COMPATIBILITY DESIGNATIONS FOR FINAL 10 CFR PART 35 – MEDICAL USE OF BYPRODUCT MATERIAL, PART 20 & PART 32

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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
§20.1002	Scope		D	N/A	N/A		
§20.1003	Definitions	§175.02 (a) (141)	A	**Definiton:** Occupational dose means the dose received by an individual in the course of employment in which the individual's assigned duties involve exposure to radiation or to radioactive material from licensed and unlicensed sources of radiation, whether in the possession of the licensee or other person. Occupational dose does not include doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under §35.75, from voluntary participation in medical research programs, or as a member of the public.	Y	N	This definition was previously submitted to NRC for review under RATS ID 1995-5 on 01/25/07 and accepted with no comment by letter dated February 23, 2007 from Deputy Director, Division of Materials Safety and State Agreements, OFSME. NYC also refers to sources in possession of “registrant”, (owners of x-ray machines, including LINACs).
§20.1003	Definitions	§175.02 (a) (161)	A	**Definiton:** Public dose means the dose received by a member of the public from exposure to radiation or to radioactive	N		

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				material released by a licensee, or to any other source of radiation under the control of a licensee. Public dose does not include occupational dose or doses received from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under §35.75, or from voluntary participation in medical research programs.			
§20.1301 (a) and (c)	Dose limits for individual members of the public	§175.03 (d) (1) §175.03 (d) (1)(i) (B)	A	(a) Each licensee shall conduct operations so that -(1) The total effective dose equivalent to individual members of the public from the licensed operation does not exceed 0.1 rem (1 mSv) in a year, exclusive of the dose contributions from background radiation, from any medical administration the individual has received, from exposure to individuals administered radioactive material and released under §35.75, from voluntary participation in medical research programs, and from the licensee's disposal of radioactive material into sanitary sewerage in	Y Y		NYC also refers to “registrant”, (owners of x-ray machines, including LINACs), as well as licensee, subject to limitations on operating radiation levels. NYC allows an exception to §175.03(d)(1)(i)(B) (1mSv/yr limit) with 5 mSv/yr limit if structural modifications to physical plant are required to meet 1 mSv/yr, with radiation equip installed before effective date of regulations.

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		§175.03 (d) (1)(i) (A)		accordance with §20.2003, and (2) The dose in any unrestricted area from external sources, exclusive of the dose contributions from patients administered radioactive material and released in accordance with §35.75, does not exceed 0.002 rem (0.02 millisievert) in any one hour.	N		
		§175.03 (d) (1)(iv)		(c) Notwithstanding paragraph (a)(1) of this section, a licensee may permit visitors to an individual who cannot be released, under §35.75, to receive a radiation dose greater than 0.1 rem (1 mSv) if— (1) The radiation dose received does not exceed 0.5 rem (5 mSv); and (2) The authorized user, as defined in 10 CFR Part 35, has determined before the visit that it is appropriate.	N		
§32.72 (b)(1)& (b)(2)(ii)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs	N/A	B	(b) A licensee described by paragraph (a)(2)(iii) or (iv) of this section: (1) May prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by	Y		Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use is not regulated by New York City DOHMH, but by the New York State Department of Health.

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	containing byproduct material for medical use under Part 35			either an authorized nuclear pharmacist, as specified in paragraphs (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.			
§32.72 (b)(2)(i)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35	N/A	B	(2) May allow a pharmacist to work as an authorized nuclear pharmacist if: (i) This individual qualifies as an authorized nuclear pharmacist as defined in 10 CFR 35.2.	Y		Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use is not regulated by New York City DOHMH, but by the New York State Department of Health.
§32.74 (a)	Manufacture and distribution of sources or devices containing byproduct material for medical use	N/A	B	(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§35.400, 35.500, and 35.600 of this chapter will be approved if: (1) The applicant satisfies the general requirements in §30.33	Y		Manufacture and distribution of sources or devices containing byproduct material for medical use is not regulated by New York City DOHMH, but by the New York State Department of Health.

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				of this chapter; (2) The applicant submits sufficient information regarding each type of source or device pertinent to an evaluation of its radiation safety, including: (i) The byproduct material contained, its chemical and physical form, and amount; (ii) Details of design and construction of the source or device; (iii) Procedures for, and results of, prototype tests to demonstrate that the source or device will maintain its integrity under stresses likely to be encountered in normal use and accidents; (iv) For devices containing byproduct material, the radiation profile of a prototype device; (v) Details of quality control procedures to assure that production sources and devices meet the standards of the design and prototype tests; (vi) Procedures and standards for calibrating sources and devices; (vii) Legend and methods for labeling sources and devices as			

