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

(FSME-12-068, August, Program, Chronology of Amendments)

August 6, 2012

ALL AGREEMENT STATES

REVISION OF THE CHRONOLOGY OF NUCLEAR REGULATORY COMMISSION (NRC) AMENDMENTS INCLUDING SUMMARY OF CHANGE DOCUMENT FOR REQUIREMENTS FOR DISTRIBUTION OF BYPRODUCT MATERIAL, PARTS 30, 31, 32, 40, and 70 [RATS ID 2012-4] (FSME-12-068)

Purpose: To provide the Agreement States with the Chronology of the U.S. Nuclear Regulatory Commission (NRC) Amendments including the addition, RATS ID 2012-4, Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70 (effective date, October 23, 2012) and the Summary of Change Document.

Background: The NRC is amending its regulations to make requirements for distributors of byproduct material clearer, less prescriptive, and more risk-informed and up to date. NRC is also redefining categories of devices to be used under exemptions, adding explicit provisions regarding the sealed source and device registration process, and adding flexibility to the licensing of users of sealed sources and devices. This action is primarily intended to make licensing processes more efficient and effective. These changes will affect manufacturers and distributors of sources and devices containing byproduct material and future users of some products currently used under a general or specific license.

Discussion: The final rules, published on July 25, 2012, are posted in the *Federal Register* (FR), 77 FR 43666, with an effective date of October 23, 2012, and can be accessed through this website: http://www.gpo.gov/fdsys/pkg/FR-2012-07-25/pdf/2012-17711.pdf. The chronology is enclosed in its entirety and includes RATS ID: 2012-4, as maintained by the Office of Federal and State Materials and Environmental Management Programs (FSME). The chronology is for your use to plan rulemaking actions that are needed to satisfy the compatibility and health and safety category designations of the NRC regulations. This document will also be used by the Integrated Materials Performance Evaluation Program teams during upcoming program reviews.

In addition, a summary of change document for the July 25, 2012, amendments has been enclosed with this letter. These summaries are for your use to identify the changes to the *Code of Federal Regulations* text as well as the compatibility categories associated with the changes. These regulations are due for adoption by the Agreement States no later than October 23, 2015. We request that both proposed regulations and final regulations be provided to us for review in accordance with FSME Procedure SA-201, “Review of State Regulatory Requirements.”

If you have any questions regarding this correspondence, please contact me or the individual named below.

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Enclosures:
1. Chronology of NRC Amendments
2. Summary of Change Document

Chronology of NRC Amendments

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
Safety Requirements for Radiographic Equipment-Part 34	55 FR 843; (1/10/94)	1991-1
ASNT Certification of Radiographers-Part 34	56 FR 11504; (none)	1991-2
Standards for Protection Against Radiation-Part 20	56 FR 23360; 56 FR 61352; 57 FR 38588; 57 FR 57877; 58 FR 67657; 59 FR 41641; 60 FR 20183; (1/1/94)	1991-3
Notification of Incidents-Parts 20, 30, 31, 34, 39, 40, 70	56 FR 64980; (10/15/94)	1991-4
Quality Management Program and Misadministrations-Part 35	56 FR 34104; (1/27/95)	1992-1
Eliminating the Recordkeeping Requirements for Departures from Manufacturer's Instructions-Parts 30,35	57 FR 45566; (none)	1992-2
Decommissioning Recordkeeping and License Termination: Documentation Additions [Restricted areas and spill sites]-Parts 30, 40	58 FR 39628; (1 0/25/96)	1993-1
Licensing and Radiation Safety Requirements for Irradiators-Part 36	58 FR 7715; (7/1/96)	1993-2
Definition of Land Disposal and Waste Site QA Program-Part 61	58 FR 33886; (7/22/96)	1993-3
Self-Guarantee as an Additional Financial Mechanism-Parts 30, 40, 70	58 FR 68726; 59 FR 1618; (none)	1994-1
Uranium Mill Tailings Regulations: Conforming NRC Requirements to EPA Standards - Part 40	59 FR 28220; (7/1/97)	1994-2
Timeliness in Decommissioning Material Facilities-Parts 30, 40, 70	59 FR 36026; (8/15/97)	1994-3
Preparation, Transfer for Commercial Distribution, and Use of Byproduct Material for Medical Use-Parts 30, 32, 35	59 FR 61767; 59 FR 65243; 60 FR 322; (1/1/98)	1995-1
Frequency of Medical Examinations for Use of Respiratory Protection Equipment-Part 20	60 FR 7900; (3/13/98)	1995-2
Low-Level Waste Shipment Manifest Information and Reporting-Parts 20, 61	60 FR 15649; 60 FR 25983; (3/1/98)	1995-3

