

COMPATIBILITY DESIGNATIONS FOR FINAL 10 CFR PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL, PART 20 & PART 32

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§20.1002	Scope	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§20.1003	Definitions		
	Occupational dose	A	
	Public dose	A	
§20.1301 (a) and (c)	Dose limits for individual members of the public	A	
§32.72 (b)(1) and (b)(2)(ii)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35	B	
§32.74 (a) and (a)(3)	Manufacture and distribution of sources or devices containing byproduct material for medical use	B	
§35.1	Purpose and scope	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2	Definitions		
	Address of use	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Agreement State	[B]	This definition also appears in 10 CFR §150.3(b). For purposes of compatibility, the language of the Part 150 definition should be used and it is assigned to Compatibility Category B.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Area of use	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	*Authorized medical physicist	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
	* Authorized nuclear pharmacist	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
	* Authorized user	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
	Brachytherapy	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Brachytherapy source	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Client's address	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Dedicated check source	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Dentist	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	High dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Low dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Management	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Manual Brachytherapy	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Medical event	D	Does not meet any of the criteria of Category A, B, C, or H&S since the term was not defined in this section, but is defined in 35.3045(a).
	Medical institution	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	* Medical use	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(e), this definition was identified as a Category C. The essential objectives of this definition should be adopted because the lack of it could potentially impair effective communication. The essential objective of this definition is to establish a common understanding regarding the application of radioactive materials and the radiation therefrom to humans as directed by an authorized user.
	Medium dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Mobile medical service	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Output	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Patient intervention	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Pharmacist	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Physician	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Podiatrist	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Preceptor	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	* Prescribed dosage	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(c) and (2)(e), this definition was identified as a Category C. The essential objectives of this definition should be adopted because the lack of it could potentially preclude an effective review or evaluation by the Commission and Agreement State programs for agreement materials with respect to protection of public health and safety and impair effective communication. The essential objective of this definition is to establish a common understanding regarding the correct quantity of radiopharmaceutical activity prescribed by the authorized user for administration to a patient.
	* Prescribed dose	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(c) and (2)(e), this definition was identified as a Category C. The essential objective of this definition should be adopted because the lack of it could potentially preclude an effective review or evaluation by the Commission and Agreement State programs for agreement materials with respect to protection of public health and safety and impair effective communication. The essential objective of this definition is to establish a common understanding regarding the correct quantity of radiopharmaceutical activity prescribed by the authorized user for administration to a patient.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Pulsed dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	* Radiation safety officer	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
	Sealed source	[B]	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (2)(c), this definition was identified as a Category B because it is a definition of a product that licensees routinely transport in multiple jurisdictions. This definition also appears in 10 CFR §30.4. For purposes of compatibility, the language of the Part 30 definition should be used and it is assigned to Compatibility Category B.
	Sealed source and device registry	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Stereotactic radiosurgery	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Structured educational program	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Teletherapy	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Temporary jobsite	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Therapeutic dosage	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Therapeutic dose	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	* Treatment site	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(c) and (2)(e), this definition was identified as a Category C. The essential objective of this definition should be adopted because the lack of it could potentially preclude an effective review or evaluation by the Commission and Agreement State programs for agreement materials with respect to protection of public health and safety and impair effective communication. The essential objective of this definition is to establish a common understanding of the correct anatomical description of the area intended to receive a radiation dose.
	Type of use	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Unit dosage	D	Does not meet any of the criteria of Category A, B, C, or H&S.
	Written directive	D	Does not meet any of the criteria of Category A, B, C, or H&S since the term was not defined in this section, but is defined in 35.40.
§35.5	Maintenance of records	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.6	Provisions for the protection of human research subjects	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (1), this requirement was designated a Category C. The lack of this requirement could create a gap whereby the Federal Policy for the Protection of Human Subjects would not be applied. The essential objective of this requirement is to assure the consistent application of the Federal Policy.
§35.7	FDA, other Federal, and State requirements	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.8	Information collection requirements: OMB Approval	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.10	Implementation	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.11	License required	[C]	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), this requirement was designated a Category C because Agreement States should adopt the Part 30 provision as a minimum requirement for their licensees. The general requirement for activities to be licensed appears in 10 CFR § 30.3 which has been designated compatibility category C. If an Agreement State has adopted 10 CFR § 30.3, it is not necessary to adopt this section since the requirements are covered in Part 30.3 and this section would be a duplication of those provisions.
