



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 15, 2017

ALL AGREEMENT STATES, VERMONT, WYOMING

CLARIFICATION OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS* PART 71
REQUIREMENTS IDENTIFIED IN REGULATION AMENDMENT TRACKING SYSTEM
IDENTIFICATION NUMBER RATS ID 2015-3 (STC-17-060)

Purpose: To clarify the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71 regarding the Agreement States' authority to review their general licensees' quality assurance programs for the use of U.S. Nuclear Regulatory Commission (NRC) approved packaging for transportation of radioactive material. As this communication describes clarifications to existing regulations, a response is not required.

Background: On June 12, 2015, the NRC published the final rule, "Revisions to Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements" (80 FR 33987). The Agreement States were notified of this rulemaking in State and Tribal Communications Letter 15-044, dated June 23, 2015, "Revision Of The Chronology Of The U.S. Nuclear Regulatory Commission Amendments Including Summary of Change Document for Revisions To Transportation Safety Requirements and Harmonization with International Atomic Energy Agency Transportation Requirements, 10 CFR Part 71 [RATS ID 2015-3]." As stated in the *Federal Register* notice for the final rule, "The NRC's final rule revises 10 CFR Part 71 to: (1) update administrative procedures for the quality assurance program requirements described in subpart H of 10 CFR Part 71; (2) re-establish restrictions on material that qualifies for the fissile material exemption; (3) clarify the requirements for a general license; (4) clarify the responsibilities of certificate holders and licensees when making preliminary safety determinations on packaging to be used for transporting radioactive material; and (5) make editorial changes." The Agreement States were given three years to adopt compatible requirements.

Discussion: Recently, as some of the Agreement States were in the process of submitting their proposed regulations to incorporate RATS ID 2015-3 for a NRC compatibility review, the Office of Nuclear Material Safety and Safeguards staff received questions regarding the Agreement States' authority and responsibilities required by 71.17 and 71.101(c) for approving general licensees' quality assurance programs.

While the revisions made to these sections during the 2015 rulemaking appear to place additional responsibilities on the Agreement States, these provisions have been codified in the NRC's regulations since 2004 (69 FR 3786). As noted on page 3781 of this FR, Section VI, Issues of Compatibility for Agreement States, for 71.101, the comment in the Table stated, "Paragraphs (a), (b) and (c)(1) are designated Category C and the essential objectives of these provisions should be adopted by those Agreement States which have licensees who use Type B packages. The essential objective of paragraph (c)(1) is that each licensee who uses a Type B

package shall, prior to the use of any package for the shipment of any material subject to this part, obtain approval of its quality assurance program by the *regulatory agency*.”

This issue may have come to light during the 2015 rulemaking due to the following: 1) the 2015 rulemaking changed the Compatibility Category designation of 71.17 from a [B] to a B which now requires these regulations to be co-located with the Agreement States’ transportation regulations. The Agreement States may have had these regulations in their States’ DOT regulations in the past, and therefore were not fully aware of this requirement; 2) the regulations in 71.101(c)(1) went from a D or C designation to only a C designation in this rulemaking, now requiring all Agreement States to have compatible regulations. Previously, Agreement States were required to adopt compatible regulations only if they had users of Type B packages other than industrial radiography. However, States without users of Type B packages could ask for an exemption from these requirements in accordance with 80 FR 34009; and 3) NRC compatibility reviews of the Agreement States’ equivalent regulations incorporating RATS ID 2004-1 may not have identified these issues.

The Standing Committee on Compatibility (SCC) met on July 12, 2017, to deliberate this issue. The SCC agreed that the Agreement States are the regulatory authority and should approve licensee’s quality assurance programs. The SCC recommended that guidance be issued to the Agreement States to clarify these requirements. Accordingly, the NRC staff has prepared the enclosed guidance.

In addition, specific guidance on reviewing Quality Assurance Programs can be found in [Regulatory Guide 7.10](#). We also intend to present webinar training on this topic in September 2017. A Radiation Control Program Directors letter will be sent with information for this webinar at a later date.

We note that some Agreement States have submitted their final regulations to RATS ID 2015-3 prior to our recognition and clarification of these issues. In those cases, we encourage those States to review and revise their final regulations, if applicable, to make the identified clarifications regarding the approval authority and agency contact information for the required submittals, and submit the revised final regulations for NRC review, or to request an exemption to the requirements if they have no users of Type B packages, other than industrial radiography. The regulations amended by RATS ID 2015-3 are due for adoption by the Agreement States no later than July 13, 2018. To allow sufficient time for Agreement States to make clarifying revisions and implement the program element, the Agreement States are given three years to adopt compatible requirements in RATS ID 2015-3 from the date of this letter, or August 15, 2020.

If you have any questions on this correspondence, please contact me at (301) 415-3340 or the individuals named below:

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Enclosure:
As stated

/RA Kevin Williams for/

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SUBJECT: CLARIFICATION OF TITLE 10 OF THE *CODE OF FEDERAL REGULATIONS*
 PART 71 REQUIREMENTS IDENTIFIED IN REGULATION AMENDMENT
 TRACKING SYSTEM IDENTIFICATION NUMBER (RATS ID) 2015-3
 (STC-17-060)

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**CLARIFICATION GUIDANCE ON 10 CFR PART 71 REQUIREMENTS
IN RATS ID 2015-3**

GENERAL NOTES: The NRC is the sole authority for package approvals and the issuance of a Certificate of Compliance. The Quality Assurance Programs from the general licensees are approved by either the Agreement State Agency, if they are located in an Agreement State, or the NRC if under NRC jurisdiction. Agreement States that do not have users of Type B packages, other than industrial radiography, can ask for an exemption to the requirements.