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Performance Requirements for Radiography Equipment-Part 34	60 FR 28323; (6/30/98)	1995-4
Radiation Protection Requirements: Amended Definitions and Criteria-Parts 19, 20	60 FR 36038; (8/14/98)	1995-5
Clarification of Decommissioning Funding Requirements-Parts 30, 40, 70	60 FR 38235; (11/24/98)	1995-6
Medical Administration of Radiation and Radioactive Materials-Parts 20, 35	60 FR 48623; (10/20/98)	1995-7
10 CFR Part 71: Compatibility with the International Atomic Energy Agency-Part 71	60 FR 50248; 61 FR 28724; (4/1/99)	1996-1
One Time Extension of Certain Byproduct, Source and Special Nuclear Materials Licenses-Parts 30, 40, 70	61 FR 1109; (none)	1996-2
Termination or Transfer of Licensed Activities: Recordkeeping Requirements-Parts 20, 30, 40, 61, 70	61 FR 24669; (6/17/99)	1996-3
Resolution of Dual Regulation of Airborne Effluents of Radioactive Materials; Clean Air Act-Part 20	61 FR 65120; (1/9/00)	1997-1
Recognition of Agreement State Licenses in Areas Under Exclusive Federal Jurisdiction Within an Agreement State-Part 150	62 FR 1662; (2/27/00)	1997-2
Criteria for the Release of Individuals Administered Radioactive Material-Parts 20, 35	62 FR 4120; (5/29/00)	1997-3
Fissile Material Shipments and Exemptions-Part 71	62 FR 5907; (none)	1997-4
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiography Operations-Parts 30, 34, 71, 150	62 FR 28947; (6/27/00)	1997-5
Radiological Criteria for License Termination-Parts 20, 30, 40, 70	62 FR 39057; (8/20/00)	1997-6
Exempt Distribution of a Radioactive Drug Containing One Microcurie of Carbon-14 Urea-Part 30	62 FR 63634; (1/02/01)	1997-7
Deliberate Misconduct by Unlicensed Persons-Parts 30, 40, 61, 70, 71, 150	63 FR 1890; 63 FR 13773; (2/12/01)	1998-1
Self-Guarantee of Decommissioning Funding by Nonprofit and Non-Bond-Issuing Licensees-Parts 30, 40, 70	63 FR 29535; (none)	1998-2
License Term for Medical Use Licenses-Part 35	63 FR 31604; (none)	1998-3
Licenses for Industrial Radiography and Radiation Safety Requirements for Industrial Radiographic Operations-Part 34	63 FR 37059; (7/9/01)	1998-4

NRC Chronology Identification	FR Notice Number (State Implementation Due Date)	RATS ID
Minor Corrections, Clarifying Changes, and a Minor Policy Change-Parts 20, 32, 35, 36 and 39	63 FR 39477; 63 FR 45393; (10/26/01)	1998-5
Transfer for Disposal and Manifests: Minor Technical Conforming Amendment-Part 20	63 FR 50127; (11/20/01)	1998-6
Radiological Criteria for License Termination of Uranium Recovery Facilities-Part 40	64 FR 17506; (6/11/02)	1999-1
Requirements for Those Who Possess Certain Industrial Devices Containing Byproduct Material to Provide Requested Information-Part 31	64 FR 42269; (none)	1999-2
Respiratory Protection and Controls to Restrict Internal Exposure-Part 20	64 FR 54543; 64 FR 55524; (2/2/03)	1999-3
Energy Compensation Sources for Well Logging and Other Regulatory Clarifications-Part 39	65 FR 20337; (5/17/03)	2000-1
New Dosimetry Technology-Parts 34, 36, 39	65 FR 63750; (1/8/04)	2000-2
Requirements for Certain Generally Licensed Industrial Devices Containing Byproduct Material - Parts 30, 31, 32	65 FR 79162; (2/16/04)	2001-1
Revision of the Skin Dose Limit-Part 20	67 FR 16298; (4/5/05)	2002-1
Medical Use of Byproduct Material-Parts 20, 32, and 35	67 FR 20249; (10/24/05)	2002-2
Financial Assurance for Materials Licensees - Parts 30, 40, 70	68 FR 57327; (12/3/06)	2003-1
Compatibility With IAEA Transportation Safety Standards and Other Transportation Safety Amendments - Part 71.	69 FR 3697; (10/01/07)	2004-1
Security Requirements for Portable Gauges Containing Byproduct Material - Part 30	70 FR 2001; (7/11/08)	2005-1
Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35	70 FR 16336; 71 FR 1926 (4/29/08)	2005-2
Increased Controls for Risk-Significant Radioactive Sources (NRC Order EA-05-090)	70 FR 72128 (1 2/01/2005)	2005-3
Minor Amendments -Parts 20, 30,32, 35, 40, 70	71 FR 15005 (03/27/09)	2006-1

