

Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments

10 CFR Parts 30, 32, and 35

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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
§ 30.34(g)	Terms and conditions of licenses	3701:1-40-16	B	<p>In § 30.34, add a third sentence to paragraph (g) to read as follows:</p> <p align="center">* * * *</p> <p align="center">(g) * *</p> <p>*The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter.</p> <p align="center">* * * *</p>			
§ 32.72: (a)(4) revised; (b)(5)(i) revised;	Manufacture, preparation, or transfer for commercial distribution of radioactive	3701:1-46-43	B	<p>In § 32.72:</p> <p>(a) Revise the introductory text of (a)(4);</p> <p>(b) Revise (b)(5)(i);</p> <p>(c) Redesignate paragraph (d) as paragraph (e); and</p>			

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(d) new	drugs containing byproduct material for medical use under part 35.			<p>(d) Add new paragraph (d). to read as follows:</p> <p>(a) * * *</p> <p>(4) The applicant commits to the following labeling requirements:</p> <p>* * * * *</p> <p>(b) * * *</p> <p>(5) * * *</p> <p>(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or</p> <p>* * * * *</p> <p>(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.</p> <p>* * * * *</p>			
§ 35.2: New definitions for Associate	Definitions	3701:1-58-01	B: for Associate Radiation Safety Officer	In § 35.2, add, in alphabetical order, the definitions for Associate Radiation Safety Officer and Ophthalmic			

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Radiation Safety Officer and Ophthalmic physicist; Revised definition for Preceptor			and Ophthalmic physicist; D: for Preceptor	<p>physicist, and revise the definition for Preceptor to read as follows:</p> <p>§ 35.2 Definitions. * * * * *</p> <p>Associate Radiation Safety Officer means an individual who —</p> <p>(1) Meets the requirements in §§ 35.50 and 35.59; and</p> <p>(2) Is currently identified as an Associate Radiation Safety Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on —</p> <p>(i) A specific medical use license issued by the Commission or an Agreement State; or</p> <p>(ii) A medical use permit issued by a Commission master material licensee. * * * * *</p> <p>Ophthalmic physicist means an individual who—</p>			

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				<p>(1) Meets the requirements in § 35.433(a)(2) and § 35.59; and</p> <p>(2) Is identified as an ophthalmic physicist on a—</p> <p>(i) Specific medical use license issued by the Commission or an Agreement State;</p> <p>(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;</p> <p>(iii) Medical use permit issued by a Commission master material licensee; or</p> <p>(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.</p> <p>* * * * *</p> <p>Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation</p>			

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				Safety Officer, or an Associate Radiation Safety Officer. * * * * *			
§ 35.12	Application for license, amendment, or renewal	3701:1-58-07	D	<p>In § 35.12, revise paragraphs (b)(1), (c)(1), (c)(1)(ii) and (d) to read as follows:</p> <p>§ 35.12 Application for license, amendment, or renewal. * * * * *</p> <p>(b) * * *</p> <p>(1) Filing an original NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, Associate Radiation Safety Officer(s), authorized user(s), authorized medical physicist(s), ophthalmic physicist(s), and authorized nuclear pharmacist(s); and * * * * *</p> <p>(c) * * *</p> <p>(1) Submitting an original of either—</p> <p>(i) * * *</p>			

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				<p>(ii) A letter containing all information required by NRC Form 313; and</p> <p>* * * * *</p> <p>(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include:</p> <p>(1) Any additional aspects of the medical use of the material that are applicable to radiation safety that are not addressed in, or differ from, subparts A through C, L, and M of this part;</p> <p>(2) Identification of and commitment to follow the applicable radiation safety program requirements in subparts D through H of this part that are appropriate for the specific § 35.1000 medical use;</p> <p>(3) Any additional specific information on--</p> <p>(i) Radiation safety precautions and instructions;</p>			

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				(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and (4) Any other information requested by the Commission in its review of the application. * * * * *			
§ 35.13	License amendments	3701:1-58-08	D	<p>In § 35.13:</p> <p>(a) Revise paragraph (b); (b) Redesignate paragraphs (d) through (g) as paragraphs (e) through (h); (c) Revise newly redesignated paragraphs (g) and (h); and (d) Add new paragraphs (d) and (i) to read as follows:</p> <p>§ 35.13 License amendments. * * * * *</p> <p>(b) Before it permits anyone to work as an authorized user,</p>			

