed from [B] to B signifying that Agreement States should ensure that they have regulations compatible with this			

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			changed from [B] to B.	<p>section that are collocated with their transportation regulations. In § 71.17, revise paragraph (c) to read as follows:</p> <p>(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package for which a license, certificate of compliance (CoC), or other approval has been issued by the NRC.</p> <p>(b) This general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the provisions of subpart H of this part.</p> <p>(c) Each licensee issued a general license under paragraph (a) of this section shall—</p> <p>(1) Maintain a copy of the Certificate of Compliance, or other approval of the package, and the drawings and other documents referenced in the approval relating to the use and maintenance of the packaging and to the actions to be taken before shipment;</p>			

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				<p>(2) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of subparts A, G, and H of this part; and</p> <p>(3) Submit in writing before the first use of the package to: ATTN: Document Control Desk, Director, Division of Spent Fuel Storage and Transportation, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in § 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.</p> <p>(d) This general license applies only when the package approval authorizes use of the package under this general license.</p> <p>(e) For a Type B or fissile material package, the design of which was approved by NRC before April 1, 1996, the general license is subject to the additional restrictions of § 71.19.</p>			

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§ 71.19 Revised	Previously approved package	NA	NRC	<p>In § 71.19, redesignate paragraphs (b) through (e) as paragraphs (a) through (d), and revise newly redesignated paragraph (b)(2) to read as follows:</p> <p>(b) * * *</p> <p>(2) A package used for a shipment to a location outside the United States is subject to multilateral approval as defined in the DOT's regulations at 49 CFR 173.403.</p>			
§ 71.21 Revised, Removal of Brackets on Compatibility Category	General license: Use of foreign approved package	.0316	<p>B</p> <p>Note: The Compatibility Category for §71.21 has changed from [B] to B.</p>	<p>The Compatibility Category for all of § 71.21 has changed from [B] to B signifying that Agreement States should ensure that they have regulations compatible with this section that are collocated with their transportation regulations. In § 71.21, revise paragraphs (a) and (d) to read as follows:</p> <p>(a) A general license is issued to any licensee of the Commission to transport, or to deliver to a carrier for transport, licensed material in a package, the design of which has been approved in a foreign national competent authority</p>			

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				<p>certificate, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.</p> <p>(b) Except as otherwise provided in this section, the general license applies only to a licensee who has a quality assurance program approved by the Commission as satisfying the applicable provisions of subpart H of this part.</p> <p>(c) This general license applies only to shipments made to or from locations outside the United States.</p> <p>(d) Each licensee issued a general license under paragraph (a) of this section shall—</p> <p>(1) Maintain a copy of the applicable certificate, the revalidation, and the drawings and other documents referenced in the certificate, relating to the use and maintenance of the packaging and to the actions to be taken before shipment; and</p> <p>(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of</p>			

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				subparts A, G, and H of this part.			
§ 71.31(b) Revised	Contents of application	NA (Note, .0117 is not being amended at this time. It excludes § 71.31 from incorporation by ref.)	NRC	In § 71.31, paragraph (b), remove the reference “§ 71.13” and add, in its place, the reference “§ 71.19.”			
§ 71.38 Retitled, Revised	Renewal of a certificate of compliance	.0117 (Note, .0117 is not being amended at this time. It excludes § 71.38 from incorporation by ref.)	NRC	Revise § 71.38 to read as follows: § 71.38 Renewal of a certificate of compliance. (a) Except as provided in paragraph (b) of this section, each Certificate of Compliance expires at the end of the day, in the month and year stated in the approval. (b) In any case in which a person, not less than 30 days before the expiration of an existing Certificate of Compliance issued pursuant to the part, has filed an application in proper form for renewal, the			

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				<p>existing Certificate of Compliance for which the renewal application was filed shall not be deemed to have expired until final action on the application for renewal has been taken by the Commission.</p> <p>(c) In applying for renewal of an existing Certificate of Compliance, an applicant may be required to submit a consolidated application that is comprised of as few documents as possible. The consolidated application should incorporate all changes to its certificate, including changes that are incorporated by reference in the existing certificate.</p>			
§ 71.70 New	Incorporations by reference	NA (Note, .0117 is not being amended at this time. It excludes § 71.70 from incorporation by ref.)	NRC	<p>Add § 71.70 to subpart F to read as follows:</p> <p>§ 71.70 Incorporations by reference.</p> <p>(a) The materials listed in this section are incorporated by reference in the corresponding sections noted and made a part of the regulations in part 71. These incorporations by reference were approved by the Director of the Federal Register under 5 U.S.C. 552(a) and 1 CFR part 51. These</p>			

