

**SECTION 4.
TRANSPORTATION OF RADIOACTIVE MATERIALS**

**PART A.
GENERAL**

RH-3002. **Purpose and Scope. ...**

- d. 1. Exemptions from ~~the requirement for license in RH 3004. Section 4 requirements~~ are specified in ~~RH-3202 Part C of this Section.~~ General licenses for which no NRC package approval is required are issued in RH-3304. through RH-3306. The general license in RH-3301. requires that an NRC ~~e~~Certificate of ~~e~~Compliance or other package approval be issued for the package to be used under this general license.

**PART D.
GENERAL LICENSES**

RH-3301. **General License for NRC-Approved Packages.**

- b. This general license applies only to a licensee who has a quality assurance program approved by the **Department** as satisfying the provisions of **RH-3600, Part G, of this Section** and the provisions of ~~Subpart H of 10 CFR Part 71.~~
- c. This general ~~Each licensee applies only to a licensee who~~ issued a general license under paragraph a. of this section shall:
3. Submit in writing ~~B~~before the licensee's first use of the package; ~~submits in writing~~ to the U.S. Nuclear Regulatory Commission: ATTN: Document Control Desk, Director, Division of Spent Fuel Project Office ~~Storage and Transportation Management~~, Office of Nuclear Material Safety and Safeguards, using an appropriate method listed in 10 CFR 71.1(a), the licensee's name and license number and the package identification number specified in the package approval.

RH-3304. **General License for Use of Foreign Approved Package.**

- 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 **Department** as satisfying the applicable provisions of **RH 3600, Part G, of this Section** and the provisions of ~~Subpart H of 10 CFR Part 71.~~

Red – reflects a return to current rule language

Italics – changes to the proposed rule

Underline/strike-through – already present in proposed rule

RH-3305. **General License: Fissile Material.**

- a. A general license is issued to any licensee of the Department to transport fissile material, or to deliver fissile material to a carrier for transport, if the material is shipped in accordance with this section. The fissile material need not be contained in a package which meets the standards of Part E of *this* Section 4 entitled “~~Package Approval Standards~~” and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).
- b. The general license applies only to a licensee who has a quality assurance program approved by the **Department** as satisfying the provisions of ~~RH-3600, Part G, of this Section~~ and the provisions of ~~Subpart H of 10 CFR Part 71~~.

RH-3306. **General license: Plutonium-Beryllium Special Form Material.**

- a. A general license is issued to any licensee of the Department to transport fissile material in the form of plutonium-beryllium (Pu-Be) special form sealed sources, or to deliver Pu-Be sealed sources to a carrier for transport, if the material is shipped in accordance with this section. This material need not be contained in a package which meets the standards of Part E of *this* Section 4 entitled “~~Package Approval Standards~~” and 10 CFR Part 71, Subparts E and F; however, the material must be contained in a Type A package. The Type A package must also meet the DOT requirements of 49 CFR 173.417(a).
- b. The general license applies only to a licensee who has a quality assurance program approved by the **Department** as satisfying the provisions of ~~RH-3600, Part G, of this Section~~ and the provisions of ~~Subpart H of 10 CFR Part 71~~.

**PART F.
OPERATING CONTROLS AND PROCEDURES**

RH-3506. **Records.**

- ~~d.~~ c. 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 ~~shall include, but not be limited to,~~ results of the determinations required by RH-3502.; **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 three (3) years after the life of the packaging to which they apply.

RH-3508. **Reports.**

~~d. c.~~ **Report legibility.**

The reports submitted by licensees and/or certificate holders under this section must be of sufficient quality to permit reproduction and micrographic processing.

