216-RICR-40-20-12

TITLE 216 – DEPARTMENT OF HEALTH

CHAPTER 40 – PROFESSIONAL LICENSING AND FACILITY REGULATION

SUBCHAPTER 20 – RADIATION

PART 12 – Packaging and Transportation of Radioactive Material

12.1 Authority

A. This Part is promulgated pursuant to the authority conferred under R.I. Gen. Laws § 23-1.3-5.

B. This Part establishes requirements for packaging, preparation for shipment, and transportation of licensed material.

C. The packaging and transportation of licensed material are also subject to the requirements of other agencies (e.g., the U.S. Department of Transportation, the U.S. Nuclear Regulatory Commission and the U.S. Postal Service) having jurisdiction over means of transport. The requirements of this Part are in addition to, and not in substitution for, other requirements.

D. This Part applies to any licensee authorized by specific or general license issued by the Agency to receive, possess, use or transfer licensed material, if the licensee delivers that material to a carrier for transport, transports the material outside the site of usage as specified in the Agency license, or transports that material on public highways. No provision of this Part authorizes possession of licensed material.

12.2 Incorporated Material

A. Except as provided in this Part, the requirements of 10 C.F.R. Part 71 (2021) are incorporated by reference, not including any further editions or amendments thereof and only to the extent that the provisions therein are not inconsistent with this Part.

B. Postal Service Manual (Domestic Mail Manual), § 124, is incorporated by reference at 39 C.F.R. § 111.1 (2021).

C. Notwithstanding the provisions of § 12.2(A) of this Part, 10 C.F.R. §§ 71.0, 71.1, 71.2, 71.3, 71.8, 71.9, 71.10, 71.11, 71.12, 71.14(b), 71.16, 71.18, 71.19, 71.24, 71.25, 71.31, 71.33, 71.35, 71.37, 71.38, 71.39, 71.41, 71.43, 71.45, 71.51, 71.53, 71.55, 71.57, 71.59, 71.61, 71.63, 71.64, 71.65, 71.70, 71.71, 71.73, 71.74, 71.75, 71.77, 71.85(a) (b) and (c), 71.91(b), 71.93, 71.95, 71.101(c)(1),

(c)(2), (d) and (e), 71.107, 71.109, 71.111, 71.113, 71.115, 71.117, 71.119, 71.121, 71.123, and 71.125 are not incorporated by reference.

D. Effect of incorporation of 10 C.F.R. Part 71. To reconcile differences between this Part and the incorporated sections of 10 C.F.R. Part 71, the following words and phrases shall be substituted for the language in 10 C.F.R. Part 71 as follows:

1. Where the words “NRC,” “Commission,” “Nuclear Regulatory Commission,” “United States Nuclear Regulatory Commission” or “Administrator of the appropriate Regional Office” appear in 10 C.F.R. Part 71, substitute the words Agency except when used in 10 C.F.R. §§ 71.5(b), 71.10, 71.17(c)(3) and (e), 71.85(c), 71.88(a)(4), 71.93(c), 71.95, 71.97(c), (c)(3)(iii), and (f).

2. The terms “certificate of compliance, compliance holder or applicant” apply to the NRC as they are the sole authority for issuing a package Certificate of Compliance.

3. Form RCA-1, “Notice to Employees”, must be posted instead of NRC Form 3 that is specified in 10 C.F.R. Part 71.

12.3 Definitions

A. In addition to the definitions contained in 10 C.F.R. § 71.4, whenever used in this Part, the following terms shall be construed as follows:

1. “Act” means R.I. Gen. Laws Chapter 23-1.3 entitled "Radiation Control."

2. “Agency” means Rhode Island Radiation Control Agency (RCA), Center for Health Facilities Regulation – Radiation Control Program, Rhode Island Department of Health.

12.4 General Provisions

12.4.1 Requirement for License

No person shall transport radioactive material or deliver radioactive material to a carrier for transport except as authorized in a general or specific license issued by the Agency or as exempted in § 12.5 of this Part.