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National Source Tracking System - Serialization Requirements Part 32 (with reference to Part 20 Appendix E)	71 FR 65685 (02/06/07)	2006-2
National Source Tracking System Part 20	71 FR 65685 (01/31/09 Cat I and Cat II)	2006-3
Medical Use of Byproduct Material - Minor Corrections and Clarifications Parts 32 and 35	72 FR 45147, 54207 (10/29/10)	2007-1
Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements Parts 30, 31, 32, and 150	72 FR 58473 (12/17/10)	2007-2
Requirements for Expanded Definition of Byproduct Material Parts - 20, 30, 31, 32, 33, 35, 61, and 150	72 FR 55864, 73 FR 42672 (11/30/10)	2007-3
Order Imposing Fingerprinting Requirements and Criminal History Records Check Requirements for Unescorted Access to Certain Radioactive Material (Order EA-07-305)	72 FR 70901 (06/05/08)	2007-4
Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20	72 FR 68043, 72233 (02/15/11)	2008-1
Medical Use of Byproduct Material—Authorized User Clarification, Part 35	74 FR 33901 (09/28/12)	2009-1
Decommissioning Planning, Parts 20, 30, 40, and 70	76 FR 35512 (12/17/2015)	2011-1
Licenses, Certifications, and Approvals for Materials Licensees, Parts 30, 36, 39, 40, 51, 70, and 150	76 FR 56951 (11/14/2014)	2011-2
Change of Compatibility of 10 CFR 31.5 and 31.6 in the Withdrawal of Proposed Rule and Closure of Petition For Rulemaking: Organization of Agreement States and Florida Department of Health, Bureau of Radiation Control	77 FR 3640 (01/25/2015)	2012-1
Advance Notification to Native American Tribes of Transportation of Certain Types of Nuclear Waste – Part 71	77 FR 34194 (08/10/2015)	2012-2

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Technical Corrections – Parts 30, 34, 40, and 71	77 FR 39899 (08/06/2015)	2012-3
Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70	77 FR 43666 (10/23/2015)	2012-4

Requirements for Distribution of Byproduct Material, Parts 30, 31, 32, 40, and 70 (77 FR 43666, Published July 25, 2012) RATS ID: 2012-4 Effective: October 23, 2012 Date Due for State Adoption: October 23, 2015

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
§30.6(b)(1)(iv)	Communications		D	N/A			
§30.8(c)(1)	Information collection requirements: OMB approval		D	N/A			
§30.15(a)(2)	Certain items containing byproduct material		B	**In § 30.15, paragraph (a)(2) is added to read as follows:** (a) * * * (2)(i) Static elimination devices which contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device. (ii) Ion generating tubes designed for ionization of air that contain, as a sealed source or sources, byproduct material consisting of a total of not more than 18.5 MBq (500 µCi) of polonium-210 per device or of a total of not more than 1.85 GBq (50 mCi) of hydrogen-3 (tritium) per device. (iii) Such devices authorized before October 23, 2012 for use			

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				under the general license then provided in § 31.3 and equivalent regulations of Agreement States and manufactured, tested, and labeled by the manufacturer in accordance with the specifications contained in a specific license issued by the Commission.			
§30.19(b)	Self-luminous products containing tritium, krypton-85, or promethium-147		B	**In § 30.19, paragraph (b) is revised to read as follows:** (b) Any person who desires to manufacture, process, or produce, or initially transfer for sale or distribution self-luminous products containing tritium, krypton-85, or promethium-147 for use under paragraph (a) of this section, should apply for a license under § 32.22 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.			
§30.20	Gas and aerosol detectors containing byproduct material		B	**Section 30.20 is revised to read as follows:** (a) Except for persons who			

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				manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, and 30 through 36 and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect health, safety, or property, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007, in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.			

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				(b) Any person who desires to manufacture, process, or produce gas and aerosol detectors containing byproduct material, or to initially transfer such products for use under paragraph (a) of this section, should apply for a license under § 32.26 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.			
§30.22	Certain industrial devices		B	**Section 30.22 is added under the u ndesignated heading Exemptions to read as follows:** (a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material designed and manufactured for the purpose of detecting, measuring, gauging or controlling thickness, density, level, interface location, radiation, leakage, or qualitative or quantitative chemical composition, or for producing an ionized atmosphere, any person is			

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				exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, 21, 30 through 36, and 39 of this chapter to the extent that such person receives, possesses, uses, transfers, owns, or acquires byproduct material, in these certain detecting, measuring, gauging, or controlling devices and certain devices for producing an ionized atmosphere, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under § 32.30 of this chapter, which license authorizes the initial transfer of the device for use under this section. This exemption does not cover sources not incorporated into a device, such as calibration and reference sources. (b) Any person who desires to manufacture, process, produce, or initially transfer for sale or distribution industrial devices containing byproduct material for use under paragraph (a) of this section, should			

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
				apply for a license under § 32.30 of this chapter and for a certificate of registration in accordance with § 32.210 of this chapter.			
§30.32(g)	Application for specific licenses		C	**In ' 30.32, paragraph (g) is revised to read as follows:** **(g)(1)** Except as provided in paragraphs (g)(2), (g)(3), and (g)(4) of this section, an application for a specific license to use byproduct material in the form of a sealed source or in a device that contains the sealed source must either-- (i) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or (ii) Contain the information identified in § 32.210(c) of this chapter.			