10 CFR 71.17

**GENERAL LICENSE: NRC APPROVED PACKAGE
(COMPATIBILITY CATEGORY B)**

In the 2015 final rule, the Compatibility Category designation was changed from a [B] to a B as there are no corresponding DOT regulations. Paragraph (c) was revised to clarify that the general licensee must comply with the requirements in 71.17(c)(1) through (c)(3). As this applies to general licensees in both NRC and Agreement States, the Agreement State should adopt requirements that are essentially identical, but written from their jurisdictional perspective, as follows:

(a) A general license is issued to any licensee of the ~~Commission~~ **State Agency** 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.

(b) This general license applies only to a licensee who has a quality assurance program approved by the ~~Commission~~ **State Agency** as satisfying the provisions of **10 CFR Part 71*** subpart H of this part **OR insert State equivalent regulations***.

(c) Each licensee issued a general license under paragraph (a) of this section shall—

(1) Maintain a copy of the **[State can insert "NRC issued" here to indicate that the NRC is the sole authority for issuing CoCs]** 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;

(2) Comply with the terms and conditions of the license, certificate, or other approval, as applicable, and the applicable requirements of **10 CFR Part 71*** subparts A, G, and H of this part **OR equivalent State regulations***; and

(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.**

(d) This general license applies only when the package approval authorizes use of the package under this general license.

(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.

*The State can adopt NRC regulations by reference OR, if the State has equivalent requirements, they should list those, and not refer to NRC regulations as this would cause a duplication of requirements.

Enclosure

** As discussed in IN 2004-13, Agreement State licensees must notify the NRC in writing before first use of packaging. The reasoning behind this is that the NRC tracks all package users under both NRC and Agreement State jurisdiction in case there is an issue identified by a NRC CoC holder.

**10 CFR 71.21
GENERAL LICENSE: USE OF FOREIGN APPROVED PACKAGE
(COMPATIBILITY CATEGORY B)**

In the 2015 final rule, the Compatibility Category for all of § 71.21 was 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, paragraph (d) was revised to clarify that the general licensee must comply with the requirements in 71.21(d)(1) and (d)(2). Paragraph (d)(2) was revised to require general licensees to comply “with the terms and conditions of the certificate and revalidation...”. As this applies to general licensees in both NRC and Agreement States, the Agreement State should adopt requirements that are essentially identical, but written from their jurisdictional perspective, as follows:

(a) A general license is issued to any licensee of the State Agency 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 certificate, that has been revalidated by the DOT as meeting the applicable requirements of 49 CFR 171.23.

(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 State Agency Commission as satisfying the applicable provisions of 10 CFR Part 71* subpart H of this part OR equivalent State regulations*.

(c) This general license applies only to shipments made to or from locations outside the United States.

(d) Each licensee issued a general license under paragraph (a) of this section shall—

(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

(2) Comply with the terms and conditions of the certificate and revalidation, and with the applicable requirements of 10 CFR Part 71* subparts A, G, and H of this part OR equivalent State regulations*.

*The State can adopt NRC regulations by reference OR if the State has equivalent requirements, they should list those, and not refer to NRC regulations as this would cause a duplication of requirements.

**10 CFR 71.85(a), (b), and (c)
(COMPATIBILITY CATEGORY NRC)
71.85(d)
(COMPATIBILITY CATEGORY B)
PRELIMINARY DETERMINATIONS**

In the 2015 final rule, paragraphs (a), (b), and (c) “licensee” was replaced by “certificate holder.” Paragraph (d) was added to address the responsibilities of licensees using a package for transportation. Although NRC certificate holders are required to make the preliminary determinations in (a), (b), and (c), NRC and Agreement State licensees are responsible for ensuring that these determinations have been made before their first use of the packaging. The Agreement States should adopt requirements that are essentially identical to 71.85(d) as follows:

(d) The licensee shall ascertain that the determinations in 10 CFR 71.85(a) through (c) have been made.

**10 CFR 71.101(a), (b), and (c)(1)
QUALITY ASSURANCE REQUIREMENTS
(COMPATIBILITY CATEGORY C for 71.101(c)(1))**

In the 2015 final rule, the Compatibility Category designation was changed from a D or C to only C. Paragraph (a) was revised by deleting its first reference to licensees in order to clarify that with respect to the design, fabrication, testing, and modification of packaging, only NRC certificate holders and applicants for a CoC are subject to quality assurance requirements. Note that consistent with the existing 71.101(c)(1) QA program approval requirements, under 71.101(a), as revised, licensees are still subject to quality assurance requirements with respect to their use of packages when shipping radioactive material. The Agreement States should have compatible regulations that meet the essential objectives of the NRC regulations, and are written from the State's jurisdictional perspective, as follows:

(a) *Purpose.* 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 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.

(b) *Establishment of program.* 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 **10 CFR Part* 71.101 through 71.137 OR equivalent State regulations*** 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.

(c) *Approval of program.* (1) Before the use of any package for the shipment of licensed material subject to this subpart, each licensee shall obtain **State Agency Commission** approval of its quality assurance program. Using an appropriate method listed in **State should insert their contact requirements**§ 71.1(a), each licensee shall file a description of its quality assurance program, including a discussion of which requirements of this **subpart OR State's applicable term** 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** **Insert State contact information.**

*If the State has equivalent requirements, they should list those, and not refer to NRC regulations as this would cause a duplication of requirements.