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				<p>authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist under the license, except—</p> <p>(1) For an authorized user, an individual who 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), and 35.690(a);</p> <p>(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;</p> <p>(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a) and 35.59;</p> <p>(4) An individual who is identified as an authorized user, an authorized nuclear pharmacist, authorized medical physicist, or an ophthalmic physicist—</p> <p style="text-align: center;">* * * * *</p> <p>(d) Before it permits anyone to work as an Associate Radiation Safety Officer, or before the Radiation Safety Officer assigns duties and tasks to an Associate</p>			

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				<p>Radiation Safety Officer that differ from those for which this individual is authorized on the license;</p> <p>* * * *</p> <p>(g) Before it changes the address(es) of use identified in the application or on the license;</p> <p>(h) Before it revises procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable, where such revision reduces radiation safety; and</p> <p>(i) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.</p>			
§ 35.14	Notifications	3701:1-58-09	D	<p>In § 35.14, revise paragraphs (a) and (b) to read as follows:</p> <p>(a) A licensee shall provide the Commission, no later than 30</p>			

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				<p>days after the date that the licensee permits an individual to work under the provisions of § 35.13(b) as an authorized user, authorized medical physicist, ophthalmic physicist, or authorized nuclear pharmacist —</p> <p>(1) A copy of the board certification and, as appropriate, verification of completion of:</p> <p>(i) Training for the authorized medical physicist under § 35.51(c);</p> <p>(ii) Any additional case experience required in § 35.390(b)(1)(ii)(G) for an authorized user under § 35.300; or</p> <p>(iii) Device specific training in § 35.690(c) for the authorized user under § 35.600; or</p> <p>(2) A copy of the Commission or Agreement State license, the permit issued by a Commission master material licensee, the permit issued by a Commission or Agreement State licensee of broad scope, the permit issued by a Commission master</p>			

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				<p>material license broad scope permittee, or documentation that only accelerator-produced radioactive materials, discrete sources of radium-226, or both, were used for medical use or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC for each individual whom the licensee permits to work under the provisions of this section.</p> <p>(b) A licensee shall notify the Commission no later than 30 days after:</p> <p>(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, an Associate Radiation Safety Officer, an authorized medical physicist, or ophthalmic physicist permanently discontinues performance of duties under the license or has a name change;</p>			

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				<p>(2) The licensee permits an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c);</p> <p>(3) The licensee's mailing address changes;</p> <p>(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter;</p> <p>(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET</p>			

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				<p>radioactive drug production area; or</p> <p>(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license for which it did not require a license amendment as provided in § 35.13(i). The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.</p> <p>* * * * *</p>			
§ 35.15	Exemptions regarding Type A specific licenses of broad scope	3701:1-58-10	D	<p>In § 35.15, revise paragraphs (c) and (e) to read as follows:</p> <p>* * * * *</p> <p>(c) The provisions of § 35.13(f) regarding additions to or changes in the areas of use at the addresses identified in the application or on the license;</p> <p>* * * * *</p> <p>(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear</p>			

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				pharmacist, an authorized medical physicist, or an ophthalmic physicist; * * * * *			
§ 35.24 (b) and (c)	Authority and responsibilities for the radiation protection program.	3701:1-58-12	H&S: 35.24(b) D: 35.24(c)	In § 35.24, revise paragraphs (b) and (c) to read as follows: * * * * * (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. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written			

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				<p>agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the radiation protection program.</p> <p>(c) For up to 60 days each year, a licensee may permit an individual qualified to be a Radiation Safety Officer, under §§ 35.50 and 35.59, to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section and notifies the</p>			

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				Commission in accordance with § 35.14(b). * * * *			
§ 35.40	Written directives	3701:1-58-15	H&S	<p>In § 35.40,</p> <p>(a) Revise paragraph (b)(5);</p> <p>(b) Redesignate paragraph (b)(6) as paragraph (b)(7);</p> <p>(c) Revise newly redesignated paragraph (b)(7);</p> <p>(d) Add new paragraph (b)(6);</p> <p>(e) Redesignate the introductory text of paragraph (c) as paragraph (c)(1); and</p> <p>(f) Redesignate paragraph (c)(1) as paragraph (c)(2) to read as follows:</p> <p>(b) * * *</p> <p>(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose;</p> <p>(6) For permanent implant brachytherapy:</p> <p>(i) Before implantation: the treatment site, the radionuclide,</p>			