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				(2) For sources or devices manufactured before October 23, 2012 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in § 32.210(c) of this chapter, the application must include: (i) All available information identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and (ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test. (3) For sealed sources and devices allowed to be distributed			

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				without registration of safety information in accordance with § 32.210(g)(1) of this chapter, the applicant may supply only the manufacturer, model number, and radionuclide and quantity. (4) If it is not feasible to identify each sealed source and device individually, the applicant may propose constraints on the number and type of sealed sources and devices to be used and the conditions under which they will be used, in lieu of identifying each sealed source and device.			
§30.38	Application for amendment of licenses and registration certificates		D	N/A			
§30.39	Commission action on applications to renew or amend		D	N/A			

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§30.61	Modification and revocation of licenses and registration certificates		D	N/A			
§31.3	Certain devices and equipment		B	**Section 31.3 is removed and reserved**			
§31.23(b)	Criminal penalties		D	N/A			
§32.1(a)	Purpose and scope		D	N/A			
§32.2	Definition: Committed dose		D	N/A			
§32.2	Definition: Sealed source and device registry		D	N/A			
§32.8(b)	Information collection requirements: OMB approval		D	N/A			
§32.14(b)(4) & (b)(5)	Certain items containing byproduct material; requirements for license to apply or initially transfer		NRC	**In § 32.14, paragraphs (b)(4) and (b)(5) are revised to read as follows:** (b) * * * (4) Except for electron tubes and ionization chamber smoke detectors			

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				and timepieces containing promethium-147 or tritium in the form of gaseous tritium light sources, procedures for and results of prototype testing to demonstrate that the byproduct material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product; (5) In the case of ionizing radiation measuring instruments and timepieces containing tritium in the form of paint, quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;			
§ 32.15	Same: Quality assurance, prohibition of transfer, and labeling.		NRC	**In § 32.15, paragraph (c) is removed and reserved and paragraphs (a) and (b) are revised to read as follows:** (a) Each person licensed under			

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				§ 32.14 for products for which quality control procedures are required shall: (1) Maintain quality assurance systems in the manufacture of the part or product, or the installation of the part into the product, in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed products are capable of performing their intended functions; (2) Subject inspection lots to acceptance sampling procedures, by procedures specified in the license issued under § 32.14, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded; and (3) Visually inspect each unit in inspection lots. Any unit which has an observable physical defect that could adversely affect containment of the byproduct material must be considered a defective unit. (b) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an			

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				Agreement State: (1) Any part or product tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective part or product has been repaired or reworked, retested, and found by an independent inspector to meet the applicable acceptance criteria; or (2) Any part or product contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (a)(2) of this section, unless: (i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.14; and (ii) Each individual sub-lot is sampled, tested, and accepted in accordance with the procedures specified in paragraphs (a)(2) and (b)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.14.			

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				(c) [Reserved]			
§32.22(a)(3)	Self-luminous products containing tritium, krypton-85 or promethium-147: Requirements for license to manufacture, process, produce, or initially transfer		NRC	**In § 32.22, paragraph (a)(3) is added to read as follows:** (a) * * * (3)(i) The Commission determines that the product meets the safety criteria in § 32.23; and (ii) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.			
§32.26	Gas and aerosol detectors containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer		NRC	**In § 32.26, the introductory text is revised and paragraph (c) is added to read as follows:** An application for a specific license to manufacture, process, or produce gas and aerosol detectors containing byproduct material and designed to protect health, safety, or property, or to initially transfer such products for use under § 30.20 of this chapter or equivalent regulations of an Agreement State, will be approved if: * * * * * (c)(1) The Commission determines			

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				that the product meets the safety criteria in § 32.27; and (2) The product has been evaluated by the NRC and registered in the Sealed Source and Device Registry.			
§32.30	Certain industrial devices containing byproduct material: Requirements for license to manufacture, process, produce, or initially transfer		NRC	**Section 32.30 is added under subpart A to read as follows:** An application for a specific license to manufacture, process, produce, or initially transfer for sale or distribution devices containing byproduct material for use under § 30.22 of this chapter or equivalent regulations of an Agreement State will be approved if: (a) The applicant satisfies the general requirements of § 30.33 of this chapter: However, the requirements of § 30.33(a)(2) and (a)(3) do not apply to an application for a license to transfer byproduct material in such industrial devices manufactured, processed, or produced under a license issued by an Agreement State;			

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				(b) The applicant submits sufficient information relating to the design, manufacture, prototype testing, quality control procedures, labeling or marking, and conditions of handling, storage, use, and disposal of the industrial devices to demonstrate that the device will meet the safety criteria set forth in § 32.31. The information should include: (1) A description of the device and its intended use or uses; (2) The type and quantity of byproduct material in each unit; (3) Chemical and physical form of the byproduct material in the device and changes in chemical and physical form that may occur during the useful life of the device; (4) Solubility in water and body fluids of the forms of the byproduct material identified in paragraphs (b)(3) and (b)(12) of this section; (5) Details of construction and design of the device as related to containment and shielding of the byproduct material and other safety features under normal and severe			

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				conditions of handling, storage, use, and disposal of the device; (6) Maximum external radiation levels at 5 and 30 centimeters from any external surface of the device, averaged over an area not to exceed 10 square centimeters, and the method of measurement; (7) Degree of access of human beings to the device during normal handling and use; (8) Total quantity of byproduct material expected to be distributed in the devices annually; (9) The expected useful life of the device; (10) The proposed methods of labeling or marking the device and its point-of-sale package to satisfy the requirements of § 32.32(b); (11) Procedures for prototype testing of the device to demonstrate the effectiveness of the containment, shielding, and other safety features under both normal and severe conditions of handling, storage, use, and disposal of the device; (12) Results of the prototype testing of the device, including any			

