

Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments
10 CFR Parts 30, 32, and 35
(83 FR 33046, Published July 16, 2018)
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Effective Date: January 14, 2019
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ARKANSAS CROSS REFERENCE

Change to NRC Section	Title	State Section	Comp. Category	Comments
§ 30.34(g)	Terms and conditions of licenses	RH-409.j.	B	
§ 32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35	RH-405.I.	B	Incorrect 21 CFR reference in (a)(2)(i), replacing with “Subpart B”
§ 35.2	Definitions	RH-8100	B: for Associate Radiation Safety Officer and Ophthalmic physicist; D: for Preceptor	See comment at § 35.3045.
§ 35.12	Application for license, amendment, or renewal	RH-8010	D	
§ 35.13	License amendments	RH-8011	D	
§ 35.14	Notifications	RH-8020	D	
§ 35.15	Exemptions regarding Type A specific licenses of broad scope	RH-8025.	D	

Change to NRC Section	Title	State Section	Comp. Category	Comments
§ 35.24 (b) and (c)	Authority and responsibilities for the radiation protection program.	RH-8300.b.	H&S: 35.24(b)	
		RH-8300.c.	D: 35.24(c)	
§ 35.40	Written directives	RH-8307.	H&S	
§ 35.41	Procedures for administrations requiring a written directive	RH-8308.	H&S	
§ 35.50	Training for Radiation Safety Officer and Associate Radiation Safety Officer	RH-8315.	B	(c)(3) – The second use of “license” was changed to “licensee.”
§ 35.51	Training for an authorized medical physicist.	RH-8316.	B	
§ 35.55	Training for an authorized nuclear pharmacist.	RH-8317.	B	(a)(1) – “American Council on Pharmaceutical Education” should be “Accreditation Council for Pharmacy Education.”
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	RH-8318.	B Except for D: 35.57(a)(4) and (b)(3)	
§ 35.65	Authorization for calibration, transmission, and reference sources.	RH-8404.	D	
§ 35.190	Training for uptake, dilution, and excretion studies.	RH-8510.	B	
§ 35.204	Permissible molybdenum-99, strontium-82, and strontium-85 concentrations	RH-8531.	H&S	
§ 35.290	Training for imaging and localization studies	RH-8540.	B	

Change to NRC Section	Title	State Section	Comp. Category	Comments
§ 35.300	Use of unsealed byproduct material for which a written directive is required	RH-8550.	B	
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required	RH-8560.	B	Added footnote
§ 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)	RH-8570.	B	
§ 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)	RH-8580.	B	
§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive	RH-8590.	B	
§ 35.400	Use of sources for manual brachytherapy	RH-8600.	C	
§ 35.433	Strontium-90 sources for ophthalmic treatments	RH-8608.	B: 35.433(a) (Changed from H&S to B) H&S: 35.433(b), (b)(1) and (b)(2) D: 35.433(c)	RH-8605. (§ 35.432 – H&S): e. and g. were deleted (became our new RH-8608.). New e. was created. RH-8718. (§ 35.2432 – Comp D): revised. RH-8719. (§ 35.2433 – Comp D): revised.

Change to NRC Section	Title	State Section	Comp. Category	Comments
§ 35.490	Training for use of manual brachytherapy sources	RH-8610.	B	
§ 35.491	Training for ophthalmic use of strontium-90	RH-8615.	B	
§ 35.500	Use of sealed sources and medical devices for diagnosis	RH-8620.	C (For 35.500(a) was changed from [C] to C)	RH-8310. (§ 35.49 – Comp [C]): minor revisions.
§ 35.590	Training for use of sealed sources and medical devices for diagnosis.	RH-8621.	B	
§ 35.600	Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	RH-8630.	C	
§ 35.610	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	RH-8633.	H&S	Added par. g., to include § 35.2610 (Comp D) information.
§ 35.655(a)	Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	RH-8646.	H&S	
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	RH-8660.	B	
§ 35.2024	Records of authority and responsibilities for radiation protection programs	RH-8700.	D	
§ 35.2310	Records of safety instruction	RH-8715.	D	

Change to NRC Section	Title	State Section	Comp. Category	Comments
§ 35.2655	Records of full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units	RH-8728.	D	
§ 35.3045	Report and notification of a medical event	RH-8800.	C	<p>§ 35.3045(g) requirements are partially in RH-8703.</p> <p>RH-8100 (§ 35.2) definition of “misadministration” revised to include RH-8800.a. and b. (§ 35.3045(a) and (b)) -- Compatibility D.</p>
§ 35.3204 new	Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations	RH-8805.	C	