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				<p>materials are incorporated as they exist on the date of the approval. A notice of any changes made to the material incorporated by reference will be published in the Federal Register, and the material must be available to the public. The materials can be examined, by appointment, at the NRC's Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852; telephone: 301-415-7000; email: Library.Resource@nrc.gov. The materials are also available from the sources listed below. All approved material is available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 1-202-741-6030 or go to http://www.archives.gov/federal-register/cfr/ibr-locations.html. (b) International Organization for Standardization, ISO Central Secretariat, Chemin de Blandonnet 8 CP 401, 1214 Vernier, Geneva, Switzerland;</p>			

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				<p>email: <i>central@iso.org</i>; phone: +41 22 749 01 11; Web site: <i>http://www.iso.org</i>.</p> <p>(1) ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods," First Edition (February 15, 1992), incorporation by reference approved for § 71.75(a), is available for purchase from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, 212–642–4900, <i>http://www.ansi.org</i>, or <i>info@ansi.org</i>.</p> <p>(2) ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification," Second Edition (February 15, 1999), incorporation by reference approved for § 71.75(d), is available on <i>http://www.amazon.com</i>.</p>			
§ 71.75 Revised	Qualification of special form radioactive material	NA (Note, .0117 is not being amended at this time. It	NRC	<p>In § 71.75, revise paragraphs (a)(5), (b)(2)(ii), (b)(2)(iii), (d)(1), and (d)(2) to read as follows:</p> <p>(a) * * *</p> <p>(5) A specimen that comprises or simulates radioactive material contained in a sealed capsule</p>			

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		excludes § 71.75 from incorporation by ref.)		<p>need not be subjected to the leaktightness procedure specified in this section, provided it is alternatively subjected to any of the tests prescribed in ISO 9978:1992(E), "Radiation protection—Sealed radioactive sources—Leakage test methods" (incorporated by reference, see § 71.70).</p> <p>(b) * * *</p> <p>(2) * * *</p> <p>(ii) The flat face of the billet must be 25 millimeters (mm) (1 inch) in diameter with the edge rounded off to a radius of 3 mm ± 0.3 mm (0.12 in ± 0.012 in);</p> <p>(iii) The lead must be hardness number 3.5 to 4.5 on the Vickers scale and not more than 25 mm (1 inch) thick, and must cover an area greater than that covered by the specimen;</p> <p>* * * *</p> <p>(d) * * *</p> <p>(1) The impact test and the percussion test of this section, provided that the specimen is:</p> <p>(i) Less than 200 grams and alternatively subjected to the Class 4 impact test prescribed in</p>			

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				<p>ISO 2919:1999(E), "Radiation protection—Sealed radioactive sources—General requirements and classification" (incorporated by reference, see § 71.70); or (ii) Less than 500 grams and alternatively subjected to the Class 5 impact test prescribed in ISO 2919:1999(E), "Radioactive protection—Sealed radioactive sources—General requirements and classification" (incorporated by reference, see § 71.70); and (2) The heat test of this section, provided the specimen is alternatively subjected to the Class 6 temperature test specified in ISO 2919:1999(E), "Radioactive protection—Sealed radioactive sources—General requirements and classification" (incorporated by reference, see § 71.70).</p>			
<p>§71.85(a) – (c) Revised, Compatibility Change</p>	<p>Preliminary determinations</p>	<p>.0316</p>	<p>NRC Note: The Compatibility Category for §71.85(a) – (c) has</p>	<p>In § 71.85, revise paragraphs (a), (b), and (c) to read as follows: (a) The certificate holder shall ascertain that there are no cracks, pinholes, uncontrolled voids, or other defects that could</p>			