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				to their radioactive content; (viii) Instructions for handling and storing the source or device from the radiation safety standpoint; these instructions are to be included on a durable label attached to the source or device or attached to a permanent storage container for the source or device: Provided, That instructions which are too lengthy for such label may be summarized on the label and printed in detail on a brochure which is referenced on the label; (3) The label affixed to the source or device, or to the permanent storage container for the source or device, contains information on the radionuclide, quantity and date of assay, and a statement that the U.S. Nuclear Regulatory Commission has approved distribution of the (name of source or device) to persons licensed to use byproduct material identified in §§35.65, 35.400, 35.500, and 35.600 as appropriate, and to persons who hold an equivalent license issued by an Agreement State. However, labels worded in			

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				accordance with requirements that were in place on March 30, 1987 may be used until March 30, 1989.			
§35.1	Purpose and scope	§175.103 (a) (1)	D	N/A	N/A		
§35.2	Definitions	§175.02 (a) (8)	D	**Definition:** Address of use	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a) (9)	[B]	**Definition:** Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.	Y	N	NYC also refers to Atomic Energy Act as (73 Stat. 689). NYC refers to Commission and AEC as U.S. Nuclear Regulatory Commission and U.S. Atomic Energy Commission.
§35.2	Definitions	§175.02 (a) (14)	D	**Definition:** Area of use	N/A N		
§35.2	Definitions	§175.02 (a) (reseq)	B	**Definition:** Authorized medical physicist means an individual who— (1) Meets the requirements in §§35.51(a) and 35.59; or, before October 24, 2005, meets the requirements in §§35.961(a), or (b), and 35.59; or	N		Definition newly inserted.

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				(2) Is identified as an authorized medical physicist or teletherapy physicist on— (i) A specific medical use license issued by the Commission or Agreement State; (ii) A medical use permit issued by a Commission master material licensee; (iii) A permit issued by a Commission or Agreement State broad scope medical use licensee; or (iv) A permit issued by a Commission master material license broad scope medical use permittee.			
§35.2	Definitions	§175.02 (a) (18 reseq)	B	Definition: Authorized nuclear pharmacist means a pharmacist who- (1) Meets the requirements in §§35.55(a) and 35.59; or, before October 24, 2005, meets the requirements in §§35.980(a) and 35.59; or (2) Is identified as an authorized nuclear pharmacist on— (i) A specific license issued by the Commission or Agreement State that authorizes medical use	N		Definition newly inserted.

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				or the practice of nuclear pharmacy; (ii) A permit issued by a Commission master material licensee that authorizes medical use or the practice of nuclear pharmacy; (iii) A permit issued by a Commission or Agreement State broad scope medical use licensee that authorizes medical use or the practice of nuclear pharmacy; or (iv) A permit issued by a Commission master material license broad scope medical use permittee that authorizes medical			
§35.2	Definitions	§175.02 (a) (18)	B	**Definition:** Authorized user means a physician, dentist, or podiatrist who- (1) Meets the requirements in §§35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or, before October 24, 2005, meets the requirements in §§35.910(a), 35.920(a), 35.930(a), 35.940(a), 35.950(a), or 35.960(a) and 35.59; or (2) Is identified as an authorized user on-	Y		NYC also includes in the definition of authorized user, persons named as users on i) an x-ray registration or LINAC certified registration issued by the Department, or ii) on a license for non-human use issued by the Department, Agreement State, or NRC.

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				(i) A Commission or Agreement State license that authorizes the medical use of byproduct material; (ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; (iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the			
§35.2	Definitions	§175.02 (a) (27 reseq)	D	**Definition:** Brachytherapy	N/A Y		NYC registers electronic remote after-loading devices for radiation therapy, and includes these radiation sources in the definition of brachytherapy.
§35.2	Definitions	§175.02 (a) (28 reseq)	D	**Definition:** Brachytherapy source	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a) (42 reseq)	D	**Definition:** Client's address	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a) (57 reseq)	D	**Definition:** Dedicated check source	N/A N		
§35.2	Definitions	§175.02	D	**Definition:**	N/A		Definition newly inserted.

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		(a) (59 reseq)		Dentist	N		
§35.2	Definitions	§175.02 (a) (99 reseq)	D	**Definition:** High dose-rate remote afterloader	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a) (122 reseq)	D	**Definition:** Low dose-rate afterloader	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a) (126 reseq)	D	**Definition:** Management	N/A N		
§35.2	Definitions	§175.02 (a) (127 reseq)	D	**Definition:** Manual Brachytherapy	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a)(128)	D	**Definition:** Medical event	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02 (a) (129 reseq)	D	**Definition:** Medical institution	N/A		
§35.2	Definitions	§175.02 (a) (130)	C	**Definition:** Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under	Y		NYC issues radioactive materials licenses, but also registers x-ray machines and LINACs for medical diagnosis and therapy. We must account for the radiation from those sources as well, which

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				the supervision of an authorized user.			don't originate from byproduct material, in writing NYC Code. Also, our "medical use" licenses are quite generally and interchangeably referred to also as "human use". NYC's definition reads as follows: (130) "Medical use" means the intentional internal or external administration of radiation, byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user. For purposes of this Code, "human use" is an equivalent term.
§35.2	Definitions	§175.02 (a) (131)	D	**Definition:** Medium dose-rate remote afterloader	N/A N		Definition newly inserted.
§35.2	Definitions	§175.02	D	**Definition:**	N/A		Definition newly inserted.