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				<p>and the total source strength; and</p> <p>(ii) After implantation but before the patient leaves the post-treatment recovery area: the treatment site, the number of sources implanted, the total source strength implanted, and the date; or</p> <p>(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:</p> <p>(i) Before implantation: the treatment site, radionuclide, and dose; and</p> <p>(ii) After implantation but before completion of the procedure: the radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date.</p> <p>(c)(1) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy</p>			

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				<p>dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.</p> <p>(2) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.</p> <p>* * * * *</p>			
§ 35.41	Procedures for administrations requiring a written directive	3701:1-58-16	H&S	<p>In § 35.41, revise paragraphs (b)(3) and (b)(4) and add new paragraphs (b)(5) and (b)(6) to read as follows:</p> <p>(b) * * *</p> <p>(3) Checking both manual and computer-generated dose calculations;</p> <p>(4) Verifying that any computer-generated dose calculations are</p>			

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				<p>correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000;</p> <p>(5) Determining if a medical event, as defined in § 35.3045, has occurred; and</p> <p>(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.</p> <p>* * * * *</p>			
§ 35.50	Training for Radiation Safety Officer and Associate Radiation Safety Officer	3701:1-58-18	B	<p>Revise § 35.50 to read as follows:</p> <p>Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer or an individual assigned duties and tasks as an</p>			

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				<p>Associate Radiation Safety Officer as provided in § 35.24 to be an individual who—</p> <p>(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 (d) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>(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;</p> <p>(ii) Have 5 or more years of professional experience in health physics (graduate training may</p>			

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				<p>be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and</p> <p>(iii) Pass an examination administered by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or</p> <p>(2)(i) Hold a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university;</p> <p>(ii) Have 2 years of full-time practical training and/or supervised experience in medical physics—</p> <p>(A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the</p>			

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				<p>Commission or an Agreement State; or</p> <p>(B) In clinical nuclear medicine facilities providing diagnostic or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390; and</p> <p>(iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or</p> <p>(b)(1) Has completed a structured educational program consisting of both:</p> <p>(i) 200 hours of classroom and laboratory training in the following areas-</p> <p>(A) Radiation physics and instrumentation;</p> <p>(B) Radiation protection;</p> <p>(C) Mathematics pertaining to the use and measurement of radioactivity;</p>			

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				<p>(D) Radiation biology; and (E) Radiation dosimetry; and (ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or an Agreement State license or permit issued by a Commission master material licensee that authorizes similar type(s) of use(s) of byproduct material. An Associate Radiation Safety Officer may provide supervision for those areas for which the Associate Radiation Safety Officer is authorized on a Commission or an Agreement State license or permit issued by a Commission master material licensee. The full-time radiation safety experience must involve the following— (A) Shipping, receiving, and performing related radiation surveys; (B) Using and performing checks for proper operation of</p>			

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				instruments used to determine the activity of dosages, survey meters, and instruments used to measure radionuclides; (C) Securing and controlling byproduct material; (D) Using administrative controls to avoid mistakes in the administration of byproduct material; (E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; (F) Using emergency procedures to control byproduct material; and (G) Disposing of byproduct material; and (2) This individual must obtain a written attestation, signed by a preceptor Radiation Safety Officer or Associate Radiation Safety Officer who has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual is seeking approval as a Radiation Safety			

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				<p>Officer or an Associate Radiation Safety Officer. The written attestation must state that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (d) of this section, and is able to independently fulfill the radiation safety related duties as a Radiation Safety Officer or as an Associate Radiation Safety Officer for a medical use license; or</p> <p>(c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under §35.51(a), has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as Radiation Safety Officer or an Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or</p>			

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				<p>(2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on a Commission or an Agreement State license, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State licensee of broad scope, or a permit issued by a Commission master material license broad scope permittee, has experience with the radiation safety aspects of similar types of use of byproduct material for which the licensee seeks the approval of the individual as the Radiation Safety Officer or Associate Radiation Safety Officer, and meets the requirements in paragraph (d) of this section; or</p> <p>(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking simultaneous approval both as the Radiation Safety Officer and the authorized</p>			

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				<p>user on the same new medical use license or new medical use permit issued by a Commission master material license. The individual must also meet the requirements in paragraph (d) of this section.</p> <p>(d) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, an Associate Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.</p>			
§ 35.51	Training for an authorized medical physicist.	3701:1-58-19	B	In § 35.51, revise the introductory text of paragraph (a), and revise paragraphs (a)(2)(i) and (b)(2) to read as follows:			