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				change in the form of the byproduct material contained in the device, the extent to which the byproduct material may be released to the environment, any increase in external radiation levels, and any other changes in safety features; (13) The estimated external radiation doses and committed doses resulting from the intake of byproduct material in any one year relevant to the safety criteria in § 32.31 and the basis for these estimates; (14) A determination that the probabilities with respect to the doses referred to in § 32.31(a)(4) meet the criteria of that paragraph; (15) Quality control procedures to be followed in the fabrication of production lots of the devices and the quality control standards the devices will be required to meet; and (16) Any additional information, including experimental studies and tests, required by the Commission. (c)(1) The Commission determines that the device meets the safety criteria in § 32.31.			

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				(2) The device is unlikely to be routinely used by members of the general public in a non-occupational environment. (3) The device has been registered in the Sealed Source and Device Registry.			
§32.31	Certain industrial devices containing byproduct material: Safety criteria		NRC	**Section 32.31 is added under subpart A to read as follows:** (a) An applicant for a license under § 32.30 shall demonstrate that the device is designed and will be manufactured so that: (1) In normal use, handling, and storage of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, it is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from the device will exceed 200 μSv (20 mrem).			

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				(2) It is unlikely that the external radiation dose in any one year, or the committed dose resulting from the intake of radioactive material in any one year, to a suitable sample of the group of individuals expected to be most highly exposed to radiation or radioactive material from disposal of the quantities of units likely to accumulate in the same disposal site will exceed 10 µSv (1 mrem). (3) It is unlikely that there will be a significant reduction in the effectiveness of the containment, shielding, or other safety features of the device from wear and abuse likely to occur in normal handling and use of the device during its useful life. (4) In use, handling, storage, and disposal of the quantities of exempt units likely to accumulate in one location, including during marketing, distribution, installation, and servicing of the device, the probability is low that the containment, shielding, or other safety features of the device would fail under such circumstances that a person would receive an external radiation dose or committed			

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				dose in excess of 5 mSv (500 mrem), and the probability is negligible that a person would receive an external radiation dose or committed dose of 100 mSv (10 rem) or greater. [1] (b) An applicant for a license under § 32.30 shall demonstrate that, even in unlikely scenarios of misuse, including those resulting in direct exposure to the unshielded source removed from the device for 1,000 hours at an average distance of 1 meter and those resulting in dispersal and subsequent intake of $1\ 0^{-4}$ of the quantity of byproduct material (or in the case of tritium, an intake of 10 percent), a person will not receive an external radiation dose or committed dose in excess of 100 mSv (10 rem), and, if the unshielded source is small enough to fit in a pocket, that the dose to localized areas of skin averaged over areas no larger than 1 square centimeter from carrying the unshielded source in a pocket for 80 hours will not exceed 2 Sv (200 rem).			

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				[1]It is the intent of this paragraph that as the magnitude of the potential dose increases above that permitted under normal conditions, the probability that any individual will receive such a dose must decrease. The probabilities have been expressed in general terms to emphasize the approximate nature of the estimates that are to be made. The following values may be used as guides in estimating compliance with the criteria: Low--not more than one such failure/incident per year for each 10,000 exempt units distributed. Negligible--not more than one such failure/incident per year for each one million exempt units distributed.			
§32.32	Conditions of licenses issued under § 32.30: Quality control, labeling, and reports of transfer		NRC	**Section 32.32 is added under subpart A to read as follows:** Each person licensed under § 32.30 shall: (a) Carry out adequate control procedures in the manufacture of the device to ensure that each production lot meets the quality control standards			

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				approved by the Commission; (b) Label or mark each device and its point-of-sale package so that: (1) Each item has a durable, legible, readily visible label or marking on the external surface of the device containing: (i) The following statement: "CONTAINS RADIOACTIVE MATERIAL"; (ii) The name of the radionuclide(s) and quantity(ies) of activity; (iii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and (iv) Instructions and precautions necessary to assure safe installation, operation, and servicing of the device (documents such as operating and service manuals may be identified in the label and used to provide this information). (2) The external surface of the point-of-sale package has a legible,			

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				readily visible label or marking containing: (i) The name of the radionuclide and quantity of activity; (ii) An identification of the person licensed under § 32.30 to transfer the device for use under § 30.22 of this chapter or equivalent regulations of an Agreement State; and (iii) The following or a substantially similar statement: "THIS DEVICE CONTAINS RADIOACTIVE MATERIAL AND HAS BEEN MANUFACTURED IN COMPLIANCE WITH U.S. NUCLEAR REGULATORY COMMISSION SAFETY CRITERIA IN 10 CFR 32.31. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS." (3) Each device and point-of-sale package contains such other information as may be required by the Commission; and (c) Maintain records of all transfers and file a report with the Director of the Office of Federal and State			