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		(a) (134)		Mobile medical service	N		
§35.2	Definitions	§175.02 (a) (143)	D	**Definition:** Output	N/A N		
§35.2	Definitions	§175.02 (a) (146)	D	**Definition:** Patient intervention	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (151)	D	**Definition:** Pharmacist	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (152)	D	**Definition:** Physician	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (152 reseq)	D	**Definition:** Podiatrist	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (153)	D	**Definition:** Preceptor	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (154)	C	**Definition:** Prescribed dosage means the specified activity or range of activity of unsealed byproduct material as documented-	N/A N		Definition newly added

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				(1) In a written directive; or (2) In accordance with the directions of the authorized user for procedures performed pursuant to §§35.100 and 35.200.			
§35.2	Definitions	§175.02 (a) (155)	C	**Definition:** Prescribed dose means- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; (3) For manual brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or (4) For remote brachytherapy afterloaders, the total dose and dose per fraction as documented in the written directive.	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (161)	D	**Definition:** Pulsed dose-rate remote afterloader	N/A N		Definition newly added

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§35.2	Definitions	§175.02 (a) (174)	B	**Definition:** Radiation Safety Officer means an individual who- (1) Meets the requirements in §§35.50(a) or (c)(1) and 35.59; or, before October 24, 2005, §§35.900(a) and 35.59; or (2) Is identified as a Radiation Safety Officer on— (i) A specific medical use license issued by the Commission or Agreement State; or (ii) A medical use permit issued by a Commission master material licensee.	N		
§35.2	Definitions	§175.02 (a) (198)	[B]	**Definition:** Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.	N		
§35.2	Definitions	§175.02 (a) (199)	D	**Definition:** Sealed source and device registry	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (216)	D	**Definition:** Stereotactic radiosurgery	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (217)	D	**Definition:** Structured educational program	N/A		Definition newly added

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					N		
§35.2	Definitions	§175.02 (a) (221)	D	**Definition:** Teletherapy	N/A Y		NYC also also registers high energy x-ray machines (LINACs) for medical therapy, and differentiates from gamma rays from radioactive sources. To account for this mode, NYC adds the following to the definition of teletherapy: ... “For the purposes of this Code "external beam radiation therapy" is an equivalent term”.
§35.2	Definitions	§175.02 (a) (222)	D	**Definition:** Temporary jobsite	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (223 reseq)	D	**Definition:** Therapeutic dosage	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (223 reseq)	D	**Definition:** Therapeutic dose	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (229	C	**Definition:** Treatment site means the	N/A		Definition newly added

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		reseq)		anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.	N		
§35.2	Definitions	§175.02 (a) (235)	D	**Definition:** Type of use	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (236)	D	**Definition:** Unit dosage	N/A N		Definition newly added
§35.2	Definitions	§175.02 (a) (252)	D	**Definition:** Written directive	N/A N		Definition newly added
§35.5	Maintenance of records	§175.03 (k)(38)	D	N/A	N/A		
§35.6	Provisions for the protection of human research subjects	§175. 103(a) (2)	C	(a) A licensee may conduct research involving human research subjects only if it uses the byproduct materials specified on its license for the uses authorized on its license. (b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, before			

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				conducting research- (1) Obtain review and approval of the research from an "Institutional Review Board," as defined and described in the Federal Policy; and (2) Obtain "informed consent," as defined and described in the Federal Policy, from the human research subject. (c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the licensee shall,			
§35.7	FDA, other Federal, and State requirements	§175.103(a)(3)	D	N/A	N/A		
§35.8	Information collection requirements: OMB Approval		D	N/A	N/A		
§35.10	Implementation	§175.103(a)(4)	D	N/A	N/A		
§35.11	License required	§175.103(a)(5)	[C]	(a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or			

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				transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraphs (b)(1) or (b)(2) of this section. (b) A specific license is not needed for an individual who- (1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in §35.27, unless prohibited by license condition; or (2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in §35.27, unless prohibited by license			
§35.12	Application for license, amendment, or renewal	§175.103(a)(6)	D	N/A	N/A		
§35.13	License amendments	§175.103(a)(7)	D	N/A	N/A		