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				<p>* * * * *</p> <p>(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 (c) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>* * * * *</p> <p>(2) * * *</p> <p>(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board whose certification process has been recognized under this section by the Commission or an Agreement State; or</p> <p>* * * * *</p>			

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				(b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (c) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status.			
§ 35.55	Training for an authorized nuclear pharmacist.	3701:1-58-20	B	In § 35.55, revise the introductory text of paragraph (a) and revise paragraph (b)(2) to read as follows:			

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				<p>* * * * *</p> <p>(a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>* * * * *</p> <p>(b) * * *</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized nuclear pharmacist.</p>			

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§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	3701:1-58-21	B Except for D: 35.57(a)(4)	<p>In § 35.57:</p> <p>(a) Revise paragraphs (a)(1), (b)(1), (b)(2) and (b)(3);</p> <p>(b) Add new paragraphs (a)(2), (a)(3), (b)(2)(i),(ii)(iii) and (iv);</p> <p>and</p> <p>(c) Redesignate (a)(4);</p> <p>to read as follows:</p> <p>(a)(1) An individual identified on a Commission or an Agreement State license or a permit issued by a Commission or an Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope as a Radiation Safety Officer, a teletherapy or medical physicist, an authorized medical physicist, a nuclear pharmacist or an authorized nuclear pharmacist on or before January 14, 2019 need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively, except the Radiation Safety Officers and authorized medical physicists</p>			

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				<p>identified in this paragraph must meet the training requirements in § 35.50(d) or § 35.51(c), as appropriate, for any material or uses for which they were not authorized prior to this date.</p> <p>(2) Any individual certified by the American Board of Health Physics in Comprehensive Health Physics; American Board of Radiology; American Board of Nuclear Medicine; American Board of Science in Nuclear Medicine; Board of Pharmaceutical Specialties in Nuclear Pharmacy; American Board of Medical Physics in radiation oncology physics; Royal College of Physicians and Surgeons of Canada in nuclear medicine; American Osteopathic Board of Radiology; or American Osteopathic Board of Nuclear Medicine on or before October 24, 2005, need not comply with the training requirements of § 35.50 to be identified as a Radiation Safety Officer or as an Associate Radiation Safety</p>			

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				<p>Officer on a Commission or an Agreement State license or Commission master material license permit for those materials and uses that these individuals performed on or before October 24, 2005.</p> <p>(3) Any individual certified by the American Board of Radiology in therapeutic radiological physics, Roentgen ray and gamma ray physics, x-ray and radium physics, or radiological physics, or certified by the American Board of Medical Physics in radiation oncology physics, on or before October 24, 2005, need not comply with the training requirements for an authorized medical physicist described in § 35.51, for those materials and uses that these individuals performed on or before October 24, 2005.</p> <p>(4) A Radiation Safety Officer, a medical physicist, or a nuclear pharmacist, who used only accelerator-produced radioactive materials, discrete sources of</p>			

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
				<p>radium-226, or both, for medical uses or in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of §§ 35.50, 35.51 or 35.55, respectively, when performing the same uses.</p> <p>A nuclear pharmacist, who prepared only radioactive drugs containing accelerator-produced radioactive materials, or a medical physicist, who used only accelerator-produced radioactive materials, at the locations and during the time period identified in this paragraph, qualifies as an authorized nuclear pharmacist or an authorized medical physicist, respectively, for those materials and uses performed before these dates, for the purposes of this chapter.</p>			

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
				<p>(b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee on or before January 14, 2019, who perform only those medical uses for which they were authorized on or before that date need not comply with the training requirements of subparts D through H of this part.</p> <p>(2) Physicians, dentists, or podiatrists not identified as authorized users for the medical use of byproduct material on a license issued by the Commission or an Agreement State, a permit issued by a Commission master material</p>			

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				<p>licensee, a permit issued by a Commission or an Agreement State broad scope licensee, or a permit issued by a Commission master material license of broad scope on or before October 24, 2005, need not comply with the training requirements of Subparts D through H of this part for those materials and uses that these individuals performed on or before October 24, 2005, as follows:</p> <p>(i) For uses authorized under §§ 35.100 or 35.200, or oral administration of sodium iodide I-131 requiring a written directive for imaging and localization purposes, a physician who was certified on or before October 24, 2005, in nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology by the American Board of Radiology; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; nuclear medicine by the Royal College of Physicians and</p>			

