RHODE ISLAND GOVERNMENT REGISTER

PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Packaging and Transportation of Radioactive Material (216-RICR-40-20-12)

Rule Identifier: 216-RICR-40-20-12

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: January 24, 2022

Hearing Date: February 7, 2022

End of Public Comment: February 23, 2022

Rulemaking Authority:

R.I. Gen. Laws § 23-1.3-5

Summary of Rulemaking Action:

This is a technical revision to update an incorporation by reference with the most recent version and to correct several internal cross references.

Additional Information and Public Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until February 23, 2022 by contacting the appropriate party at the address listed below:

Paula Pullano

Department of Health

3 Capitol Hill

Room 410

Providence, RI 02908-5097

Paula.Pullano@health.ri.gov

Public Hearing:

A public hearing, in accordance with R.I. Gen. Laws § 42-35-2.5, to consider the proposed amendment shall be held at which time and place all persons interested therein will be heard. This hearing is subject to R.I. Gen. Laws Chapter 42-46, Open Meetings.

Public Hearing Information:

Date: February 7, 2022

Time: 10:00 A.M.

Location: Zoom Link to Come Providence, RI, 02908

The place of the public hearing is accessible to individuals with disabilities. If communication assistance (readers/interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-3395 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting. For questions regarding available parking, please contact the agency staffperson listed above.

Regulatory Analysis Summary and Supporting Documentation:

In development of this rule, consideration was given to:
1)Alternative approaches;

2)Overlap or duplication with other statutory and regulatory provisions; and

3)Significant economic impact on small business
No alternative approach, duplication or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.

For full regulatory analysis or supporting documentation contact the agency staffperson listed above.

STATE OF RHODE ISLAND
RHODE ISLAND DEPARTMENT OF HEALTH
CONCISE STATEMENT OF PROPOSED NON-TECHNICAL AMENDMENTS
(AMENDMENTS TO AN EXISTING REGULATION)

In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-1.7(b)(8), the following is a concise statement of proposed non-technical amendments to Part 1, Part 2, Part 3, Part 4, Part 5, Part 6, Part 7, Part 8, Part 9, Part 10, Part 11, Part 12, Part 13 and Part 15 of 216-RICR-40-20, *Radiation*.

Regulation	**Rationale/Summary of Change**
§ 1.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 20
§ 2.2 (A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 19
§ 3.10(A)(4)	Revised to require submission of RCA Form 2579 in lieu of an equivalent USFDA form which is being phased out.
§ 3.13(C)(1)(c)	Corrects internal cross reference to another section in Part 3
§ 3.13(D)	Corrects internal cross reference to another section in Part 3
§ 3.14(C)	Corrects internal cross reference to another section in Part 3
§ 3.14(D)(1)	Corrects internal cross reference to another section in Part 3
Part 4 (Title)	Title of this Part has been revised to reflect the incorporation of additional requirements regarding fluoroscopically guided interventional procedures. All changes to Part 4 implement the most current revisions to Part F of the Suggested State Regulations for the Control of Radiation (SSRCR) published by the Conference of Radiation Control Program Directors, Inc. (CRCPD).
§ 4.1(B)	Clarifies that use of X-ray equipment must be under the supervision of an individual authorized by and licensed in accordance with applicable provisions of the R.I. Gen. Laws to engage in the healing arts or veterinary medicine
§ 4.1(C) &(D)	Deleted and consolidated with § 4.1(B).
§ 4.1.1(B) &(C)	Added to incorporate two additional documents by reference
§ 4.2(A)(30)	Corrects a spelling error
§ 4.2(A)(92)	"Protective garment" replaces "protective apron" for consistency with other changes
§ 4.3.1(A) and (B)	Specifies that administrative controls must include an effective radiation safety program.
§ 4.3.1(C) to (G)	Reflects the incorporation of additional administrative controls specified in the most current revision to Part F of the SSRCR.
§ 4.3.2(A)	Language added to allow limited operation of noncompliant X-ray equipment after review by a Qualified Medical Physicist