**PART G.
QUALITY ASSURANCE**

RH-3600. **Quality Assurance Requirements.**

a. **Purpose.**

This Part, *in conjunction with Subpart H of 10 CFR Part 71*, 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 Part *and Subpart H of 10 CFR Part 71*, "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. ~~The licensee, Each certificate holder, and applicant for a CoC package approval are is~~ responsible for satisfying the quality assurance requirements *in Subpart H of 10 CFR Part 71 as they that* apply to design, fabrication, testing, and modification of packaging **subject to this Part**. Each *Department* licensee is responsible for satisfying the quality assurance ~~provision~~ requirements ~~which that~~ applies to its use of a packaging for the shipment of licensed material subject to this Part ~~G or the Nuclear Regulatory Commission's~~ Subpart H to Part 71.

b. **Establishment of program.**

Each licensee, ~~certificate holder, and applicant for a CoC~~ **Certificate of Compliance** shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of ~~this Part G,~~ "Quality Assurance," and U.S. Nuclear Regulatory Commission regulations ~~10~~

~~CFR Part 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.

c. **Approval of program.**

Before the use of any package for the shipment of licensed material subject to this Part ~~G~~, each licensee shall obtain **Department** ~~and/or U.S. Nuclear Regulatory Commission~~ approval of its quality assurance program. Using an appropriate method listed in RH 3003.a. (10 CFR Part 71.1(a)), ~~e~~ **Each licensee shall file submit to the Department a description of its quality assurance program, including a discussion of which requirements of this Part G (Subpart H of Part 71) are applicable and how they will be satisfied,** by submitting the description to:

~~Arkansas Department of Health
Radiation Control Section
4815 West Markham Street, Slot 30
Little Rock, Arkansas 72205-3867~~

~~and to the U.S. Nuclear Regulatory Commission:~~

~~ATTN: Document Control Desk, Director, Spent Fuel Project Office,
Office of Nuclear Material Safety and Safeguards.~~

RH-3601. **Quality Assurance Organization.**

- a. The licensee ~~if~~, ~~certificate holder, and applicant for a CoC~~ **Certificate of Compliance** shall be responsible for the establishment and execution of the quality assurance program. The licensee, ~~certificate holder, and applicant for a CoC~~ 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.

RH-3602. **Quality Assurance Program.**

- a. The licensee, ~~certificate holder, and applicant for a CoC~~ **Certificate of Compliance** shall establish, at the earliest practicable time consistent with the schedule for accomplishing the activities, a quality assurance program that complies with the Department requirements found in this Part G,

~~“Quality Assurance,” and U.S. Nuclear Regulatory Commission regulations 10 CFR Part 71.101 through 71.137.~~ The licensee, ~~certificate holder, and applicant for a CoC~~ shall document the quality assurance program by written procedures or instructions and shall carry out the program in accordance with those procedures throughout the period during which the packaging is used. The licensee, ~~certificate holder, and applicant for a CoC~~ shall identify the material and components to be covered by the quality assurance program, the major organizations participating in the program, and the designated functions of these organizations.

- b. The licensee, ~~certificate holder, and applicant for a CoC~~, through its quality assurance program, shall provide control over activities affecting the quality of the identified materials and components to an extent consistent with their importance to safety, and as necessary to assure conformance to the approved design of each individual package used for the shipment of radioactive material. The licensee, ~~certificate holder, and applicant for a CoC~~ shall assure that activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment; suitable environmental conditions for accomplishing the activity, such as adequate cleanliness; and assurance that all prerequisites for the given activity have been satisfied. The licensee, certificate holder, and applicant for a ~~CoC~~ Certificate of Compliance shall take into account, as applicable, the need for special controls, processes, test equipment, tools, and skills to attain the required quality, and the need for verification of quality by inspection and test.
- c. The licensee, certificate holder, and applicant for a CoC shall base the requirements and procedures of ~~its~~ their respective quality assurance programs on the following considerations, as applicable, concerning the complexity and proposed use of the package and its components: ...
- d. The licensee, ~~certificate holder, and applicant for a CoC~~ shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The licensee, ~~certificate holder, and applicant for a CoC~~ shall review the status and adequacy of the quality assurance program at established intervals. Management of other organizations participating in the quality assurance program shall review regularly the status and adequacy of that part of the quality assurance program they are executing.
- e. **Changes to quality assurance program.**

1. Each quality assurance program approval holder shall submit to the U.S. Nuclear Regulatory Commission Department, in accordance

with 10 CFR 71.1(a), a description of a proposed change to its NRC Department-approved quality assurance program that will reduce commitments in the program description as approved by the NRC Department. The quality assurance program approval holder shall not implement the change before receiving NRC Department approval.

