

Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35
(70 FR 16336) RATS ID # 2005-2 Effective date 4/29/05
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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
§ 35.2	Definitions	<p align="center">§175.0 2(a) (153)</p> <p align="center">§175.0 2(a) (174)</p>	<p align="center">B</p> <p align="center">B</p>	<p>In § 35.2, the definition “Radiation Safety Officer” is amended by republishing the introductory text and revising paragraph (1) of the definition, and the definition of “Preceptor” is revised to read as follows:</p> <p align="center">* * * * *</p> <p><i>Preceptor</i> 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, or a Radiation Safety Officer.</p> <p align="center">* * * * *</p> <p><i>Radiation Safety Officer</i> means an individual who—</p> <p>(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</p> <p align="center">* * * * *</p>	<p align="center">N</p>		<p align="center">Definition newly added</p>
§ 35.8	Information collection requirements: OMB approval.		<p align="center">D</p>	<p align="center">N/A</p>			
§ 35.10	Implementation	<p align="center">§175. 103(a)</p>	<p align="center">D</p>	<p align="center">N/A</p>			

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§ 35.13	License amendments	§175.103(a)(7)	D	N/A			
§ 35.14	Notifications	§175.103(a)(8)	D	N/A			
§ 35.50	Training for Radiation Safety Officer	§175.103(j)(1)	B	<p>In § 35.50, paragraph (a), the introductory text of paragraph (b)(1)(I), paragraphs (b)(1)(ii)(G), and (c) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (d) and (e) are added to read as follows:</p> <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 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:</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</p>	N		

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				<p>professional experience in health physics (graduate training may 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 Commission or an Agreement State; or</p> <p>(B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.290, 35.390, or, before October 24, 2005, §§ 35.920, or 35.930; and</p> <p>(iii) Pass an examination, administered by diplomates of the</p>			

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				<p>specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear medicine physics and in radiation safety; or (b) * * * (1) * * * (i) 200 hours of classroom and laboratory training in the following areas- (ii) * * * (G) Disposing of byproduct material; 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) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or (2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and, (d) Has obtained written attestation, signed by a preceptor Radiation</p>			

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				<p>Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and</p> <p>(e) 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, 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.	§175.103(j)(2)	B	<p>In § 35.51, paragraphs (a) and (b) are revised, and paragraph (c) is added to read as follows:</p> <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 paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an</p>			

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				<p>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:</p> <p>(1) 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>(2) Have 2 years of full-time practical training and/or supervised experience in medical physics—</p> <p>(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or</p> <p>(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in §§ 35.490 or 35.690, or, before October 24, 2005, authorized users who meet the requirements in §§ 35.940 or 35.960; and</p> <p>(3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam</p>			

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				<p>therapy, brachytherapy, and stereotactic radiosurgery; or</p> <p>(b)(1) Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of fulltime work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include:</p> <ul style="list-style-type: none"> (i) Performing sealed source leak tests and inventories; (ii) Performing decay corrections; (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and (iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and <p>(2) Has obtained written attestation</p>			

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				<p>that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently 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, or, before October 24, 2005, § 35.961, 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; and</p> <p>(c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.</p>			
§ 35.55	Training for an authorized	§175.103(j)	B	In § 35.55, paragraphs (a), (b)(1)(I) introductory text, and (b)(2) are	N		

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	nuclear pharmacist.	(3)		<p>revised to read as follows:</p> <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 (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:</p> <p>(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;</p> <p>(2) Hold a current, active license to practice pharmacy;</p> <p>(3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and</p> <p>(4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution,</p>			

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				<p>health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or (b) * * * (1) * * * (i) 200 hours of classroom and laboratory training in the following areas— * * * * *</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.</p>			
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear	§175.103(j)(14)	B	<p>Section 35.57 is revised to read as follows:</p> <p>(a)(1) An individual identified as 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 §§</p>			

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	pharmacist.			<p>35.50, 35.51, or 35.55, respectively.</p> <p>(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 permittee 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, respectively.</p> <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 Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of this part.</p> <p>(2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued</p>			

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				by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of this part.			
§ 35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material	§175.103(c)(9)	C, paragraphs (a) and (b) D- paragraphs (c) and(d)	In § 35.75, paragraph (a), footnote 1, remove “(draft)”.			
§ 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	In § 35.100, paragraph (b)(2) is revised to read as follows: (b) (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			
§ 35.190	Training for uptake, dilution,	§175.103(j)	B	In § 35.190, paragraphs (a), the introductory text of (c)(1),			

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	and excretion studies.	(4)		<p>(c)(1)(ii)(B) and (c)(2) are revised to read as follows:</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)(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:</p> <p>(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 that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and</p> <p>(2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or</p> <p>* * * * *</p> <p>(c)</p> <p>(1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic</p>			

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				<p>radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include—</p> <p>(ii) * * *</p> <p>(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;</p> <p>* * * * *</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, or, before October 24, 2005, §§ 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.</p>			
§ 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not	§175.103(d)(2)	H&S	<p>In § 35.200, paragraph (b)(2) is revised to read as follows:</p> <p>(b) * * *</p> <p>(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</p>			