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				Materials and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution. (1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee. (2) The report must indicate that the devices are transferred for use under § 30.22 of this chapter or equivalent regulations of an Agreement State. (3) The report must include the following information on devices transferred to other persons for use under § 30.22 or equivalent regulations of an Agreement State: (i) A description or identification of the type of each device and the model number(s); (ii) For each radionuclide in each type of device and each model number, the total quantity of the radionuclide; and (iii) The number of units of each type of device transferred during			

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
				the reporting period by model number. (4)(i) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. (ii) Licensees who permanently discontinue activities authorized by the license issued under § 32.30 shall file a report for the current calendar year within 30 days after ceasing distribution. (5) If no transfers of byproduct material have been made under § 32.30 during the reporting period, the report must so indicate. (6) The licensee shall maintain the record of a transfer for a period of one year after the transfer is included in a report to the Commission.			
§32.51(a)(6)	Byproduct material contained in devices for use under § 31.5; requirements for license to manufacture, or initially transfer		B	**In § 32.51, paragraph(a)(6) is added to read as follows:** (a) * * * (6) The device has been registered in the Sealed Source and Device Registry.			

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
§32.53(b)(5)	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer		B	**In § 32.53, paragraph (b)(5) is revised as follows:** (b) * * * (5) Quality assurance procedures to be followed that are sufficient to ensure compliance with § 32.55;			
§32.53(d)(4)	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer		B	**In § 32.53, paragraph (d)(4) is revised follows:** (d) * * * (4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (e) of this section.			
§32.53(e)	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer		B	**In § 32.53, paragraph (e) is added to read as follows:** (e) The applicant shall subject at least five prototypes of the device to tests as follows: (1) The devices are subjected to tests that adequately take into account the individual, aggregate, and			

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				cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering. (2) The devices are inspected for evidence of physical damage and for loss of tritium or promethium-147, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(3) of this section. (3) Device designs are rejected for which the following has been detected for any unit: (i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; or (ii) Surface contamination of tritium or promethium-147 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or			

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				(iii) Any other evidence of physical damage.			
§32.53(f)	Luminous safety devices for use in aircraft: Requirements for license to manufacture, assemble, repair or initially transfer		B	**In § 32.53, paragraph (f) is added to read as follows:** (f) The device has been registered in the Sealed Source and Device Registry.			
§32.55	Same: Quality assurance, prohibition of transfer		B	**Section 32.55 is revised to read as follows:** (a) Each person licensed under § 32.53 shall visually inspect each device and shall reject any that has an observable physical defect that could adversely affect containment of the tritium or promethium-147. (b) Each person licensed under § 32.53 shall: (1) Maintain quality assurance systems in the manufacture of the luminous safety device in a manner sufficient to provide reasonable assurance that the safety-related			

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				components of the distributed devices are capable of performing their intended functions; and (2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (c) of this section and in the license issued under § 32.53, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded. (c) The licensee shall subject each inspection lot to: (1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of tritium or promethium-147, such as absolute pressure and water immersion. (2) Inspection for evidence of physical damage, containment failure, or for loss of tritium or promethium-147 after each stage of testing, using methods of inspection adequate for applying the following criteria for defective:			

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				(i) A leak resulting in a loss of 0.1 percent or more of the original amount of tritium or promethium-147 from the device; (ii) Levels of radiation in excess of 5 microgray (0.5 millirad) per hour at 10 centimeters from any surface when measured through 50 milligrams per square centimeter of absorber, if the device contains promethium-147; and (iii) Any other criteria specified in the license issued under § 32.53. (d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter, or under an equivalent general license of an Agreement State: (1) Any luminous safety device tested and found defective under any condition of a license issued under § 32.53, or paragraph (b) of this section, unless the defective luminous safety device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or (2) Any luminous safety device			

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				contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (b)(2) of this section, unless: (i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.53; and (ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (b)(2) and (d)(2)(i) of this section and any other criteria that may be required as a condition of the license issued under § 32.53.			
§32.56	Same: Material transfer reports		B	**Section 32.56 is revised to read as follows:** (a) Each person licensed under § 32.53 shall file an annual report with the Director, Office of Federal and State Materials and Environmental Management Programs, ATTN: Document Control Desk/GLTS, by an appropriate method listed in § 30.6(a) of this chapter, which must state the total quantity of tritium or promethium-			

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				147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter. If no transfers have been made to persons generally licensed under § 31.7 of this chapter during the reporting period, the report must so indicate. (b) Each person licensed under § 32.53 shall report annually all transfers of devices to persons for use under a general license in an Agreement State's regulations that are equivalent to § 31.7 of this chapter to the responsible Agreement State agency. The report must state the total quantity of tritium or promethium-147 transferred, identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the			

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				quantity of tritium or promethium-147 in each kind of device. If no transfers have been made to a particular Agreement State during the reporting period, this information must be reported to the responsible Agreement State agency upon request of the agency.			
§32.57(d)(2)	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer		B	**In § 32.57, paragraph (d)(2) is revised as follows:** (d) * * * (2) The source has been subjected to and has satisfactorily passed appropriate tests required by paragraph (e) of this section.			
§32.57(e)	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or initially transfer		B	**In § 32.57 paragraph (e) is added to read as follows:** (e) The applicant shall subject at least five prototypes of each source that is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 to tests as follows: (1) The initial quantity of radioactive material deposited on			