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§35.14	Notifications	§175. 103(a) (8)	D	N/A	N/A		
§35.15	Exemptions regarding Type A specific licenses of broad scope	§175. 103(a) (9)	D	N/A	N/A		
§35.18	License issuance	§175. 103(a) (10)	D	N/A	N/A		
§35.19	Specific exemptions	§175. 103(a) (11)	D	N/A	N/A		
§35.24 (b)	Authority and responsibilities for the radiation protection program	§175. 103(b) (2)	H&S	(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements.			
§35.24	Authority and	§175.	H&S	(f) Licensees that are authorized for two or more different types of			

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(f)	responsibilities for the radiation protection program	103(b)(2)		uses of byproduct material under Subparts E, F, and H of this part, or two or more types of units under Subpart H of this part, shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.			
§35.26	Radiation protection program changes	§175.03(b)(2)	D	N/A	N/A		
§35.27	Supervision	§175.103(b)(3)	H&S	(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user, as allowed by §35.11(b)(1), shall-(1) In addition to the requirements in §19.12 of this			

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				chapter, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and (2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, written directive procedures, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.			
§35.40 (a)&(b)	Written directives	§175. 103(b) (4)	H&S	(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (μCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material. (1) If, because of the emergent			

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				nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive. (b) The written directive must contain the patient or human research subject's name and the following information— (1) For any administration of quantities greater than 1.11 MBq (30 uCi) of sodium iodide I-131:			
§35.41 (a)	Procedures for administrations requiring a written directive	§175. 103(b) (5)	H&S	(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that: (1) The patient's or human research subject's identity is verified before each administration; and (2) Each administration is in accordance with the written directive.			

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§35.49	Suppliers for sealed sources or devices for medical use	§175. 103(b) (6)	[C]	For medical use, a licensee may only use- (a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued under 10 CFR Part 30 and 10 CFR 32.74 of this chapter or equivalent requirements of an Agreement State; (b) Sealed sources or devices noncommercially transferred from a Part 35 licensee; or (c) Teletherapy sources manufactured and distributed in accordance with a license issued under 10 CFR Part 30 or the equivalent requirements of an Agreement State.			

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§35.50	Training for Radiation Safety Officer	§175. 103(j) (1)	B	Except as provided in §35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in §35.24 to be an individual who— 1. (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; (ii) Have 5 or more years of	N		

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§35.51	Training for an authorized medical physicist	§175. 103(j) (2)	B	Except as provided in §35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in §35.24 to be an individual who— 2. (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1)(i) Hold a bachelor's or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; (ii) Have 5 or more years of	N		

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§35.55	Training for an authorized nuclear pharmacist	§175. 103(j) (3)	B	Except as provided in §35.57, the licensee shall require the authorized nuclear pharmacist to be a pharmacist who- (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination; (2) Hold a current, active license	N		
§35.57	Training for	§175.	B	(a)(1) An individual identified as			

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
	experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist	103(j)(14)		a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of §§35.50, 35.51, or 35.55, respectively. (2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of §§35.50, 35.51, or 35.55,			
§35.59	Recentness of training	§175.103(j)	B	The training and experience specified in Subparts B, D, E, F,			

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
		(15)		G, H, and J of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.			
§35.60	Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material	§175. 103(c) (2)	H&S	(a) For direct measurements performed in accordance with §35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject. (b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.			
§35.61	Calibration of survey instruments	§175. 103(c) (3)	H&S	(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall- (1) Calibrate all scales with readings up to 10 mSv (1000			

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
				mrem) per hour with a radiation source; (2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and (b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.			
§35.63	Determination of dosages of unsealed byproduct material for medical use	§175. 103(c) (4)	H&S	(a) A licensee shall determine and record the activity of each dosage before medical use. (b) For a unit dosage, this determination must be made by (1) Direct measurement of radioactivity; or (2) A decay correction, based on the activity or activity concentration determined by— (i) A manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or (ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND)			

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
				protocol accepted by FDA. (c) For other than unit dosages, this determination must be made by— (1) Direct measurement of radioactivity; 3. (2) Combination of measurement of radioactivity and mathematical calculations; or (3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements. (d) Unless otherwise directed by the authorized user, a licensee may not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. (e) A licensee shall retain a record of the dosage determination required by this section in accordance with §35.2063.			