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				<p>Surgeons of Canada; or American Osteopathic Board of Nuclear Medicine in nuclear medicine;</p> <p>(ii) For uses authorized under § 35.300, a physician who was certified on or before October 24, 2005, by the American Board of Nuclear Medicine; the American Board of Radiology in radiology, therapeutic radiology, or radiation oncology; nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or the American Osteopathic Board of Radiology after 1984;</p> <p>(iii) For uses authorized under §§ 35.400 or 35.600, a physician who was certified on or before October 24, 2005, in radiology, therapeutic radiology or radiation oncology by the American Board of Radiology; radiation oncology by the American Osteopathic Board of Radiology; radiology, with specialization in radiotherapy, as a British “Fellow of the Faculty of Radiology” or</p>			

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
				<p>"Fellow of the Royal College of Radiology"; or therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; and</p> <p>(iv) For uses authorized under § 35.500, a physician who was certified on or before October 24, 2005, in radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; nuclear medicine by the American Board of Nuclear Medicine; diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or nuclear medicine by the Royal College of Physicians and Surgeons of Canada.</p> <p>(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed at a Government agency or Federally recognized Indian Tribe before November 30, 2007, or at all other locations</p>			

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
				<p>of use before August 8, 2009, or an earlier date as noticed by the NRC, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for the purposes of this chapter.</p> <p style="text-align: center;">* * * * *</p>			
§ 35.65	Authorization for calibration, transmission, and reference sources.	3701:1-58-26	D	<p>In § 35.65, revised to read as follows:</p> <p>(a) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use:</p>			

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
				<p>(1) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations;</p> <p>(2) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions;</p> <p>(3) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi);</p> <p>(4) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq</p>			

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				<p>(200 µCi) or 1000 times the quantities in appendix B of part 30 of this chapter; or</p> <p>(5) Technetium-99m in amounts as needed.</p> <p>(b) Byproduct material in sealed sources authorized by this provision shall not be:</p> <p>(1) Used for medical use as defined in § 35.2 except in accordance with the requirements in § 35.500; or</p> <p>(2) Combined (i.e., bundled or aggregated) to create an activity greater than the maximum activity of any single sealed source authorized under this section.</p> <p>(c) A licensee using calibration, transmission, and reference sources in accordance with the requirements in paragraphs (a) or (b) of this section need not list these sources on a specific medical use license.</p>			
§ 35.190	Training for uptake, dilution, and excretion studies.	3701:1-58-33	B	In § 35.190, revise the introductory text of paragraph (a), revise paragraph (c)(2), and add new paragraphs			

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				<p>(c)(2)(i) and (ii) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p style="text-align: center;">* * * * *</p> <p>(c) * * *</p> <p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical</p>			

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
				<p>uses authorized under § 35.100. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements; or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training</p>			

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
				of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.			
§ 35.204	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	3701:1-58-35	H&S	<p>In § 35.204, revise paragraph (b) and add new paragraph (e) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate from a generator to demonstrate compliance with paragraph (a) of this section.</p> <p style="text-align: center;">* * * * *</p> <p>(e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204.</p>			
§ 35.290	Training for imaging and	3701:1-58-36	B	In § 35.290, revise the introductory text of			

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
	localization studies			<p>paragraphs (a) and (c)(1)(ii), and paragraph (c)(2); and add new paragraphs (c)(2)(i) and (ii) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p style="text-align: center;">* * * * *</p> <p>(c)(1) * * *</p> <p>(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent</p>			

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
				<p>Agreement State requirements. An authorized nuclear pharmacist who meets the requirements in § 35.55 or § 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve—</p> <p style="text-align: center;">* * * * *</p> <p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under §§ 35.100 and 35.200. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or</p> <p>(ii) A residency program director who affirms in writing that the</p>			

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
				attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraph (c)(1) of this section.			
§ 35.300	Use of unsealed byproduct material for which a written	3701:1-58-37	B	In § 35.300, revise the introductory text to read as follows:			

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
	directive is required			<p>A licensee may use any unsealed byproduct material identified in §35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—</p> <p style="text-align: center;">* * * * *</p>			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required	3701:1-58-40	B	<p>In § 35.390, revise the introductory text of paragraph (a), and revise paragraphs (b)(1)(ii)(G) and (b)(2); and add new paragraphs (b)(2)(i) and (ii) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(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)(1)(ii)(G) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To be recognized, a</p>			