Regulation	Rationale/Summary of Change
§ 4.3.3(C) to (F)	Clarifies required training that must be completed before an individual is allowed to operate fluoroscopic X-ray equipment.
§ 4.3.3(H)	Clarifies required training that must be completed before an individual is allowed to operate dental X-ray equipment.
§ 4.3.4(A)	Clarifies information that has to be readily available to an operator of an X-ray system.
§ 4.3.6(A)	Clarifies safety precautions for individuals (other than patient) who are in the room where an X-ray is being taken.
§ 4.3.7	Deleted to address changes in "best practices".
§ 4.3.9	Clarifies safety precautions when a patient or image receptor must be provided with auxiliary support while an X-ray is being taken.
§ 4.3.10(D)	Deleted and consolidated with other Quality Control requirements in § 4.10.1
§ 4.3.10(E) and (G)	Language revised to reflect the most current revision to Part F of the SSRCR.
§ 4.3.10(F), (H) and (I)	Deleted to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.10(J) and (K)	Language added to reflect the most current revisions to Part F of the SSRCR.
§ 4.3.13	Clarifies retention period for maintenance records and associated information
§ 4.3.14(A)(4)	Removes text which refers to a deleted section.
§ 4.3.14(D)	Clarifies record retention requirements for veterinary X-ray facilities
§ 4.3.15(C)	Language revised to synchronize wording with equivalent requirements in § 5.3.12(E)(1)(b) and 10 C.F.R. 35.3047
§ 4.4.3	Revised to reflect different labeling requirements for systems manufactured before 10 June 2006
§ 4.4.7	Deletes information on dental X-ray systems which has been moved to § 4.14
§ 4.4.10	Clarifies requirements regarding technique factors and kVp accuracy
§ 4.4.13	Clarifies requirements regarding use of calibrated dosimetry systems
§ 4.4.14(F)	Requires information pertaining to a radiation medical event be maintained as part of a patient's permanent medical record
§ 4.5.2	Language revised for consistency with other sections of this Part
§ 4.5.3	Clarifies training required before an individual can operate fluoroscopy equipment
§ 4.5.6	Language revised for consistency with other sections of this Part
§ 4.5.7	Language revised to reflect the most current revisions to Part F of the SSRCR.
§ 4.5.11	Deleted to reflect the most current revisions to Part F of the SSRCR.

Regulation	Rationale/Summary of Change
§ 4.5.12	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.5.13	Language added to reflect the most current revisions to Part F of the SSRCR regarding fluoroscopically-guided interventional (FGI) procedures.
§ 4.5.14(B)	Language revised to correct internal cross-reference
§ 4.5.16	Language revised for consistency with other sections of this Part
§ 4.6.1	Clarifies applicability of section to various types of X-ray systems
§ 4.6.2(C)(3)	Language revised to correct internal cross-reference
§ 4.6.2(D)	Clarifies operator protection requirements for veterinary X-ray systems
§ 4.6.3(A)	Removes language that is duplicated in another part of the regulations
§ 4.6.3(C)(4)	Language revised to correct internal cross-reference
§ 4.6.4(G)	Requires use of manual collimation standards when PBL is disabled
§ 4.6.5	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.6	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.6.9	Removes language that is duplicated in another part of the regulations
§ 4.6.11	Removes requirement that is superseded by MQSA standards in § 4.8
§4.6.12(A)(3)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.6.14	Language revised to reflect the most current revisions to Part F of the SSRCR
§4.6.15(A)	Removes requirement that is now included in § 4.14
§4.6.15(C)	Removes requirement that is superseded by MQSA standards in § 4.8
§4.7.1(A)	Language added to reflect the most current revisions to Part F of the SSRCR
§4.7.1(F)&(G)	Language deleted to reflect the most current revisions to Part F of the SSRCR
§ 4.7.3	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.7.5	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.6	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.7	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.7.8	Language added to reflect the most current revisions to Part F of the SSRCR
§ 4.9	Language revised to reflect the most current revisions to Part F of the SSRCR