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
§35.65	Authorization for calibration, transmission and reference sources	§175. 103(c) (5)	D	N/A	N/A		
§35.67	Requirements for possession of sealed sources and brachytherapy sources	§175. 103(c) (6)	H&S	(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer. (b) A licensee in possession of a sealed source shall- (1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and (2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry. (c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq			

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
				(0.005 uCi) of radioactive material in the sample.			
§35.69	Labeling of vials and syringes	§175. 103(c) (7)	H&S	Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.			
§35.70	Surveys of ambient radiation exposure rate	§175. 103(c) (8)	H&S	(a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered.			
§35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material	§175. 103(c) (9)	C	(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)[1]. [1] NUREG–1556, Vol. 9,			

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				"Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem). (b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed			
§35.80	Provision of mobile medical service	§175. 103(c) (12)	H&S for States that authorize activity D otherwise	(a)(2) Check instruments used to measure the activity of unsealed byproduct material for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check; (a)(3) Check survey instruments			

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				for proper operation with a dedicated check source before use at each client's address; (b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client must be received and handled in conformance with the client's license.			
§35.92	Decay-in-storage	§175. 103(c) (11)	H&S for States that authorize activity D otherwise	(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it- (1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and (2) Removes or obliterates all radiation labels, except for			

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
				radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee.			
§35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required	§175. 103(d)(1)	H&S	Except for quantities that require a written directive under §35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is- (a) Obtained from a manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by: (1) An authorized nuclear pharmacist; (2) A physician who is an authorized user and who meets the requirements specified in §§35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, §35.920; or (3) An individual under the supervision, as specified in §35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in			

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
§35.190	Training for uptake, dilution and excretion studies	§175. 103(j) (4)	B	Except as provided in §35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §35.100 to be a physician who- (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies	N		
§35.200	Use of	§175.	H&S	Except for quantities that require			

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
	unsealed byproduct material for imaging and localization studies for which a written directive is not required	103(d)(2)		a written directive under §35.40(b), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is- (a) Obtained from a manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by: (1) An authorized nuclear pharmacist; (2) A physician who is an authorized user and who meets the requirements specified in §§35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, §35.920; or (3) An individual under the supervision, as specified in §35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of this section or the physician who is an authorized user in			
§35.204	Permissible molybdenum-99 concentration	§175.103(d)(3)	H&S	(a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie			

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
				of molybdenum-99 per millicurie of technetium-99m). (b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.			
§35.290	Training for imaging and localization studies	§175. 103(j) (5)	B	Except as provided in §35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §35.200 to be a physician who- (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board	N		

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
				shall require all candidates for certification to: (1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in			
§35.300	Use of unsealed byproduct material for which a written directive is required	§175. 103(e)(1)	H&S	A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is- (a) Obtained from a manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by: (1) An authorized nuclear pharmacist; (2) A physician who is an authorized user and who meets the requirements specified in §§35.290, 35.390, or, before October 24, 2005, §35.920; or (3) An individual under the supervision, as specified in §35.27, of the authorized nuclear pharmacist in paragraph (b)(1) of			

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
				this section or the physician who is an authorized user in paragraph (b)(2) of this section; or (c) Obtained from and prepared			
§35.310	Safety instruction	§175. 103(e) (2)	H&S	In addition to the requirements of §19.12 of this chapter, (a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who cannot be released under §35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include- (1) Patient or human research subject control; (2) Visitor control, including- (i) Routine visitation to hospitalized individuals in accordance with §20.1301(a)(1) of this chapter; and (ii) Visitation authorized in accordance with §20.1301(c) of this chapter; (3) Contamination control; (4) Waste control; and (5) Notification of the Radiation			
§35.315	Safety	§175.	H&S	(a) For each patient or human			

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
	precautions	103(e)(3)		research subject who cannot be released under §35.75, a licensee shall- (1) Quarter the patient or the human research subject either in- (i) A private room with a private sanitary facility; or (ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released under §35.75; (2) Visibly post the patient's or the human research subject's room with a “Radioactive Materials” sign. (3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and (4) Either monitor material and			
§35.390	Training for use of unsealed byproduct material for which a written directive is required	§175.103(j)(6)	B	Except as provided in §35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under §35.300 to be a physician who- (a) Is certified by a medical specialty board whose			

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				certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To be recognized, a specialty board shall require all candidates for certification to: (1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as			
§35.392	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or	§175. 103(j) (7)	B	Except as provided in §35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 1.22 Gigabecquerels (33 millicuries), to be a physician who-			

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	equal to 1.22 Gigabecquerels (33 millicuries)			(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or (b) Is an authorized user under §§35.390(a), 35.390(b) for uses listed in §35.390(b)(1)(ii)(G)(1) or (2), §35.394, or, before October			
§35.394	Training for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels	§175. 103(j) (8)	B	Except as provided in §35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who—(a) Is an authorized user under §35.390 or, before October 24, 2005, §35.930 for uses listed in §§35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State			