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				<p>specialty board shall require all candidates for certification to:</p> <p>* * * *</p> <p>(b)(1) * * *</p> <p>(ii) * * *</p> <p>(G) Administering dosages of radioactive drugs to patients or human research subjects from the three categories in this paragraph. Radioactive drugs containing radionuclides in categories not included in this paragraph are regulated under § 35.1000. This work experience must involve a minimum of three cases in each of the following categories for which the individual is requesting authorized user status—</p> <p>(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;</p> <p>(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-1312;</p>			

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				<p>(3) Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or photon energy of less than 150 keV, for which a written directive is required; and</p> <p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user for the medical uses authorized under § 35.300 for which the individual is requesting authorized user status. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements and has experience in administering dosages in the same dosage category or</p>			

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
				<p>categories as the individual requesting authorized user status; or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in § 35.57, 35.390, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American</p>			

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				Osteopathic Association and must include training and experience specified in paragraph (b)(1) of this section. * * * * *			
§ 35.392	Training 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)	3701:1-58-41	B	<p>In § 35.392 revise paragraphs (a) and (c)(3); and add new paragraphs (c)(3)(i) and (ii) to read as follows:</p> <p>* * * * *</p> <p>(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. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page.; or</p> <p>* * * * *</p> <p>(c)(1) * * *</p>			

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				<p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or § 35.390(b)(1)(ii)(G)(2); or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least</p>			

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				one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or § 35.390(b)(1)(ii)(G)(2), and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.			
§ 35.394	Training for the oral administration of	3701:1-58-42	B	In § 35.394, revise paragraphs (a) and (c)(3); and add new			

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
	sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries)			<p>paragraphs (c)(3)(i) and (ii) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(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 has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page.; or</p> <p style="text-align: center;">* * * * *</p> <p>(c)(1) * * *</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for</p>			

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
				<p>oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131 for medical uses authorized under § 35.300. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, and has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2); or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements, has experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2), and concurs with the attestation provided by the residency</p>			

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
				program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (c)(1) and (2) of this section.			
§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive	3701:1-58-104	B	<p>In § 35.396 revise and redesignate paragraphs (a)(1), (a)(2), (a)(3), (b)(1), (b)(2), (b)(2)(vi), and (b)(3); and add new paragraphs (b)(3)(i) and (ii) to read as follows:</p> <p>(a) 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—</p> <p>(1) Is an authorized user under § 35.390 for uses listed in §</p>			

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				<p>35.390(b)(1)(ii)(G)(3), or equivalent Agreement State requirements; or</p> <p>(2) Is an authorized user under §§ 35.490, 35.690, or equivalent Agreement State requirements, and who meets the requirements in paragraph (b) of this section; or</p> <p>(3) 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, and who meets the requirements in paragraph (b) of this section.</p> <p>(b) The physician—</p> <p>(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations listed in § 35.390(b)(1)(ii)(G)(3). The training must include—</p> <p>(i) Radiation physics and instrumentation;</p> <p>(ii) Radiation protection;</p>			

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				<p>(iii) Mathematics pertaining to the use and measurement of radioactivity;</p> <p>(iv) Chemistry of byproduct material for medical use; and</p> <p>(v) Radiation biology; and</p> <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administrations listed in § 35.390(b)(1)(ii)(G)(3). A supervising authorized user who meets the requirements in §§ 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status. The work experience must involve—</p> <p>(i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys;</p>			

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				(ii) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; (iii) Calculating, measuring, and safely preparing patient or human research subject dosages; (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and (vi) Administering dosages to patients or human research subjects, that include at least three cases of the parenteral administrations as specified in § 35.390(b)(1)(ii)(G)(3); and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b)(1)			

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				<p>and (2) of this section, and is able to independently fulfill the radiation safety-related duties as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user who meets the requirements in § 35.390, 35.396, or equivalent Agreement State requirements, must have experience in administering dosages in the same category or categories as the individual requesting authorized user status; or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an</p>			

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				authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, has experience in administering dosages in the same dosage category or categories as the individual requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (2) of this section.			
§ 35.400	Use of sources for manual brachytherapy	3701:1-58-43	C	<p>In § 35.400 revise paragraphs (a) and (b) to read as follows:</p> <p>A licensee must use only brachytherapy sources:</p>			

