

**Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10**

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
§32.72 (b)(5)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.		B	<p>In Sec. 32.72, paragraph (b)(5) is revised to read as follows:</p> <p>(b) * * *</p> <p>(5) Shall provide to the Commission a copy of each individual's:</p> <p>(i)(A) Certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in Sec. 35.55(a) of this chapter with the written attestation signed by a preceptor as required by Sec. 35.55(b)(2) of this chapter; or</p> <p>(B) The Commission or Agreement State license; or</p> <p>(C) The permit issued by a licensee of broad scope; and</p> <p>(ii) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.</p>			

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§32.74(a)	Manufacture and distribution of sources or devices containing byproduct material for medical use		B	<p>In Sec. 32.74, the introductory text of paragraph (a) is revised to read as follows:</p> <p>(a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in Sec. Sec. 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if: * * * * *</p>			
§35.2	Definitions: Medium dose-rate remote afterloader		D	N/A	N/A		
§35.41(b)(4)	Procedures for administrations requiring a written directive		D	N/A	N/A		
§35.75(a)	Release of individuals containing unsealed byproduct material or implants		C	<p>In Sec. 35.75, the text of paragraph (a) is republished and footnote 1 is revised to read as follows:</p> <p>a) A licensee may authorize the release from its control of any</p>			

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	containing byproduct material			<p>individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).\1\</p> <p>*****</p> <p>\1\ The current revision of NUREG-1556, Vol. 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses" describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).</p>			
§35.92	Decay-in-storage is an: "H&S" for States authorizing this activity and "D" for States that do not authorize this activity	H&S		<p>In Sec. 35.92, the introductory text of paragraph (a) is revised to read as follows:</p> <p>(a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if it--</p> <p>*****</p>			

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§35.190	Training for uptake, dilution, and excretion studies	B		<p>In Sec. 35.190, paragraph (a)(1) is revised to read as follows:</p> <p>(a) * * *</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 as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and</p> <p>* * * * *</p>			
§35.290	Training for imaging and localization studies	B		<p>10. In Sec. 35.290, paragraph (a)(1) is revised to read as follows:</p> <p>(a) * * *</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 imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and</p> <p>* * * * *</p>			