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
	(33 millicuries)			requirements; or (b) Is an authorized user under §§35.490 or 35.690, or, before October 24, 2005, §§35.940 or 35.960, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or (c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under §§35.490 or 35.690, or, before October 24, 2005, §§35.940 or 35.960; and who meets the			
§35.400	Use of sealed sources for manual brachytherapy	§175. 103(f) (1)	[C]	A licensee shall use only brachytherapy sources for therapeutic medical uses: (a) As approved in the Sealed Source and Device Registry; or (b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of §35.49(a) are met.			
§35.404	Surveys after source implant and removal	§175. 103(f) (2)	H&S	(a) Immediately after implanting sources in a patient or a human research subject, the licensee			

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				shall make a survey to locate and account for all sources that have not been implanted. (b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.			
§35.406	Brachytherapy sources accountability	§175.103(f)(3)	H&S	(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. (b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.			
§35.410	Safety instruction	§175.103(f)(4)	H&S	In addition to the requirements of §19.12 of this chapter, (a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects who are receiving brachytherapy and cannot be released under			

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
				§35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the— (1) Size and appearance of the brachytherapy sources; (2) Safe handling and shielding instructions; (3) Patient or human research subject control; (4) Visitor control, including both: (i) Routine visitation of hospitalized individuals in accordance with §20.1301(a)(1) of this chapter; and			
§35.415	Safety precautions	§175. 103(f) (5)	H&S	(a) For each patient or human research subject who is receiving brachytherapy and cannot be released under §35.75, a licensee shall- (1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy; (2) Visibly post the patient's or human research subject's room with a “Radioactive Materials” sign; and (3) Note on the door or in the			

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				patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room. (b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source- (1) Dislodged from the patient; and			
§35.432	Calibration measurements of brachytherapy sources	§175. 103(f) (7)	H&S	(a) Before the first medical use of a brachytherapy source on or after October 24, 2002, a licensee shall have- (1) Determined the source output or activity using a dosimetry system that meets the requirements of §35.630(a); (2) Determined source positioning accuracy within applicators; and (3) Used published protocols currently accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section. (b) Instead of a licensee making its own measurements as required in paragraph (a) of this section, the licensee may use			

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				measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in			
§35.433	Decay of strontium-90 sources for ophthalmic treatments	§175. 103(f) (8)	H&S	(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under §35.432.			
§35.457	Therapy-related computer systems	§175. 103(f) (9)	H&S	The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of: (a) The source-specific input parameters required by the dose calculation algorithm; (b) The accuracy of dose, dwell time, and treatment time calculations at representative			

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				points; (c) The accuracy of isodose plots and graphic displays; and (d) The accuracy of the software used to determine sealed source positions from radiographic images.			
§35.490	Training for use of manual brachytherapy sources	§175. 103(j) (10)	B	Except as provided in §35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under §35.400 to be a physician who- (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Successfully complete a minimum of 3 years of residency training in a radiation oncology			

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
				program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or			
§35.491	Training for ophthalmic use of strontium-90	§175. 103(j) (11)	B	Except as provided in §35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who- (a) Is an authorized user under §35.490, or, before October 24, 2005, §§35.940 or 35.941, or equivalent Agreement State requirements; or (b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include— (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; and (2) Supervised clinical training			
§35.500	Use of sealed sources for diagnosis	§175. 103(g) (1)	[C]	A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed			

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
				Source and Device Registry.			
§35.590	Training for use of sealed sources for diagnosis	§175. 103(j) (12)	B	Except as provided in §35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under §35.500 to be a physician, dentist, or podiatrist who- (a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's Web page.); or (b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must include- (1) Radiation physics and instrumentation;			

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§35.600	Use of a sealed sources in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	§175. 103(h) (1)	[C]	A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses: (a) As approved in the Sealed Source and Device Registry; or (b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of §35.49(a) are met.			
§35.604	Surveys of patients and human research subjects treated with a remote afterloader unit	§175. 103(h) (2)	H&S	(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.			
§35.605	Installation, maintenance, adjustment and repair	§175. 103(h) (3)	H&S	(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a			

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				remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). (b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units. (c) For a low dose-rate remote afterloader unit, only a person			
§35.610	Safety procedures and instructions for remote afterloader units, teletherapy	§175. 103(h) (5)	H&S	(a) A licensee shall- (1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended; (2) Permit only individuals approved by the authorized user,			

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	units, and gamma stereotactic radiosurgery units			Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s); (3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and (4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must			
§35.615	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	§175. 103(h) (6)	H&S	(a) A licensee shall control access to the treatment room by a door at each entrance. (b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will- (1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed; (2) Cause the source(s) to be			

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				shielded when an entrance door is opened; and (3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console. (c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned			
§35.630	Dosimetry equipment	§175. 103(h) (8)	H&S	(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met. (1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or			

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				by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or (2) The system must have been calibrated within the previous 4 years. Eighteen to thirty			
§35.632	Full calibration measurements on teletherapy units	§175. 103(h) (9)	H&S	(a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit- (1) Before the first medical use of the unit; and (2) Before medical use under the following conditions: (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location;			

