Medical Use of Byproduct Material—Authorized User Clarification, Part 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
§ 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 §§ 35.57, 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			

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				electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and * * * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(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, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is			

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				requesting authorized medical physicist status; and * * * * *			
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist**.**		B	**In § 35.57, a new paragraph (c) is added to read as follows:** (c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.			
§ 35.190	Training for uptake, dilution, and excretion studies.		B	**In § 35.190, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (c)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 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 §§ 35.57, 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.			
§ 35.290	Training for imaging and localization studies.		B	**In § 35.290, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (c)(1) * * * (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 Agreement State requirements, involving—			

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				* * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 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.			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.		B	**In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:** (b)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in			

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				§ 35.390(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— * * * * * (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 §§ 35.57, 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.,			

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				§ 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, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 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 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 competency sufficient to function			

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				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 §§ 35.57, 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 dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(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, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have			

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				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 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 §§ 35.57, 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 osages as specified in § 35.390(b)(1)(ii)(G)(2).			
§ 35.396	Training for the parenteral administration of unsealed		B	**In § 35.396, the introductory text of paragraph (d)(2) and paragraph (d)(3) are revised to read as follows:**			

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	byproduct material requiring a written directive.			(d) * * * (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 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— * * * * * (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			

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				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 §§ 35.57, 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 of manual brachytherapy sources.		B	**In § 35.490, 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 §§ 35.57, 35.490, or equivalent			

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				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 §§ 35.57, 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 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 §§ 35.57, 35.490, or equivalent			

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				Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (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, paragraph (b)(3) is revised to read as follows:** (b) * * * (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 paragraph (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		B	**In § 35.690, the introductory**			

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	use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.			**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 §§ 35.57, 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 §§ 35.57, 35.690, 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			

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				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 paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (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 §§ 35.57, 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			