12.4.2 Transportation of Licensed Material

For the purpose of this Part, requirements for transportation of licensed material are defined by 10 C.F.R. § 71.5.

12.5 Exemptions

12.5.1 Exemption of Physicians

For the purpose of this Part, requirements for exemption of physicians are defined by 10 C.F.R. § 71.13.

12.5.2 Exemption for Low-Level Materials

For the purpose of this Part, requirements for exemption for low-level materials are defined by 10 C.F.R. § 71.14(a).

12.5.3 Exemption from Classification as Fissile Material

For the purpose of this Part, requirements for exemption from classification as fissile material are defined by 10 C.F.R. § 71.15.

12.6 General Licenses

12.6.1 NRC-Approved Package

For the purpose of this Part, requirements for a general license for an NRC-approved package are defined by 10 C.F.R. § 71.17.

12.6.2 General license: Use of foreign approved package

For the purpose of this Part, requirements for a general license for use of a foreign approved package are defined by 10 C.F.R. § 71.21.

12.6.3 Fissile Material

For the purpose of this Part, requirements for a general license for fissile material are defined by 10 C.F.R. § 71.22.

12.6.4 Plutonium-Beryllium Special Form Material

For the purpose of this Part, requirements for a general license for plutonium-beryllium special form material are defined by 10 C.F.R. § 71.23.

12.7 External Radiation Standards for All Packages

For the purpose of this Part, requirements for external radiation standards for all packages are defined by 10 C.F.R. § 71.47.

12.8 Operating Controls and Procedures

12.8.1 Applicability of Operating Controls and Procedures

For the purpose of this Part, requirements for applicability of operating controls and procedures are defined by 10 C.F.R. § 71.81.

12.8.2 Assumptions as to Unknown Properties

For the purpose of this Part, requirements for assumptions as to unknown properties are defined by 10 C.F.R. § 71.83.

12.8.3 Preliminary Determinations

For the purpose of this Part, requirements for preliminary determinations are defined by 10 C.F.R. § 71.85(d).

12.8.4 Routine Determinations

For the purpose of this Part, requirements for routine determinations are defined by 10 C.F.R. § 71.87.

12.8.5 Air Transport of Plutonium

For the purpose of this Part, requirements for air transport of plutonium are defined by 10 C.F.R. § 71.88.

12.8.6 Opening Instructions

For the purpose of this Part, requirements for opening instructions are defined by 10 C.F.R. § 71.89.

12.8.7 Shipment Records

For the purpose of this Part, requirements for shipment records are defined by 10 C.F.R. §§ 71.91(a), (c) and (d).

12.8.8 Shipment Reports

A. The licensee, after requesting the certificate holder's input, shall submit a written report to the Agency of:

1. Instances in which there is significant reduction in the effectiveness of any NRC-approved Type B or Type AF packaging during use;

2. Details of any defects with safety significance in any NRC-approved Type B or fissile material packaging after first use;

3. Instances in which the conditions of approval in the certificate of compliance were not observed in making a shipment.

B. The licensee shall submit a written report to the Agency of instances in which the conditions in the certificate of compliance were not followed during a shipment.

C. Each licensee shall submit a written report required by §§ 12.8.8(A) or (B) of this Part within sixty (60) days of the event or discovery of the event. The licensee shall also provide a copy of each report submitted to the Agency to the applicable certificate holder. Written reports prepared under other Regulations may be

submitted to fulfill this requirement if the reports contain all the necessary information, and the appropriate distribution is made. These written reports must include the following:

1. A brief abstract describing the major occurrences during the event, including all component or system failures that contributed to the event and significant corrective action taken or planned to prevent recurrence.