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				<p>(a) Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy uses that are not explicitly listed in the Sealed Source and Device Registry, but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry; or</p> <p>(b) In research to deliver therapeutic doses for medical use in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.</p>			
§ 35.433	Strontium-90 sources for ophthalmic treatments	3701:1-58-49	B: 35.433(a) (The compatibility category for 35.433(a) has changed from H&S to B).	In § 35.433, revise paragraph (a), add new paragraphs (b), (b)(1) and (2), and redesignate paragraph (c) to read as follows:			

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			<p>H&S: 35.433(b), (b)(1) and (b)(2)</p> <p>D: 35.433(c)</p>	<p>(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:</p> <p>(1) An authorized medical physicist; or</p> <p>(2) An individual who:</p> <p>(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and</p> <p>(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and</p>			

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				<p>(iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and</p> <p>(iv) Has documented training in:</p> <p>(A) The creation, modification, and completion of written directives;</p> <p>(B) Procedures for administrations requiring a written directive; and</p> <p>(C) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.</p> <p>(b) The individuals who are identified in paragraph (a) of this section must:</p> <p>(1) 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; and</p> <p>(2) Assist the licensee in developing, implementing, and</p>			

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				<p>maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.</p> <p>(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433.</p>			
§ 35.490	Training for use of manual brachytherapy sources	3701:1-58-51	B	<p>In § 35.490, revise the introductory text of paragraphs (a) and (b)(1)(ii), and paragraph (b)(3), and add new paragraphs (b)(3)(i) and (ii) to read as follows:</p> <p style="text-align: center;">* * * * *</p>			

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				<p>(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty board shall require all candidates for certification to:</p> <p>* * * *</p> <p>(b)(1) * * *</p> <p>(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, at a medical facility authorized to use byproduct materials under § 35.400, involving—</p> <p>* * * *</p>			

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				<p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and is able to independently fulfill the radiation safety-related duties as an authorized user of manual brachytherapy sources for the medical uses authorized under §35.400. The attestation must be obtained from either:</p> <p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements; or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, and concurs with the attestation provided by the residency program director.</p>			

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				The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (b)(2) of this section.			
§ 35.491	Training for ophthalmic use of strontium-90	3701:1-58-52	B	<p>In § 35.491, revise paragraph (b)(3) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(b) * * *</p> <p>(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section</p>			

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				and is able to independently fulfill the radiation safety-related duties as an authorized user of strontium-90 for ophthalmic use.			
§ 35.500	Use of sealed sources and medical devices for diagnosis	3701:1-58-53	C (The compatibility category for 35.500(a) was changed from [C] to C)	<p>In § 35.500 revise paragraph (a), and add new paragraphs (b) and (c) to read as follows:</p> <p>(a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.</p> <p>(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are</p>			

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				<p>approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry.</p> <p>(c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.</p>			
§ 35.590	Training for use of sealed sources and medical devices for diagnosis.	3701:1-58-54	B	<p>In § 35.590 revise paragraph (a), add new paragraph (b), and redesignate paragraphs (c) and (d) to read as follows:</p> <p>Except as provided in § 35.57, the licensee shall require the</p>			

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				<p>authorized user of a diagnostic sealed source or a device authorized under § 35.500 to be a physician, dentist, or podiatrist who—</p> <p>(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (c) and (d) of this section and whose certification has been recognized by the Commission or an Agreement State. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page; or</p> <p>(b) Is an authorized user for uses listed in § 35.200 or equivalent Agreement State requirements; or</p> <p>(c) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the</p>			

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				device. The training must include— (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; and (d) Has completed training in the use of the device for the uses requested.			
§ 35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	3701:1-58-55	C	In § 35.600 revise paragraphs (a) and (b) to read as follows: (a) A licensee must only use sealed sources: (1) Approved and as provided for in the Sealed Source and Device Registry in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units to deliver therapeutic doses for medical uses: or (2) In research involving photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units in			

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				<p>accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.</p> <p>(b) A licensee must use photon-emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:</p> <p>(1) Approved in the Sealed Source and Device Registry to deliver a therapeutic dose for medical use. These devices may be used for therapeutic medical treatments that are not explicitly provided for in the Sealed Source and Device Registry, but must be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or</p> <p>(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA</p>			

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				provided the requirements of § 35.49(a) are met.			
§ 35.610	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3701:1-58-58	H&S	<p>In § 35.610, add new paragraph (d)(1) and revise paragraphs (d) and (g) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.</p> <p>(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as</p>			