§35.12	Application for license, amendment, or renewal	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.13	License amendments	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.14	Notifications	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.15	Exemptions regarding Type A specific licenses of broad scope	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.18	License issuance	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.19	Specific exemptions	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.24	Authority and responsibilities for the radiation protection program	D - paragraphs (a) (1), (a) (2), (a)(3), (c), (d), (e), (g) and (h) H&S- paragraph (b) and (f)	<p>Paragraphs (a)(1), (a)(2), (a)(3), (d) and (g), do not meet any of the criteria of Category A, B, C, or H&S. In addition, paragraph (a)(2) was not required because the definitions and training of authorized users, authorized nuclear pharmacists, radiation safety officers and authorized medical physicists are required as a matter of compatibility and would prevent an unqualified individual from working in these positions. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (E), paragraphs (b) and (f) were designated Category H&S because they assist in establishing a minimum level of safety for the medical use of agreement materials since they deal with the implementation of the radiation protection program. The essential objective of paragraph (b) is to assure that the RSO agrees to implement the radiation safety program. The essential objective of paragraph (f) is to require that management provides the RSO with sufficient authority, time and resources to identify radiation problems, initiate corrective actions, stop unsafe operations and verify the implementation of corrective actions.</p> <p>The H&S two or fewer failure test scenario: If unapproved changes are made to the radiation safety program, or if unsafe operations are not stopped, the public and workers could receive radiation exposures in excess of the radiation protection limits in Parts 20 & 35 and a medical event may occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.26	Radiation protection program changes	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.27	Supervision	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a worker overexposure and medical event. The essential objectives of this requirement are to assure the instruction of the supervised individuals in radiation safety procedures and policies, and for the supervised individuals to request clarification from authorized users as needed.</p> <p>The H&S two or fewer failure test scenario: If a licensee fails to instruct supervised individuals in radiation safety procedures, regulations and license conditions and radioactive material is mishandled, the public and workers could receive radiation exposures in excess of limits and a medical event could occur.</p>
§35.40	Written directives	H&S, (a) and (b) except paragraphs (c) and (d) are D	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that correct information on the prescribed dose is communicated to the licensee's staff.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not use written directives for therapeutic medical use and a misinterpretation of the authorized users' orders occurs, a medical event could occur.</p>
§35.41	Procedures for administrations requiring a written directive	H&S, except paragraphs (b) and (c) are D	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure patient identification and dose verification prior to administration to human beings.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not verify patient identity, radioactive material or radiation could be administered to the wrong person, and an exposure in excess of limits could occur. In addition, if the prescribed dose is not verified before administration, the prescribed dose could be exceeded and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.49	Suppliers for sealed sources or devices for medical use	[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires that licensees, authorized to possess and use sealed sources or devices for medical use, obtain these products from a licensed vendor. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.
§35.50	Training for Radiation Safety Officer	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§35.51	Training for an authorized medical physicist	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§35.55	Training for an authorized nuclear pharmacist	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§35.59	Recentness of training	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§35.60	Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure the measurement of the dosage with proper instrumentation prior to administration.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not properly measure the dosage with the appropriate instrumentation, the administered dose could differ from the prescribed dose and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.61	Calibration of survey instruments	H&S, except paragraphs (a)(3) & (c) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials. Without properly calibrated survey instruments over exposures could occur and is needed to demonstrate compliance with Part 20 requirements. The essential objective of this requirement is to assure the possession of calibrated survey instruments.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not calibrate or check survey instruments as required by this rule, and a contamination event occurs, radiation levels in excess of Part 20 limits could occur.</p>
§35.63	Determination of dosages of unsealed byproduct material for medical use	H&S, except paragraph (e) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S because it assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure proper determination of prescribed dosages by proper measurement and/or calculation prior to human use.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not measure a dosage, and a preparation error occurs, a medical event could occur.</p>
§35.65	Authorization for calibration, transmission and reference sources	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.67	Requirements for possession of sealed sources and brachytherapy sources	H&S, except paragraphs (d) & (f) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure. The essential objective of this requirement is to assure the safe handling, periodic leak testing, and inventory of sealed sources.</p> <p>The H&S two or fewer failure test scenario: if the licensee does not follow the manufacturers' instructions, including testing for leakage, and a source is damaged or misplaced, public and worker exposures in excess of limits and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.69	Labeling of vials and syringes	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure. The essential objective of this requirement is to make sure that licensees develop, implement and maintain written procedures for labeling syringes, syringe shields, and vial shields that contain radiopharmaceuticals.</p> <p>The H&S two or fewer failure test scenario: If the syringe, syringe shield, or vial shield is not labeled, then the wrong radiopharmaceutical could be administered, and a medical event could occur. If syringe and vial shields are not used, then a worker could be overexposed.</p>