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			changed from [B] to NRC.	<p>significantly reduce the effectiveness of the packaging;</p> <p>(b) Where the maximum normal operating pressure will exceed 35 kPa (5 lbf/in²) gauge, the certificate holder shall test the containment system at an internal pressure at least 50 percent higher than the maximum normal operating pressure, to verify the capability of that system to maintain its structural integrity at that pressure;</p> <p>(c) The certificate holder shall conspicuously and durably mark the packaging with its model number, serial number, gross weight, and a package identification number assigned by the NRC. Before applying the model number, the certificate holder shall determine that the packaging has been fabricated in accordance with the design approved by the Commission; and</p>			
§ 71.85(d) New	Preliminary determinations	.0316	B	<p>In § 71.85, add paragraph (d) to read as follows:</p> <p>(d) The licensee shall ascertain that the determinations in</p>			

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				paragraphs (a) through (c) of this section have been made.			
§ 71.91(a) Revised, Compatibility Change	Records	.0316	C Note: The Compatibility Category for § 71.91(a) has changed from D to C.	In § 71.91, in paragraph (a) introductory text, remove the reference “§ 71.10” and add, in its place, the reference “§ 71.14.”			
§ 71.91(b) Compatibility Change	Records	.0316	NRC Note: The Compatibility Category for § 71.91(b) has changed from D to NRC.	The Compatibility Category has changed. b) Each certificate holder shall maintain, for a period of 3 years after the life of the packaging to which they apply, records identifying the packaging by model number, serial number, and date of manufacture.			
§ 71.91(c) and (d) Compatibility Change	Records	.0316	C Note: The Compatibility Category for § 71.91(c) and (d) has	The Compatibility Category has changed. (c) The licensee, certificate holder, and an applicant for a CoC, shall make available to the Commission for inspection, upon reasonable			

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			changed from D to C.	<p>notice, all records required by this part. Records are only valid if stamped, initialed, or signed and dated by authorized personnel, or otherwise authenticated.</p> <p>(d) The licensee, certificate holder, and an applicant for a CoC shall maintain sufficient written records to furnish evidence of the quality of packaging. The records to be maintained include results of the determinations required by § 71.85; design, fabrication, and assembly records; results of reviews, inspections, tests, and audits; results of monitoring work performance and materials analyses; and results of maintenance, modification, and repair activities. Inspection, test, and audit records must identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. These records must be retained for 3 years after the life of the packaging to which they apply.</p>			

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§ 71.101(a) Revised, Compatibility Change	Quality assurance requirements	.0316	<p>C**</p> <p>Note: The Compatibility Category for § 71.101(a) has changed from D or C to only C.</p> <p>** See last page for additional note.</p>	<p>In § 71.101, revise paragraph (a) to read as follows:</p> <p>(a) <i>Purpose.</i> This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. As used in this subpart, “quality assurance” comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements. Each certificate holder and applicant for a package approval is responsible for satisfying the quality assurance requirements that apply to design, fabrication, testing, and modification of</p>			

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				packaging subject to this subpart. Each licensee is responsible for satisfying the quality assurance requirements that apply to its use of a packaging for the shipment of licensed material subject to this subpart.			
§ 71.101(b) and (c)(1) Compatibility Change	Quality assurance requirements	.0316	<p>C**</p> <p>Note: The Compatibility Category for § 71.101(b) and (c)(1) has changed from D or C to only C.</p> <p>** See last page for additional note.</p>	<p>The Compatibility Category has changed.</p> <p>(b) <i>Establishment of program.</i> Each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of §§ 71.101 through 71.137 and satisfying any specific provisions that are applicable to the licensee's activities including procurement of packaging. The licensee, certificate holder, and applicant for a CoC shall execute the applicable criteria in a graded approach to an extent that is commensurate with the quality assurance requirement's importance to safety.</p> <p>(c) <i>Approval of program.</i> (1) Before the use of any package for the shipment of licensed material</p>			