Regulation	Rationale/Summary of Change
§ 4.10	Language revised to consolidate QA/QC requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 4.13	Language revised to reflect the most current revisions to Part F of the SSRCR
§ 4.14	New section added to consolidate all dental X-ray system requirements in a single section to reflect the most current revisions to Part F of the SSRCR
§ 5.3.12(E)(1)(b)	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3045
§ 5.4.2(A)(4)	Language revised to remove obsolete cross-reference to another section of this Subpart
§ 5.4.4	Language added to clarify that "records" refers to "records of surveys"
§§ 5.5.2 & 5.5.3	Synchronize wording with equivalent requirements in 10 C.F.R. 35.3047
§ 5.6.17(F)	Review interval revised to synchronize with equivalent requirements in 10 C.F.R. 35.642
§ 5.6.18(A)	Corrects internal cross-reference to another section of this Part
§ 5.7.1	Corrects internal cross-reference to another section of this Part
§ 5.7.4(B)	Corrects internal cross-reference to another section of this Part
§§ 5.11.11(D) & (H)	Corrects internal cross-references to other sections of this Part
§§ 6.5(D)(1) & (D)(2)	Corrects internal cross-references to other sections of this Part
§ 6.6(A)(1)	Corrects internal cross-reference to another section of this Subchapter
§ 7.2.1(A)	Revises incorporate on by reference date to 2021 to capture updates to 10 C.F.R. § 30.34 published in the Federal Register [83 FR 33046]. This C.F.R. section is already incorporated by reference in § 7.6.3
§ 7.2.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 31
§ 7.2.3(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 32.72 published in the Federal Register [83 FR 33046 & 83 FR 57231]. This C.F.R. section is already incorporated by reference in §§ 7.6.3 and 7.6.16(A).
§ 7.2.3(B)	Corrects typo regarding portions of 10 C.F.R Part 32 that are not being incorporated by reference.
§ 7.2.4(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 33
§ 7.2.5(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 40
§ 7.2.5(B)	Corrects typo regarding portions of 10 C.F.R Part 40 that are not being incorporated by reference.
§ 7.2.6(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 70

Regulation	Rationale/Summary of Change
§ 7.2.6(C)	Incorporates the provisions of 10 C.F.R. § 150.11(b) by reference.
§ 7.4.10	Revises wording for consistency with U.S. Nuclear Regulatory Commission usage.
§ 7.6.7(B)	Language added to further clarify when a license amendment is required
§ 7.6.8	Revise language to remove duplicate reference
§ 7.6.13	Revises paragraph numbering for consistency with other sections in this Part
§ 8.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 37 published in the Federal Register [83 FR 57231]. These 10 C.F.R. Part 37 sections are already incorporated by reference in §§ 8.6.4 and 8.6.6.
§ 8.4.4(B)	Updates mailing address
§ 8.5.9	Adds a specific incorporation by reference citation for reporting of certain events
§ 9.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 35 published in the Federal Register [83 FR 33046, 85 FR 33527 and 85 FR 44685]. These 10 C.F.R. Part 35 sections are already incorporated by reference in §§ 9.3, 9.4.7, 9.5.5, 9.5.10, 9.5.11(A), 9.5.12(A), 9.5.13(A), 9.5.18, 9.6.4, 9.7.2, 9.7.4(A), 9.7.5, 9.8.1, 9.8.4, 9.8.5, 9.8.6, 9.8.7, 9.9.1, 9.9.7, 9.9.9, 9.9.10, 9.10.1, 9.10.2, 9.11.1, 9.11.4, 9.11.15, and 9.11.17.
§ 9.2(B)	Identifies 10 C.F.R. Part 35 amendments published in the Federal Register [83 FR 33046] which are not incorporated by reference.
§ 9.4.3(B)(2)	Implements 83 FR 33046 requirements for training & qualifications of Associate Radiation Safety Officer and Ophthalmic Physicist as part of a radioactive materials license application.
§ 9.4.3(B)(4)	Corrects internal cross-reference to another section of this Subchapter
§ 9.4.5(A)(2)	Clarifies utilization of a Visiting Ophthalmic Physicist without requiring a radioactive materials license amendment [related to 83 FR 33046 amendments].
§ 9.4.5(A)(9) and (A)(10)	Implements 83 FR 33046 requirements for obtaining a radioactive materials license amendment prior to performing certain specified activities.
§ 9.4.6(A)(1) (A)(5) & (A)(6)	Implements 83 FR 33046 requirements for certain notifications that must be submitted to the RI Radiation Control Agency.
§ 9.5.1(A)(2)	Implements a requirement for written management approval to utilize a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments].
§ 9.5.1(B)	Implements 83 FR 33046 requirements for approval of Associate Radiation Safety Officer.
§ 9.5.1(C)	Eliminates unnecessary language [related to 83 FR 33046 amendments].
§ 9.5.1(K)	Implements 83 FR 33046 recordkeeping requirements for approval of Associate Radiation Safety Officer.