A. The description of a proposed change to the NRC Department-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 10 CFR Part 71 this Part.

B. Reserved.

2. Each quality assurance program approval holder may change a previously approved quality assurance program without prior NRC Department approval, if the change does not reduce the commitments in the quality assurance program previously approved by the NRC Department. Changes to the quality assurance program that do not reduce the commitments shall be submitted to the NRC Department every 24 months, ~~in accordance with 10 CFR 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:

A. The use of a quality assurance standard approved by the NRC Department that is more recent than the quality assurance standard in the ~~certificate holder's or applicant's licensee's~~ current quality assurance program at the time of the change; ...

RH-3603. **Handling, Storage, and Shipping Control.**

The licensee, ~~certificate holder, and applicant for a CoC~~ **Certificate of Compliance** shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels must be specified and provided.

RH-3604. **Inspection, Test, and Operating Status.**

- a. The licensee, ~~certificate holder, and applicant for a CoC~~ Certificate of Compliance shall establish measures to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the packaging. These measures must provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of the inspections and tests. ...

RH-3605. **Nonconforming Materials, Parts, or Components.**

The licensee, ~~certificate holder, and applicant for a CoC~~ Certificate of Compliance shall establish measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their inadvertent use or installation. These measures must include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations. Nonconforming items must be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

RH-3606. **Corrective Action.**

The licensee, ~~certificate holder, and applicant for a CoC~~ Certificate of Compliance shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected. In the case of a significant condition adverse to quality, the measures must assure that the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken must be documented and reported to appropriate levels of management.

RH-3607. **Quality Assurance Records.**

The licensee, ~~certificate holder, and applicant for a CoC~~ Certificate of Compliance shall maintain sufficient written records to describe the activities affecting quality. ~~The~~ These records must include changes to the quality assurance program as required by RH-3602.e.; the instructions, procedures, and drawings required by ~~U.S. Nuclear Regulatory Commission regulation~~ 10 CFR 71.111 to prescribe quality assurance activities; and ~~must include~~ closely related specifications such as required qualifications of personnel, procedures, and equipment. The records must include the instructions or procedures ~~which~~ 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 applicant for a CoC~~ shall retain these records for

three (3) years beyond the date when the licensee, ~~certificate holder, and applicant for a CoC~~ last engage_s 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 CoC~~ shall retain the superseded material for three (3) years after it is superseded.

RH-3608. **Audits.**

The licensee, ~~certificate holder, and applicant for a CoC~~ **Certificate of Compliance** shall carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits must be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Audited results must be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, must be taken where indicated.

SECTION 12.
PHYSICAL PROTECTION OF CATEGORY 1 AND
CATEGORY 2 QUANTITIES OF RADIOACTIVE MATERIAL

PART B.
BACKGROUND INVESTIGATIONS AND ACCESS AUTHORIZATION PROGRAM

RH-11027. **Requirements for Criminal History Records Checks of Individuals Granted Unescorted Access to Category 1 or Category 2 Quantities of Radioactive Material.**

c. **Procedures for processing of fingerprint checks.**

1. For the purpose of complying with this Part, licensees shall submit to the U.S. Nuclear Regulatory Commission, Director, Division of Facilities and Security, 11545 Rockville Pike, Rockville, Maryland 20852-2738, ATTN: Criminal History Program, Mail Stop ~~F-03B46M~~ TWB-05 B32M, one completed, legible standard fingerprint card (Form FD-258, ORIMDNRCOOOZ), electronic fingerprint scan or, where practicable, other fingerprint record for each individual requiring unescorted access to category 1 or category 2 quantities of radioactive material. Copies of these forms may be obtained by writing the Office of ~~Information Services~~ the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, by calling ~~1-301-415-7513~~ 1-630-829-9565, or by email to FORMS.Resource@nrc.gov.

Guidance on submitting electronic fingerprints can be found at <https://www.nrc.gov/site-help/e-submittals.html>.

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