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	required.						
§ 35.290	Training for imaging and localization studies.	§175.103(j)(5)	B	<p>In § 35.290, paragraphs (a), (b), the introductory text of (c)(1) and (c)(1)(ii) introductory text, (c)(1)(ii)(B), and (c)(2) are revised to read as follows:</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)(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:</p> <p>(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 paragraphs (c)(1)(i) and (c)(1)(ii) of</p>			

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				<p>this section; and</p> <p>(2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or</p> <p>(b) Is an authorized user under § 35.390 and meets the requirements in § 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements; or</p> <p>(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum— * * * * *</p> <p>(ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, involving— * * * * *</p> <p>(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;</p>			

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				<p>*****</p> <p>(2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, § 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.</p>			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.	§175.103(j)(6)	B	<p>In § 35.390, paragraph (a), the introductory text of paragraphs (b)(1) and (b)(1)(ii) introductory text, paragraphs (b)(1)(ii)(B), (b)(1)(ii)(G)(1), (3) and (4), and (b)(2) are revised, and paragraph (b)(1)(ii)(F) is removed and reserved.</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) 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</p>			

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				<p>specialty board shall require all candidates for certification to:</p> <p>(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 described in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and</p> <p>(2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or</p> <p>(b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and</p>			

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				<p>experience must include— ***** (ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390 or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b) or, before October 24, 2005, § 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involve— ***** (B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; ***** (G) *** (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; ***** (3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or (4) Parenteral administration of any other radionuclide, for which a written directive is required; and</p>			

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				<p>(2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in § 35.390 or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b), or, before October 24, 2005, § 35.930(b), must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.</p>			
§ 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).	§175.103(j)(7)	B	<p>In § 35.392, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:</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 and who meets the requirements in paragraph (c)(3) of this section. (The</p>			

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				<p>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 ***** (c) * * * (2) * * * (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; ***** (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.392, or 35.394, or, before October 24, 2005, §§ 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(1) or (2).</p>			
§ 35.394	Training for the oral	§175.103(j)	B	In § 35.394, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as			

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	administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).	(8)		<p>follows:</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, 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 * * * * *</p> <p>(c) * * * (2) * * *</p> <p>(ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; * * * * *</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 has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390 or 35.394, or, before October 24, 2005, §§ 35.930 or</p>			

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				35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2).			
§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	§175.103(j)(9)	B	<p>Section 35.396 is added to read as follows:</p> <p>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 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</p>			

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				<p>24, 2005, §§ 35.940 or 35.960; and who meets the requirements in paragraph (d) of this section.</p> <p>(d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include—</p> <ul style="list-style-type: none"> (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Chemistry of byproduct material for medical use; and (v) Radiation biology; and <p>(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390 or 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising</p>			

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				<p>authorized user who meets the requirements in §§ 35.390 or 35.930 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve—</p> <ul style="list-style-type: none"> (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys; (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 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and 			

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				<p>(3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.390, 35.396, or, before October 24, 2005, § 35.930, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, or, before October 24, 2005, § 35.930, must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).</p>			
§ 35.490	Training for use of manual brachytherapy sources.	§175.103(j)(10)	B	<p>In § 35.490, paragraphs (a), (b)(2) and (b)(3) are revised to read as follows:(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</p>			

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				<p>process recognized, a specialty board shall require all candidates for certification to:</p> <p>(1) Successfully complete a minimum of 3 years of residency training in a radiation oncology program 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 Committee on Post-Graduate Training of the American Osteopathic Association; and</p> <p>(2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or</p> <p>(b) * * *</p> <p>(2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, 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</p>			

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				<p>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, signed by a preceptor authorized user who meets the requirements in § 35.490, or, before October 24, 2005, § 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.</p>			
§ 35.491	Training for ophthalmic use of strontium-90.	§175.103(j)(11)	B	<p>In § 35.491, paragraph (b)(3) is revised to read as follows:</p> <p>(b) * * *</p> <p>(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.490 or 35.491, or, before October 24, 2005, §§ 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to</p>			

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				function independently as an authorized user of strontium-90 for ophthalmic use.			
§ 35.590	Training for use of sealed sources for diagnosis.	§175.103(j)(12)	B	<p>In § 35.590, paragraphs (a) and (b) are revised and paragraph (c) is added to read as follows:</p> <p>(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</p> <p>(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—</p> <p>(1) Radiation physics and instrumentation;</p> <p>(2) Radiation protection;(3) Mathematics pertaining to the use and measurement of radioactivity; and</p> <p>(4) Radiation biology; and</p> <p>(c) Has completed training in the use of the device for the uses requested.</p>			
§ 35.690	Training for use of remote afterloader	§175.103(j)(13)	B	<p>In § 35.690, paragraphs (a), (b)(2) and (b)(3) are revised, and paragraph (c) is added to read as</p>			

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	units, teletherapy units, and gamma stereotactic radiosurgery units.			<p>follows:</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)(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:</p> <p>(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 the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and</p> <p>(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</p>			

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				<p>(b) * * *</p> <p>(2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the 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</p> <p>(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 signed by a preceptor authorized user who meets the requirements in § 35.690, or, before October 24, 2005, § 35.960, or equivalent Agreement State</p>			

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				<p>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.</p>			
§ 35.980	Training for an authorized nuclear pharmacist.	§175.103(j)(3)	D	N/A			