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				<p>subject to this subpart, each licensee shall obtain Commission approval of its quality assurance program. Using an appropriate method listed in § 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied, by submitting the description to: ATTN: Document Control Desk, Director, Division of Spent Fuel Management, Office of Nuclear Material Safety and Safeguards.</p>			
<p>§ 71.101(c)(2) Revised</p>	<p>Quality assurance requirements</p>	<p>NA (Note .0117 is not being amended at this time. It excludes § 71.101(c)(2) from incorporation by ref.)</p>	<p>NRC</p>	<p>In § 71.101, revise paragraphs (c)(2) to read as follows: (c) * * * (2) Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this subpart, each certificate holder, or applicant for a Certificate of Compliance shall obtain Commission approval of its quality assurance program. Each certificate holder or applicant for a</p>			

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				CoC shall, in accordance with § 71.1, file a description of its quality assurance program, including a discussion of which requirements of this subpart are applicable and how they will be satisfied.			
§ 71.101(g) Compatibility Note Revised	Quality assurance requirements	.0316	C** ** See last page for note.	The Compatibility Category note has been revised. (g) Radiography containers. A program for transport container inspection and maintenance limited to radiographic exposure devices, source changers, or packages transporting these devices and meeting the requirements of § 34.31(b) of this chapter or equivalent Agreement State requirement, is deemed to satisfy the requirements of §§ 71.17(b) and 71.101(b).			
§ 71.103(a) Revised, Compatibility Change	Quality assurance organization	.0316	C** Note: The Compatibility Category for § 71.103(a) has changed from	In § 71.103, revise paragraph (a) to read as follows: (a) The licensee, certificate holder, and applicant for a Certificate of Compliance shall be responsible for the establishment and execution of the quality assurance program. The licensee, certificate			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
			D or [C] to only C. ** See last page for additional note.	holder, and applicant for a Certificate of Compliance may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part of the quality assurance program, but shall retain responsibility for the program. These activities include performing the functions associated with attaining quality objectives and the quality assurance functions.			
§ 71.103(b) Compatibility Note Revised	Quality assurance organization	.0316	C** ** See last page for note.	The Compatibility Category note has been revised. (b) The quality assurance functions are-- (1) Assuring that an appropriate quality assurance program is established and effectively executed; and (2) Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 71.106 New	Changes to quality assurance program	.0316	C	<p>Add § 71.106 to subpart H to read as follows:</p> <p>§ 71.106 Changes to quality assurance program.</p> <p>(a) Each quality assurance program approval holder shall submit, in accordance with § 71.1(a), a description of a proposed change to its NRC-approved quality assurance program that will reduce commitments in the program description as approved by the NRC. The quality assurance program approval holder shall not implement the change before receiving NRC approval.</p> <p>(1) The description of a proposed change to the NRC-approved quality assurance program must identify the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the applicable requirements of subpart H of this part.</p> <p>(2) [Reserved]</p> <p>(b) Each quality assurance program approval holder may change a previously approved</p>			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				<p>quality assurance program without prior NRC approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC every 24 months, in accordance with § 71.1(a). In addition to quality assurance program changes involving administrative improvements and clarifications, spelling corrections, and non-substantive changes to punctuation or editorial items, the following changes are not considered reductions in commitment:</p> <p>(1) The use of a quality assurance standard approved by the NRC that is more recent than the quality assurance standard in the certificate holder's or applicant's current quality assurance program at the time of the change;</p> <p>(2) The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text,</p>			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				<p>rather than specific titles, provided that there is no substantive change to either the functions of the position or reporting responsibilities;</p> <p>(3) The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or alternatively, the use of descriptive text, provided that there is no substantive change to the functional relationships, authorities, or responsibilities;</p> <p>(4) The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the quality assurance program approval holder has committed to on record; and</p> <p>(5) Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.</p>			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(c) Each quality assurance program approval holder shall maintain records of quality assurance program changes.			
§ 71.135 Revised, Compatibility Change	Quality assurance records	.0316	<p>C**</p> <p>Note: The Compatibility Category for § 71.135 has changed from D or C to only C.</p> <p>** See last page for additional note.</p>	<p>Revise § 71.135 to read as follows:</p> <p>The licensee, certificate holder, and applicant for a Certificate of Compliance shall maintain sufficient written records to describe the activities affecting quality. These records must include changes to the quality assurance program as required by § 71.106, the instructions, procedures, and drawings required by § 71.111 to prescribe quality assurance activities, and closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures that establish a records retention program that is consistent with applicable regulations and designates factors such as duration, location, and assigned responsibility. The licensee, certificate holder, and</p>			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				<p>applicant for a Certificate of Compliance shall retain these records for 3 years beyond the date when the licensee, certificate holder, and applicant for a Certificate of Compliance last engage in the activity for which the quality assurance program was developed. If any portion of the quality assurance program, written procedures or instructions is superseded, the licensee, certificate holder, and applicant for a Certificate of Compliance shall retain the superseded material for 3 years after it is superseded.</p>			
Appendix A Revised	Determination of A1 and A2	.0316	[B]	<p>In appendix A to part 71, revise paragraphs IV.a. and IV.b., redesignate paragraphs IV.c. through IV.f. as paragraphs IV.d. through IV.g., add new paragraph IV.c., revise newly redesignated paragraphs IV.d. through IV.g., redesignate paragraph V. as paragraph V.a., and add new paragraph V.b..</p> <p>Revisions detailed below under "Appendix A to Part 71 – Determination of A1 and A2."</p>			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
Appendix A, Table A-1 Revised	A1 and A2 Values for Radionuclides	.0316	[B]	<p>In Table A-1 of Appendix A, add an entry for Kr-79 in alphanumeric order; revise the entries for Cf 252, Ir-192, Kr-81, and Mo 99; revise footnotes a and c; remove footnote h; and redesignate footnote i as footnote h.</p> <p>Revisions detailed below under "Table A-1—A1 and A2 VALUES FOR RADIONUCLIDES."</p>			
Appendix A, Table A-2 Revised	Exempt Material Activity Concentrations and Exempt Consignment Activity Limits for Radionuclides.	.0316	[B]	<p>In Table A-2 of Appendix A, add the entry for Kr-79 in alphanumeric order, revise the entries for Kr 81 and Te 121m, and revise footnote b.</p> <p>Revisions detailed below under "Table A-2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES."</p>			
Appendix A, Table A-3 Revised	General Values for A1 and A2	.0316	[B]	<p>In Table A-3 of Appendix A, revise the second and third</p>			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				<p>entries and add a new footnote a.</p> <p>Revisions detailed below under "TABLE A-3—GENERAL VALUES FOR A1 and A2."</p>			