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				each source is measured by direct counting of the source. (2) The sources are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment or binding of americium-241 or radium-226, such as physical handling, moisture, and water immersion. (3) The sources are inspected for evidence of physical damage and for loss of americium-241 or radium-226, after each stage of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (e)(4) of this section. (4) Source designs are rejected for which the following has been detected for any unit: removal of more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 from the source or any other evidence of physical damage.			
§32.59	Same: Leak		B	**Section 32.59 is revised to read as**			

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	testing of each source			**follows:** Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter or under equivalent regulations of an Agreement State. This test must be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger pressure. The radioactivity on the filter paper must be measured using methods capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If a source has been shown to be leaking or losing more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226 by the methods described in this section, the source must be rejected and must not be transferred to a general licensee under § 31.8 of this chapter, or equivalent regulations of an			

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				Agreement State.			
§32.61(e)(4)	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer		B	**In § 32.61, paragraph (e)(4) is revised as follows:** e) * * * (4) Prototypes of the device have been subjected to and have satisfactorily passed the tests required by paragraph (f) of this section.			
§32.61(f)	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer		B	**In § 32.61, paragraph (f) is added to read as follows:** (f) The applicant shall subject at least five prototypes of the device to tests as follows: (1) The devices are subjected to tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could adversely affect the effective containment of strontium-90, such as temperature, moisture, absolute pressure, water immersion, vibration, shock, and weathering. (2) The devices are inspected for evidence of physical damage and for loss of strontium-90 after each stage			

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				of testing, using methods of inspection adequate for determining compliance with the criteria in paragraph (f)(3) of this section. (3) Device designs are rejected for which the following has been detected for any unit: (i) A leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device; or (ii) Surface contamination of strontium-90 on the device of more than 2,200 disintegrations per minute per 100 square centimeters of surface area; or (iii) Any other evidence of physical damage.			
§32.61(g)	Ice detection devices containing strontium-90; requirements for license to manufacture or initially transfer		B	**In § 32.61, paragraph (f) is added to read as follows:** (g) The device has been registered in the Sealed Source and Device Registry.			
§32.62(c), (d), & (e)	Same: Quality assurance;		B	**In § 32.62, paragraphs (c), (d), and (e) are revised to read as follows:**			

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	prohibition of transfer			(c) Each person licensed under § 32.61 shall: (1) Maintain quality assurance systems in the manufacture of the ice detection device containing strontium-90 in a manner sufficient to provide reasonable assurance that the safety-related components of the distributed devices are capable of performing their intended functions; and (2) Subject inspection lots to acceptance sampling procedures, by procedures specified in paragraph (d) of this section and in the license issued under § 32.61, to provide at least 95 percent confidence that the Lot Tolerance Percent Defective of 5.0 percent will not be exceeded. (d) Each person licensed under § 32.61 shall subject each inspection lot to: (1) Tests that adequately take into account the individual, aggregate, and cumulative effects of environmental conditions expected in service that could possibly affect the effective containment of strontium-90, such as			

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				absolute pressure and water immersion. (2) Inspection for evidence of physical damage, containment failure, or for loss of strontium-90 after each stage of testing, using methods of inspection adequate to determine compliance with the following criteria for defective: a leak resulting in a loss of 0.1 percent or more of the original amount of strontium-90 from the device and any other criteria specified in the license issued under § 32.61. (e) No person licensed under § 32.61 shall transfer to persons generally licensed under § 31.10 of this chapter, or under an equivalent general license of an Agreement State: (1) Any ice detection device containing strontium-90 tested and found defective under the criteria specified in a license issued under § 32.61, unless the defective ice detection device has been repaired or reworked, retested, and determined by an independent inspector to meet the applicable acceptance criteria; or			

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				(2) Any ice detection device containing strontium-90 contained within any lot that has been sampled and rejected as a result of the procedures in paragraph (c)(2) of this section, unless: (i) A procedure for defining sub-lot size, independence, and additional testing procedures is contained in the license issued under § 32.61; and (ii) Each individual sub-lot is sampled, tested, and accepted in accordance with paragraphs (c)(2) and (e)(2)(i) of this section and any other criteria as may be required as a condition of the license issued under § 32.61.			
§32.74(a)(4)	Manufacture and distribution of sources or devices containing byproduct material for medical use		B	**Section 32.74 is amended by adding paragraph (a)(4) to read as follows:** (a) * * * (4) The source or device has been registered in the Sealed Source and Device Registry.			