2. A clear, specific, narrative description of the event that occurred so that knowledgeable readers conversant with the requirements of 10 C.F.R. Part 71, but not familiar with the design of the packaging, can understand the complete event. The narrative description must include the following specific information as appropriate for the particular event:

    a. Status of components or systems that were inoperable at the start of the event and that contributed to the event;

    b. Dates and approximate times of occurrences;

    c. The cause of each component or system failure or personnel error, if known;

    d. The failure mode, mechanism, and effect of each failed component, if known;

    e. A list of systems or secondary functions that were also affected for failures of components with multiple functions;

    f. The method of discovery of each component or system failure or procedural error;

    g. For each human performance-related root cause, a discussion of the cause(s) and circumstances;

    h. The manufacturer and model number (or other identification) of each component that failed during the event; and

    i. For events occurring during use of a packaging, the quantities and chemical and physical form(s) of the package contents.

3. An assessment of the safety consequences and implications of the event. This assessment must include the availability of other systems or components that could have performed the same function as the components and systems that failed during the event.

4. A description of any corrective actions planned as a result of the event, including the means employed to repair any defects, and actions taken to reduce the probability of similar events occurring in the future.

5. Reference to any previous similar events involving the same packaging that are known to the licensee or certificate holder.

6. The name and telephone number of a person within the licensee's organization who is knowledgeable about the event and can provide additional information.

7. The extent of exposure of individuals to radiation or to radioactive materials without identification of individuals by name.

D. The reports submitted by licensees and/or certificate holders under § 12.8.8 of this Part must be of sufficient quality to permit reproduction and micrographic processing.

12.8.9 Advance Notification of Shipment of Irradiated Reactor Fuel and Nuclear Waste

For the purpose of this Part, requirements for advance notification of shipment of irradiated reactor fuel and nuclear waste are defined by 10 C.F.R. § 71.97.

12.9 Quality Assurance

12.9.1 Quality Assurance Requirements

A. Before the use of any package for the shipment of licensed material subject to this Subchapter, each licensee shall obtain Agency approval of its quality assurance program. 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 the Agency.

B. Before the fabrication, testing, or modification of any package for the shipment of licensed material subject to this Subchapter, each certificate holder, or applicant for a Certificate of Compliance (CoC) shall obtain Agency approval of its quality assurance program. Each certificate holder or applicant for a CoC shall file a description of its quality assurance program, including a discussion of which requirements of this Subchapter are applicable and how they will be satisfied.

C. For the purpose of this Part, quality assurance requirements are defined by 10 C.F.R. §§ 71.101(a), (b), (f) and (g).

12.9.2 Quality Assurance Organization

For the purpose of this Part, quality assurance organization requirements are defined by 10 C.F.R. § 71.103.

12.9.3 Quality Assurance Program

For the purpose of this Part, quality assurance program requirements are defined by 10 C.F.R. § 71.105.

12.9.4 Changes to Quality Assurance Program

For the purpose of this Part, requirements for changes to a quality assurance program are defined by 10 C.F.R. § 71.106.

12.9.5 Handling, Storage, and Shipping Control

For the purpose of this Part, requirements for handling, storage, and shipping control are defined by 10 C.F.R. § 71.127.

12.9.6 Inspection, Test, and Operating Status

For the purpose of this Part, requirements for inspection, test, and operating status are defined by 10 C.F.R. § 71.129.

12.9.7 Nonconforming Materials, Parts, or Components

For the purpose of this Part, requirements for nonconforming materials, parts, or components are defined by 10 C.F.R. § 71.131.

12.9.8 Corrective Action

For the purpose of this Part, corrective action requirements are defined by 10 C.F.R. § 71.133.

12.9.9 Quality Assurance Records

For the purpose of this Part, requirements for quality assurance records are defined by 10 C.F.R. § 71.135.

12.9.10 Audits

For the purpose of this Part, requirements for audits are defined by 10 C.F.R. § 71.137.

12.10 Determination of A_1 and A_2

For the purpose of this Part, requirements for determination of A_1 and A_2 are defined by Appendix A to 10 C.F.R. Part 71.

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