** Note: §71.101(g) indicates that QA programs for industrial radiography Type B package users are covered by §34.31(b). It also indicated that this section satisfies §71.17(b) and therefore will satisfy those sections referenced in this provision (§§71.101 through 71.137).

Appendix A to Part 71 – Determination of A₁ and A₂

* * * * *

IV. * * *

a. For special form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} \leq 1$$

where B(i) is the activity of radionuclide i in special form, and A₁(i) is the A₁ value for radionuclide i.

b. For normal form radioactive material, the maximum quantity transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_2(i)} \leq 1$$

where B(i) is the activity of radionuclide i in normal form, and A₂(i) is the A₂ value for radionuclide i.

c. If the package contains both special and normal form radioactive material, the activity that may be transported in a Type A package is as follows:

$$\sum_i \frac{B(i)}{A_1(i)} + \sum_j \frac{C(j)}{A_2(j)} \leq 1$$

where B(i) is the activity of radionuclide i as special form radioactive material, A₁(i) is the A₁ value for radionuclide i, C(j) is the activity of radionuclide j as normal form radioactive material, and A₂(j) is the A₂ value for radionuclide j.

d. Alternatively, the A₁ value for mixtures of special form material may be determined as follows:

$$A_1 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_1(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and A₁(i) is the appropriate A₁ value for radionuclide i.

e. Alternatively, the A₂ value for mixtures of normal form material may be determined as follows:

$$A_2 \text{ for mixture} = \frac{1}{\sum_i \frac{f(i)}{A_2(i)}}$$

where f(i) is the fraction of activity for radionuclide i in the mixture and A₂(i) is the appropriate A₂ value for radionuclide i.

f. The exempt activity concentration for mixtures of nuclides may be determined as follows:

$$\text{Exempt activity concentration for mixture} = \frac{1}{\sum_i \frac{f(i)}{[A](i)}}$$

where f(i) is the fraction of activity concentration of radionuclide i in the mixture and [A](i) is the activity concentration for exempt material containing radionuclide i.

g. The activity limit for an exempt consignment for mixtures of radionuclides may be determined as follows:

$$\text{Exempt consignment activity limit for mixture} = \frac{1}{\sum_i \frac{f(i)}{A(i)}}$$

where f(i) is the fraction of activity of radionuclide i in the mixture and A(i) is the activity limit for exempt consignments for radionuclide i.