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				(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and			
§35.633	Full calibration measurements on remote afterloader units	§175. 103(h) (10)	H&S	(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit- (1) Before the first medical use of the unit; (2) Before medical use under the following conditions: (i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and (ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and (3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and (4) At intervals not exceeding 1			

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§35.635	Full calibration measurements on gamma stereotactic radiosurgery units	§175. 103(h) (11)	H&S	(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit- (1) Before the first medical use of the unit; (2) Before medical use under the following conditions— (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; (ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and (iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or			
§35.642	Periodic spot-checks for teletherapy units	§175. 103(h) (12)	H&S	(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of-			

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				(1) Timer accuracy, and timer linearity over the range of use; (2) On-off error; (3) The coincidence of the radiation field and the field indicated by the light beam localizing device; (4) The accuracy of all distance measuring and localization devices used for medical use; (5) The output for one typical set of operating conditions measured with the dosimetry system described in §35.630(b); and (6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output,			
§35.643	Periodic spot-checks for remote afterloader units	§175. 103(h) (13)	H&S	(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit- (1) Before the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day; (2) Before each patient treatment with a low dose-rate remote afterloader unit; and (3) After each source installation.			

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				(b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements. (c) A licensee shall have the authorized medical physicist			
§35.645	Periodic spot-checks for gamma stereotactic radiosurgery units	§175. 103(h) (14)	H&S	(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit- (1) Monthly; (2) Before the first use of the unit on a given day; and (3) After each source installation. (b) A licensee shall- (1) Perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements. (2) Have the authorized medical			

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				physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each			
§35.647	Additional technical requirements for mobile remote afterloader units	§175. 103(h) (15)	H&S for States that authorize activity D otherwise	(a) A licensee providing mobile remote afterloader service shall- (1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and (2) Account for all sources before departure from a client's address of use. (b) In addition to the periodic spot-checks required by §35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of- (1) Electrical interlocks on treatment area access points; (2) Source exposure indicator lights on the remote afterloader unit, on the control console,			

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§35.652	Radiation surveys	§175. 103(h) (16)	H&S	(a) In addition to the survey requirement in §20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry. (b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).			
§35.655	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units	§175. 103(h) (19)	H&S	(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source			

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				exposure mechanism. (b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.			
§35.657	Therapy-related computer systems	§175. 103(h) (20)	H&S	The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of: (a) The source-specific input parameters required by the dose calculation algorithm; (b) The accuracy of dose, dwell time, and treatment time calculations at representative points; (c) The accuracy of isodose plots and graphic displays; (d) The accuracy of the software used to determine sealed source positions from radiographic images; and (e) The accuracy of electronic transfer of the treatment delivery parameters to the			

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§35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	§175. 103(j) (13)	B	Except as provided in §35.57, the licensee shall require an authorized user of a sealed source for a use authorized under §35.600 to be a physician who- (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC's web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or			

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				the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and (2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or (b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes— (i) 200 hours of classroom and laboratory training in the following areas— (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; and (D) Radiation biology; and			

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				(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §35.690, or, before October 24, 2005, §35.960, or equivalent Agreement State requirements at a medical institution, involving— (A) Reviewing full calibration measurements and periodic spot-checks; (B) Preparing treatment plans and calculating treatment doses and times; (C) Using administrative controls to prevent a medical event involving the use of byproduct material; (D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; (E) Checking and using survey meters; and (F) Selecting the proper dose and how it is to be administered; and (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the			

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				requirements in §35.690, or, before October 24, 2005, §35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be			

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				signed by a preceptor authorized user who meets the requirements in §35.690, or, before October 24, 2005, §35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and (c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the individual is seeking authorization.			
§35.900	Radiation Safety Officer	§175. 103(j) (1)	D	N/A	N/A		Note – 35.900 series training has not been explicitly incorporated.
‘35.910	Training for uptake, dilution,	§175. 103(j)	D	N/A	N/A		Sections shown for 900 series training are for information purposes only,

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	and excretion studies	(4)					where comparable text appears (typ).
§35.920	Training for imaging and localization studies	§175.103(j)(5)	D	N/A	N/A		Text in training section 175.103(j) has actually been taken from 35.190, 290, 390, 490, 590, …
§35.930	Training for Therapeutic use of unsealed byproduct material	§175.103(j)(6)	D	N/A	N/A		
§35.932	Training for treatment of hyperthyroidism		D	N/A	N/A		
§35.934	Training for treatment of thyroid carcinoma	§175.103(j)(6)	D	N/A	N/A		
§35.940	Training for use of brachytherapy sources	§175.103(j)(10)	D	N/A	N/A		
§35.941	Training for ophthalmic use of strontium-90	§175.103(j)(11)	D	N/A	N/A		

