Minor Amendments- Part 20, 30, 32, 35, 40, and 70
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06
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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
20. Appendix B	Standards For Protection Against Radiation "List of Elements"		A	In Appendix B to Part 20, ''List of Elements,'' the Element ''Thalium,'' Atomic Number 69, should be changed to read as ''Thulium.''			
20. Appendix D	Standards For Protection Against Radiation "United States Nuclear Regulatory Commission Regional Offices"		D	N/A	N/A		
§ 30.6	Communications		D	N/A	N/A		
§ 32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use		B	**In § 32.72, paragraph (b)(2)(ii) is revised to read as follows:** (b) * * * (2) * * * (ii) This individual meets the requirements specified in 10 CFR 35.55(b) and 35.59 and the licensee has received an approved license amendment			

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	under part 35.			identifying this individual as an authorized nuclear pharmacist, or * * * *			
§ 32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use.		B	**In § 32.74, the introductory text of paragraph (a) is revised to read as follows:** (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, and 35.600 of this chapter will be approved if: * * * * *			
§ 35.2	Definitions		B	*Authorized medical physicist* means an individual who— (1) Meets the requirements in §§ 35.51(a) and 35.59; or			
§ 35.2	Definitions		B	*Authorized nuclear pharmacist* means a pharmacist who— (1) Meets the requirements in §§ 35.55(a) and 35.59; or			
§ 35.2	Definitions		B	*Authorized user* means a physician, dentist, or podiatrist			

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				who— (1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or			
§ 35.2	Definitions		B	*Radiation Safety Officer* means an individual who— (1) Meets the requirements in §§ 35.50(a) or (c)(1) and 35.59; or			
§ 35.2	Definitions		D	*Medical event*	N/A		
§ 35.8	Information collection requirements: OMB approval.		D	N/A	N/A		
§ 35.10	Implementation		D	N/A	N/A		
§ 35.13	License Amendments		D	N/A	N/A		
§ 35.14	Notifications		D	N/A	N/A		
§ 35.49	Suppliers for sealed sources or devices for medical use.		C	**In § 35.49, paragraph (b) is revised to read as follows:** (b) Sealed sources or devices noncommercially transferred from a Part 35 licensee or an			

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				Agreement State medical use licensee.			
§ 35.50	Training for Radiation Safety Officer.		B	**In § 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:** (a) * * * (2) * * * (ii) * * * (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 or 35.390;			
§ 35.51	Training for an authorized medical physicist.		B	**In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:** (a) * * * (2) * * * (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; and * * * * *			

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				(b) * * * (2) Has obtained written attestation 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 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 * * * * *			
§ 35.59	Recentness of training.		B	**Section 35.59 is revised to read as follows:** The training and experience specified in Subparts B, D, E, F, G, and H of this part must			

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				have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.			
§ 35.65	Authorization for calibration, transmission, and reference sources.		D	N/A	N/A		
§ 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.		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 * * * * *			
§ 35.190	Training for uptake, dilution, and excretion studies.		B	**In § 35.190, paragraphs (b), (c)(1)(ii) and (c)(2) are revised to read as follows:** (b) Is an authorized user under §§ 35.290, 35.390, or equivalent Agreement State requirements; or (c)(1)* * * (ii) Work experience, under the			

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				supervision of an authorized user who meets the requirements in §§ 35.190, 35.290, 35.390, or equivalent Agreement State requirements, involving— * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390, 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.			
§ 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.		H&S	**In § 35.200, 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 * * * * *			

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§ 35.290	Training for imaging and localization studies.		B	**In § 35.290, paragraphs (a)(1), (b), the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (a) * * * (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 imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and * * * * * (b) Is an authorized user under § 35.390 and meets the requirements in 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or (c)(1) * * * (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 equivalent Agreement State requirements, involving— * * * *			

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				(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 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.			
§ 35.300	Use of unsealed byproduct material for which a written directive is required.		H&S	**In § 35.300, 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, 35.390, or * * * * *			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.		B	**In § 35.390, paragraphs (b)(1)(ii) introductory text, (b)(1)(ii)(G)(*3*), and (b)(2) are revised to read as follows:** (b)(1) * * * (ii) Work experience, under the			

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				supervision of an authorized user who meets the requirements in § 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experiencein 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— * * * * * (G) * * * (*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 * * * * * (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			

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				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 equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(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.			
§ 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).		B	**In § 35.392, paragraph (b), the introductory text of paragraph ©)(2) and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(*1*) or (*2*), § 35.394, or equivalent Agreement State requirements; or (c) * * * (2) Has work experience, under the supervision of an			

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				authorized user who meets the requirements in §§ 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising 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)(*1*) or (*2*). The work experience must involve— * * * * * (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, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering			

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				dosages as specified in § 35.390(b)(1)(ii)(G)(*1*) or (*2*).			
§ 35.394	Training for the oral administration of sodium iodide I–131 requiring a written directive in quantities greater than 1.22 gigabecquerels (33 millicuries).		B	**In § 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under § 35.390 for uses listed in § 35.390(b)(1)(ii)(G)(*2*) or equivalent Agreement State requirements; or (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.394, or equivalent Agreement State requirements. A supervising 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*). The work experience must involve— * * * (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			

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				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, 35.394, 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.		B	**In § 35.396, the introductory paragraph, paragraphs (a), (b), (c), the introductory text of paragraphs (d)(1) and (d)(2), paragraph (d)(2)(vi), and paragraph (d)(3) are revised to read as follows:** 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 for uses listed in §§ 35.390(b)(1)(ii)(G)(*3*) or 35.390(b)(1)(ii)(G)(*4*), or			

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				equivalent Agreement State requirements; or (b) Is an authorized user under §§ 35.490, 35.690, 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, and who meets the requirements in paragraph (d) of this section. (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— * * * * *			

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				(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390, 35.396, 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 authorized user who meets the requirements in § 35.390 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— * * * * * (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			

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				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 (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 equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, 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*).			
§ 35.490	Training for use		B	**In § 35.490, the introductory text of**			

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	of manual brachytherapy sources.			**paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 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			

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				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 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.			
35.491	Training for ophthalmic use of strontium-90.		B	**In § 35.491, paragraphs (a) and (b)(3) are revised to read as follows:** (a) Is an authorized user under § 35.490 or equivalent Agreement State requirements; or (b) * * * (3) Has obtained written attestation, signed by a			

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				preceptor authorized user who meets the requirements in §§ 35.490, 35.491, 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 function independently as an authorized user of strontium-90 for ophthalmic use.			
35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.		B	**In § 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or, equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in § 35.690 or			

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

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				authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and * * * * *			
§ 40.5	Communications		D	N/A	N/A		
§ 70.5	Communications		D	N/A	N/A		
§ 70.14	Foreign military aircraft		D	N/A	N/A		