Regulation	Rationale/Summary of Change
§ 9.5.4(B)(5)	Implements 83 FR 33046 requirements regarding the contents of a written directive for permanent implant brachytherapy.
§ 9.5.4(B)(6)	Renumbers current § 9.5.4(B)(5) as § 9.5.4(B)(6)
§ 9.5.6 and § 9.5.6(D)	Clarifies utilization of a Visiting Ophthalmic Physicist [related to 83 FR 33046 amendments] and corrects internal cross-reference to other section of this Part
§ 9.5.6(E) & (F)	Renumbers current § 9.5.6(D) and (E) as § 9.5.4(E) and (F) respectively.
§ 9.5.9(A)	Implements 83 FR 33046 requirements regarding the definition of a misadministration.
§ 9.5.9(G)(3)	Implements 85 FR 33527and 85 FR 44685 requirements regarding the use of a social security number to identify an individual in a misadministration report.
§ 9.5.10	Implements 83 FR 33046 requirements regarding training for an Associate Radiation Safety Officer.
§ 9.5.11(B)	Corrects internal cross-reference to another section of this Subchapter
§ 9.5.16(F)(1)	Corrects internal cross-reference to another section of this Part
§ 9.7.4(B), (C) and (D)	Implements 83 FR 33046 recordkeeping requirements regarding elution of radionuclide generators.
§ 9.11.15	Implements 83 FR 33046 requirements regarding full-inspection servicing of teletherapy and gamma stereotactic radiosurgery units.
§ 9.5.19(A)	Clarifies wording to indicate that the dose limits established in § 1.8 are being referenced
§ 9.5.19(B)	Corrects internal cross-reference to another section of this Part
§ 9.6.3(B)	Clarifies rcord maintenance requirement for consistency with § 9.6.2(B)
§ 9.6.8(F)	Clarifies wording regarding detection limit for consistency with other applicable NRC guidance
§ 9.6.8(H)	Corrects internal cross-reference to another section of this Part
§ 9.6.9(E)	Corrects internal cross-reference to another section of this Part
§ 9.7.6(D)	Corrects internal cross-reference to another section of this Subchapter
§ 9.11.6(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.6(A)
§ 9.11.7(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.7(A)
§ 9.11.8(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.8(A)
§ 9.11.9(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.9(A)
§ 9.11.15(B)	Clarifies wording to link recordkeeping requirements with surveys required under § 9.11.15(A)
§ 9.12.1	Header is removed and contents of section are collapsed into § 9.12

Regulation	Rationale/Summary of Change
§ 10.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 34 published in the Federal Register [85 FR 15347]. These 10 C.F.R. Part 34 sections are already incorporated by reference in §§ 10.6.6 and 10.7.7.
§ 10.6.3(C) (2)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(C) (4)	Corrects internal cross-reference to another section of this Part
§ 10.6.3(H)	Corrects internal cross-reference to another section of this Part
§ 10.7.1(A) (7), (8) & (9)	Corrects internal cross-references to other sections of this Part
§ 10.7.10(A)	Corrects internal cross-reference to another section of this Part
§ 10.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 10.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 11.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. Part 39 published in the Federal Register [85 FR 15347]. This 10 C.F.R. Part 39 section is already incorporated by reference in § 11.6.3.
§ 11.7.2(A)(9)	Corrects internal cross-reference to another section of this Part
§ 11.7.3(A)(2)	Corrects internal cross-reference to another section of this Part
§ 12.2(A)	Revises incorporation by reference date to 2021 to capture updates to 10 C.F.R. § 71.97 published in the Federal Register [83 FR 57231]. This C.F.R. section is already incorporated by reference in § 12.8.9.
§ 12.2(B)	Revises incorporation by reference date to 2021 to capture updates to 39 C.F.R. § 111.1
§ 12.2(C)	Identifies an additional subsection of 71 C.F.R. 101 that is not incorporated by reference
§ 12.8.8	Corrects section title for consistency with 10 C.F.R. 71.95
§ 12.9.1	Clarifies that RCA and not NRC is responsible for certificate approval.
§ 13.4.7(A) & (B)	Corrects internal cross-references to another section of this Subchapter
§ 15.5.7(C) (11)(c)	Language added to clarify that Category 3K also includes all other use of unsealed radioactive material not authorized for commercial distribution.

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 (~~2018~~ 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 (~~2018~~ 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) & (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 ~~Records~~ 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), ~~(c)(1),~~ (f) & (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.