V. * * *

b. When the identity of each radionuclide is known but the individual activities of some of the radionuclides are not known, the radionuclides may be grouped and the lowest [A] (activity concentration for exempt material) or A (activity limit for exempt consignment) value, as appropriate, for the radionuclides in each group may be used in applying the formulas in paragraph IV of this appendix. Groups may be based on the total alpha activity and the total beta/gamma activity when these are known, using the lowest [A] or A values for the alpha emitters and beta/gamma emitters, respectively.

* * * * *

Table A-1—A1 and A2 VALUES FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	A ₁ (TBq)	A ₁ (Ci) ^b	A ₂ (TBq)	A ₂ (Ci) ^b	Specific activity	
						(TBq/g)	(Ci/g)
*	*	*		*	*	*	*
Cf-252		1.0x10 ⁻¹	2.7	3.0x10 ⁻³	8.1x10 ⁻²	2.0x10 ¹	5.4x10 ²
*	*	*		*	*	*	*
Ir-192		^c 1.0	^c 2.7x10 ¹	6.0x10 ⁻¹	1.6x10 ¹	3.4x10 ²	9.2x10 ³
*	*	*		*	*	*	*
Kr-79	Krypton (36)	4.0	1.1x10 ²	2.0	5.4x10 ¹	4.2x10 ⁴	1.1x10 ⁶
Kr-81		4.0x10 ¹	1.1x10 ³	4.0x10 ¹	1.1x10 ³	7.8x10 ⁻⁴	2.1x10 ⁻²
*	*	*		*	*	*	*
Mo-99 ^{a h}		1.0	2.7x10 ¹	6.0x10 ⁻¹	1.6x10 ¹	1.8x10 ⁴	4.8x10 ⁵
*	*	*		*	*	*	*

^a A₁ and/or A₂ values include contributions from daughter nuclides with half-lives less than 10 days, as listed in the following:

- | | |
|---------|---------------|
| Mg-28 | Al-28 |
| Ca-47 | Sc-47 |
| Ti-44 | Sc-44 |
| Fe-52 | Mn-52m |
| Fe-60 | Co-60m |
| Zn-69m | Zn-69 |
| Ge-68 | Ga-68 |
| Rb-83 | Kr-83m |
| Sr-82 | Rb-82 |
| Sr-90 | Y-90 |
| Sr-91 | Y-91m |
| Sr-92 | Y-92 |
| Y-87 | Sr-87m |
| Zr-95 | Nb-95m |
| Zr-97 | Nb-97m, Nb-97 |
| Mo-99 | Tc-99m |
| Tc-95m | Tc-95 |
| Tc-96m | Tc-96 |
| Ru-103 | Rh-103m |
| Ru-106 | Rh-106 |
| Pd-103 | Rh-103m |
| Ag-108m | Ag-108 |
| Ag-110m | Ag-110 |
| Cd-115 | In-115m |
| In-114m | In-114 |
| Sn-113 | In-113m |
| Sn-121m | Sn-121 |
| Sn-126 | Sb-126m |
| Te-127m | Te-127 |
| Te-129m | Te-129 |
| Te-131m | Te-131 |
| Te-132 | I-132 |
| I-135 | Xe-135m |