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§35.950	Training for use of sealed sources for diagnosis	§175.103(j)(12)	D	N/A	N/A		
§35.960	Training for use of therapeutic medical devices		D	N/A	N/A		
§35.961	Training for authorized medical physicist	§175.103(j)(2)	D	N/A	N/A		
§35.980	Training for an authorized nuclear pharmacist	§175.103(j)(3)	D	N/A	N/A		
§35.981	Training for experienced nuclear pharmacist	§175.103(j)(14)	D	N/A	N/A		
§35.1000	Other medical uses of byproduct material or radiation from byproduct material	§175.103(i)(1)	D	N/A	N/A		

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§35.2024	Records of authority and responsibilities for radiation protection programs	§175.03(k)(3)	D	N/A	N/A		
§35.2026	Records of radiation protection program changes	§175.03(k)(4)	D	N/A	N/A		
§35.2040	Records of written directives	§175.03(k)(12)	D	N/A	N/A		
§35.2041	Records for procedures for administrations requiring a written directive	§175.03(k)(13)	D	N/A	N/A		
§35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	§175.03(k)(14)	D	N/A	N/A		

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§35.2061	Records of radiation survey instrument calibrations	§175.03(k)(15)	D	N/A	N/A		
§35.2063	Records of dosage of unsealed byproduct material for medical use	§175.03(k)(16)	D	N/A	N/A		
§35.2067	Records of leak test and inventory of sealed sources and brachytherapy sources	§175.03(k)(17)	D	N/A	N/A		
§35.2070	Records of surveys for ambient radiation exposure rate	§175.03(k)(18)	D	N/A	N/A		
§35.2075	Records of the release of individuals containing unsealed byproduct	§175.03(k)(19)	D	N/A	N/A		

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	material or implants containing byproduct material						
§35.2080	Records of mobile medical services	§175.03(k)(20)	D	N/A	N/A		
§35.2092	Records of decay-in-storage	§175.03(k)(21)	D	N/A	N/A		
§35.2204	Records of molybdenum-99 concentrations	§175.03(k)(22)	D	N/A	N/A		
§35.2310	Records of safety instruction	§175.03(k)(23)	D	N/A	N/A		
§35.2404	Records of surveys after source implant and removal	§175.03(k)(24)	D	N/A	N/A		
§35.2406	Records of brachytherapy source	§175.03(k)(25)	D	N/A	N/A		

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	accountability						
§35.2432	Records of calibration measurements of brachytherapy sources	§175.03(k)(26)	D	N/A	N/A		
§35.2433	Records of decay of strontium-90 sources for ophthalmic treatments	§175.03(k)(27)	D	N/A	N/A		
§35.2605	Records of installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	§175.03(k)(28)	D	N/A	N/A		
§35.2610	Records of safety	§175.03(k)	D	N/A	N/A		

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
	procedures	(29)					
§35.2630	Records of dosimetry equipment used for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	§175.03(k)(30)	D	N/A	N/A		
§35.2632	Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	§175.03(k)(31)	D	N/A	N/A		
§35.2642	Records of periodic spot-checks for teletherapy units	§175.03(k)(32)	D	N/A	N/A		
§35.2643	Records of periodic spot-	§175.03(k)	D	N/A	N/A		

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	checks for remote afterloader units	(33)					
§35.2645	Records of periodic spot-checks for gamma stereotactic radiosurgery units	§175.03(k)(34)	D	N/A	N/A		
§35.2647	Records of additional technical requirements for mobile remote afterloader units	§175.03(k)(35)	D	N/A	N/A		
§35.2652	Records of surveys of therapeutic treatment units	§175.03(k)(36)	D	N/A	N/A		
§35.2655	Records of 5-year inspection of teletherapy and gamma stereotactic radiosurgery	§175.03(k)(37)	D	N/A	N/A		

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	units						
§35.3045	Report and notification of a medical event	§175.03(l)(8)	C	a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in- (1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and (i) The total dose delivered differs from the prescribed dose by 20 percent or more; (ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or (iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.			

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§35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	§175. 03(l) (9)	C	(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user. (b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that— (1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or (2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician. (c) The licensee shall notify by telephone the NRC Operations			
§35.3067	Report of a leaking source	§175. 03(l) (10)	C	A licensee shall file a report within 5 days if a leak test required by §35.67 reveals the presence of 185 Bq (0.005 μCi) or more of removable contamination. The report must			

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				be filed with the appropriate NRC Regional Office listed in §30.6 of this chapter, by an appropriate method listed in §30.6(a), with a copy to the Director, Office of Nuclear Material Safety and Safeguards. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.			
§35.4001	Violations		D	N/A	N/A		
§35.4002	Criminal penalties		D	N/A	N/A		