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				<p>appropriate to the individual's assigned duties. The instructions shall include instruction in—</p> <p>(i) The procedures identified in paragraph (a)(4) of this section; and</p> <p>(ii) The operating procedures for the unit.</p> <p style="text-align: center;">* * * * *</p> <p>(g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.</p>			
§ 35.655(a)	Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	3701:1-58-69	H&S	<p>In § 35.655, revise the section heading and paragraph (a) to read as follows:</p> <p>(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full inspection servicing shall not</p>			

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				<p>exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.</p> <p>* * * * *</p>			
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	3701:1-58-71	B	<p>In § 35.690, revise the introductory text of paragraphs (a) and (b)(1)(ii), and (b)(3), and add new paragraphs (b)(3)(i) and (ii) to read as follows:</p> <p>* * * * *</p> <p>(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) of this section. The names of board certifications that have been recognized by the Commission or an Agreement State are posted on the NRC's Medical Uses Licensee Toolkit Web page. To have its certification process recognized, a specialty</p>			

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				<p>board shall require all candidates for certification to:</p> <p>* * * *</p> <p>(b)(1) * *</p> <p>(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, at a medical facility that is authorized to use byproduct materials in § 35.600, involving—</p> <p>* * *</p> <p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (b)(1), (b)(2), and (c) of this section; and is able to independently fulfill the radiation safety-related duties as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The attestation must be obtained from either:</p>			

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				<p>(i) A preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status; or</p> <p>(ii) A residency program director who affirms in writing that the attestation represents the consensus of the residency program faculty where at least one faculty member is an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, for the type(s) of therapeutic medical unit for which the individual is requesting authorized user status, and concurs with the attestation provided by the residency program director. The residency training program must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or</p>			

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				the Royal College of Physicians and Surgeons of Canada or the Council on Postdoctoral Training of the American Osteopathic Association and must include training and experience specified in paragraphs (b)(1) and (b)(2) of this section.			
§ 35.2024	Records of authority and responsibilities for radiation protection programs	3701:1-58-73	D	<p>In § 35.2024, add new paragraph (c) to read as follows:</p> <p style="text-align: center;">* * * * *</p> <p>(c) For each Associate Radiation Safety Officer appointed under § 35.24(b), the licensee shall retain, for 5 years after the Associate Radiation Safety Officer is removed from the license, a copy of the written document appointing the Associate Radiation Safety Officer signed by the licensee's management.</p>			
§ 35.2310	Records of safety instruction	3701:1-58-86	D	Revise § 35.2310 to read as follows:			

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				A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and the operational and safety instructions required by § 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.			
§ 35.2655	Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	3701:1-58-100	D	<p>In § 35.2655, revise the section heading and paragraph (a) to read as follows:</p> <p>(a) A licensee shall maintain a record of the full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of the use of the unit.</p> <p style="text-align: center;">* * * * *</p>			
§ 35.3045	Report and notification of a medical event	3701:1-58-101	C	<p>In § 35.3045, revise paragraph (a) to read as follows:</p> <p>(a) A licensee shall report any event as a medical event, except</p>			

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				<p>for an event that results from patient intervention, in which—</p> <p>(1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in—</p> <p>(i) 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</p> <p>(A) The total dose delivered differs from the prescribed dose by 20 percent or more;</p> <p>(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or</p> <p>(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.</p>			

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				<p>(ii) A dose that exceeds 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 from any of the following—</p> <p>(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;</p> <p>(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;</p> <p>(C) An administration of a dose or dosage to the wrong individual or human research subject;</p> <p>(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or</p> <p>(E) A leaking sealed source.</p> <p>(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:</p> <p>(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the</p>			

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				<p>administration had been given in accordance with the written directive prepared or revised before administration; and</p> <p>(B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.</p> <p>(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—</p> <p>(i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive;</p> <p>(ii) The total source strength administered outside of the treatment site exceeding</p>			

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				<p>20 percent of the total source strength documented in the post-implantation portion of the written directive; or</p> <p>(iii) An administration that includes any of the following:</p> <p>(A) The wrong radionuclide;</p> <p>(B) The wrong individual or human research subject;</p> <p>(C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or</p> <p>(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.</p> <p style="text-align: center;">* * * *</p>			
§ 35.3204 new	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-	3701:1-58-105	C	<p>Add a new § 35.3204 to subpart M to read as follows:</p> <p>(a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible</p>			

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	85 concentrations			<p>concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken.</p> <p>(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate</p>			

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				was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.			