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§32.101	Schedule B-- prototype tests for luminous safety devices for use in aircraft		B	**Section 32.101 is removed.**			
§32.102	Schedule C— prototype tests for calibration or reference sources containing americium-241 or radium-226		B	**Section 32.102 is removed.**			
§32.103	Schedule D-- prototype tests for ice detection devices containing strontium-90		B	**Section 32.103 is removed.**			
§32.110	Acceptance sampling procedures under certain specific licenses		B	**Section 32.110 is removed.**			
§32.210(a)	Registration of product information		B - States with authority for sealed source and device (SS&D)	**In § 32.210, paragraph (a) is revised as follows:** (a) Any manufacturer or initial distributor of a sealed source or device containing a sealed source			

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			evaluations D - States without SS&D authority	may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.			
§32.210(b)	Registration of product information		B - States with authority for sealed source and device (SS&D) evaluations D - States without SS&D authority	**In § 32.210, paragraph (b) is revised as follows:** (b) The request for review must be sent to the NRC's Office of Federal and State Materials and Environmental Management Programs, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter.			
§32.210(d)	Registration of product information		B - States with authority for sealed source and device (SS&D) evaluations D - States without SS&D authority	**In § 32.210, paragraph (d) is revised as follows:** (d) The NRC normally evaluates a sealed source or a device using radiation safety criteria in accepted industry standards. If these standards and criteria do not readily apply to a particular case, the NRC formulates reasonable standards and criteria with the help of the manufacturer or distributor. The NRC shall use criteria and standards			

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				sufficient to ensure that the radiation safety properties of the device or sealed source are adequate to protect health and minimize danger to life and property. Subpart A of this part includes specific criteria that apply to certain exempt products and subpart B includes specific criteria applicable to certain generally licensed devices. Subpart C includes specific provisions that apply to certain specifically licensed items.			
§32.210(e)	Registration of product information		B - States with authority for sealed source and device (SS&D) evaluations D - States without SS&D authority	**In § 32.210, paragraph (e) is revised as follows:** (e) After completion of the evaluation, the Commission issues a certificate of registration to the person making the request. The certificate of registration acknowledges the availability of the submitted information for inclusion in an application for a specific license proposing use of the product, or concerning use under an exemption from licensing or general license as applicable for the category of certificate.			

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§32.210(g)	Registration of product information		B - States with authority for sealed source and device (SS&D) evaluations D - States without SS&D authority	**In § 32.210, paragraph (g) is added to read as follows:** (g) Authority to manufacture or initially distribute a sealed source or device to specific licensees may be provided in the license without the issuance of a certificate of registration in the following cases: (1) Calibration and reference sources containing no more than: (i) 37 MBq (1 mCi), for beta and/or gamma emitting radionuclides; or (ii) 0.37 MBq (10 µCi), for alpha emitting radionuclides; or (2) The intended recipients are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in any form in the case of unregistered sources or, for registered sealed sources contained in unregistered devices, are qualified by training and experience and have sufficient facilities and equipment to safely use and handle the requested quantity of radioactive material in			

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				unshielded form, as specified in their licenses; and (i) The intended recipients are licensed under part 33 of this chapter or comparable provisions of an Agreement State; or (ii) The recipients are authorized for research and development; or (iii) The sources and devices are to be built to the unique specifications of the particular recipient and contain no more than 740 GBq (20 Ci) of tritium or 7.4 GBq (200 mCi) of any other radionuclide.			
§32.210(h)	Registration of product information		C - States with authority for sealed source and device (SS&D) evaluations D - States without SS&D authority	**In § 32.210, paragraph (h) is added to read as follows:** (h) After the certificate is issued, the Commission may conduct an additional review as it determines is necessary to ensure compliance with current regulatory standards. In conducting its review, the Commission will complete its evaluation in accordance with criteria specified in this section. The Commission may request such additional information as it considers			

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				necessary to conduct its review and the certificate holder shall provide the information as requested.			
§32.211	Inactivation of certificates of registration of sealed sources and devices		B - States with authority for sealed source and device (SS&D) evaluations D - States without SS&D authority	**Section 32.211 is added to read as follows:** (a) A certificate holder who no longer manufactures or initially transfers any of the sealed source(s) or device(s) covered by a particular certificate issued by the Commission shall request inactivation of the registration certificate. Such a request must be made to the NRC's Office of Federal and State Materials and Environmental Management Programs, ATTN: SSDR by an appropriate method listed in § 30.6(a) of this chapter and must normally be made no later than two years after initial distribution of all of the source(s) or device(s) covered by the certificate has ceased. However, if the certificate holder determines that an initial transfer was in fact the last initial transfer more than two years after that transfer, the certificate holder shall request inactivation of the certificate within 90 days of this			

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				determination and briefly describe the circumstances of the delay. (b) If a distribution license is to be terminated in accordance with § 30.36 of this chapter, the licensee shall request inactivation of its registration certificates associated with that distribution license before the Commission will terminate the license. Such a request for inactivation of certificate(s) must indicate that the license is being terminated and include the associated specific license number. (c) A specific license to manufacture or initially transfer a source or device covered only by an inactivated certificate no longer authorizes the licensee to initially transfer such sources or devices for use. Servicing of devices must be in accordance with any conditions in the certificate, including in the case of an inactive certificate.			
§32.303(b)	Criminal penalties		D	N/A			
§40.5(b)(1)(iv)	Communications		D	N/A			

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§70.5(b)(1)(iv)	Communications		D	N/A			