Xe-122	I-122
Cs-137	Ba-137m
Ba-131	Cs-131
Ba-140	La-140
Ce-144	Pr-144m, Pr-144
Pm-148m	Pm-148
Gd-146	Eu-146
Dy-166	Ho-166
Hf-172	Lu-172
W-178	Ta-178
W-188	Re-188
Re-189	Os-189m
Os-194	Ir-194
Ir-189	Os-189m
Pt-188	Ir-188
Hg-194	Au-194
Hg-195m	Hg-195
Pb-210	Bi-210
Pb-212	Bi-212, Tl-208, Po-212
Bi-210m	Tl-206
Bi-212	Tl-208, Po-212
At-211	Po-211
Rn-222	Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Po-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Ra-225	Ac-225, Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ra-226	Rn-222, Po-218, Pb-214, At-218, Bi-214, Po-214
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Tl-209, Po-213, Pb-209
Ac-227	Fr-223
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212
Th-234	Pa-234m, Pa-234
Pa-230	Ac-226, Th-226, Fr-222, Ra-222, Rn-218, Po-214
U-230	Th-226, Ra-222, Rn-218, Po-214
U-235	Th-231
Pu-241	U-237
Pu-244	U-240, Np-240m
Am-242m	Am-242, Np-238
Am-243	Np-239
Cm-247	Pu-243
Bk-249	Am-245
Cf-253	Cm-249
* * * * *	

^c The activity of Ir-192 in special form may be determined from a measurement of the rate of decay or a measurement of the radiation level at a prescribed distance from the source.

* * * * *

^h A₂ = 0.74 TBq (20 Ci) for Mo-99 for domestic use.

* * * * *

Table A-2—EXEMPT MATERIAL ACTIVITY CONCENTRATIONS AND EXEMPT CONSIGNMENT ACTIVITY LIMITS FOR RADIONUCLIDES

Symbol of radionuclide	Element and atomic number	Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limit for exempt consignment (Bq)	Activity limit for exempt consignment (Ci)
*	*	*	**	*	*
Kr-79	Krypton (36)	1.0x10 ³	2.7x10 ⁻⁸	1.0x10 ⁵	2.7x10 ⁻⁶
Kr-81		1.0x10 ⁴	2.7x10 ⁻⁷	1.0x10 ⁷	2.7x10 ⁻⁴
*	*	*	**	*	*
Te-121m		1.0x10 ²	2.7x10 ⁻⁹	1.0x10 ⁶	2.7x10 ⁻⁵
*	*	*	**	*	*

* * * * *

^b Parent nuclides and their progeny included in secular equilibrium are listed as follows:

- Sr-90 Y-90
- Zr-93 Nb-93m
- Zr-97 Nb-97
- Ru-106 Rh-106
- Ag-108m Ag-108
- Cs-137 Ba-137m
- Ce-144 Pr-144
- Ba-140 La-140
- Bi-212 Tl-208 (0.36), Po-212 (0.64)
- Pb-210 Bi-210, Po-210
- Pb-212 Bi-212, Tl-208 (0.36), Po-212 (0.64)
- Rn-222 Po-218, Pb-214, Bi-214, Po-214
- Ra-223 Rn-219, Po-215, Pb-211, Bi-211, Tl-207
- Ra-224 Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
- Ra-226 Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
- Ra-228 Ac-228
- Th-228 Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212(0.64)
- Th-229 Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
- Th-nat Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
- Th-234 Pa-234m
- U-230 Th-226, Ra-222, Rn-218, Po-214
- U-232 Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
- U-235 Th-231
- U-238 Th-234, Pa-234m
- U-nat Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
- Np-237 Pa-233
- Am-242m Am-242
- Am-243 Np-239

* * * * *

TABLE A-3—GENERAL VALUES FOR A1 and A2

Contents	A ₁		A ₂		Activity concentration for exempt material (Bq/g)	Activity concentration for exempt material (Ci/g)	Activity limits for exempt consignments (Bq)	Activity limits for exempt consignments (Ci)
	(TBq)	(Ci)	(TBq)	(Ci)				
*		*	*	*	*	*		*
Alpha emitting nuclides, but no neutron emitters, are known to be present ^a	2x10 ⁻¹	5.4x10 ⁰	9x10 ⁻⁵	2.4x10 ⁻³	1x10 ⁻¹	2.7x10 ⁻¹²	1x10 ³	2.7x10 ⁻⁸
Neutron emitting nuclides are known to be present or no relevant data are available	1x10 ⁻³	2.7x10 ⁻²	9x10 ⁻⁵	2.4x10 ⁻³	1x10 ⁻¹	2.7x10 ⁻¹²	1x10 ³	2.7x10 ⁻⁸

^a If beta or gamma emitting nuclides are known to be present, the A₁ value of 0.1 TBq (2.7 Ci) should be used.

* * * * *