§35.70	Surveys of ambient radiation exposure rate	H&S, except paragraphs (b) and (c) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and worker overexposure. The essential objective of this requirement is to assure that daily radiation surveys are performed in areas where therapeutic radiopharmaceuticals are used.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not conduct surveys for ambient radiation exposure rates, and an unplanned release of radioactive material occurs, contamination could go undetected and cause public and worker exposure in excess of the radiation protection limits in Part 20.</p>
§35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material	C, except paragraphs (c) and (d) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(a) and (f), this requirement was designated a Category C. This provision assists in establishing a minimum level of safety for the medical use of agreement materials on a nationwide basis by reducing the likelihood of public overexposures in multiple jurisdictions. The essential objective of this requirement is to assure that 0.5 rem TEDE is not exceeded by any individual, and that instructions are provided so that a breast-feeding infant/child does not receive an exposure exceeding 0.1 rem TEDE.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.80	Provision of mobile medical service	H&S (a)(2),(a)(3) & (b) for those States which authorize this activity D for other States	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&S those Agreement States which authorize this service. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a public exposure. The essential objective of this requirement is to make sure that instruments are possessed, used, calibrated and checked as described in §35.60 and §35.61, that properly operating survey instruments are used and that radiation surveys are performed in areas where therapeutic radiopharmaceuticals are used.</p> <p>The H&S two or fewer failure test scenario: Paragraphs (a)(2) and (a)(3) require that the requirements in §35.60 and §35.61 be applied to mobile services and that survey instruments are operating properly. If a mobile service licensee does not measure dosages with a proper operating instrumentation, then the prescribed dose could be exceeded, causing a medical event and the radiation protection limits in Part 20 for workers and the public could be exceeded. Paragraph (a)(4) requires that the mobile service survey all areas of use to assure compliance with Part 20 before leaving the client's address of use. If an exit survey is not conducted and byproduct material is left at the client's address of use, radiation protection limits in Part 20 for workers and the public could be exceeded.</p>
§35.92	Decay-in-storage	H&S - for those States which authorize this activity, except paragraph (b) is D. D - for other States	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) are designated as H&S for those Agreement States which authorize this activity. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a public overexposure. The essential objective of this requirement is to allow decay in storage for byproduct materials with less than 120 day half-life and to assure that surveys will be performed on the material before disposal.</p> <p>The H&S two or fewer failure test scenario: If byproduct material is allowed to decay-in-storage and is improperly surveyed, it may be disposed of as normal trash. Byproduct material could then be released into the public domain and overexpose workers and members of the public.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this provision was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that radiopharmaceuticals are obtained from a licensed vendor or authorized preparer.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not obtain radiopharmaceuticals from a licensed manufacturer or authorized preparer, a preparation error could occur, and a medical event could occur.</p>
§35.190	Training for uptake, dilution and excretion studies	B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>
§35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this section was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that radiopharmaceuticals are obtained from a licensed vendor or authorized preparer.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not obtain radiopharmaceuticals from a licensed manufacturer or authorized preparer, and a preparation error occurs, a patient could receive a radiation exposure and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.204	Permissible molybdenum-99 concentration	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that 5.55kBq is not exceeded.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform a Mo-99 measurement and the 5.55kBq limit is exceeded, and this contaminant is administered, a medical event could occur.</p>
§35.290	Training for imaging and localization studies	B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>
§35.300	Use of unsealed byproduct material for which a written directive is required	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&S for those Agreement States which authorize this activity. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that radiopharmaceuticals are obtained from a licensed vendor or authorized preparer.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not obtain radiopharmaceuticals from a licensed manufacturer or authorized preparer, a preparation error or medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.310	Safety instruction	H&S, except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of exposure to members of the public. The essential objective of this requirement is to assure that personnel caring for patients receive initial and annual radiation safety instruction.</p> <p>The H&S two or fewer failure test scenario: If the personnel caring for patients are not properly instructed, then personnel could be overexposed and persons visiting the patient could be overexposed. In addition, contaminated material could be released into the public domain, and a public overexposure could occur.</p>
§35.315	Safety precautions	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of worker and public exposure. The essential objective of this requirement is to limit unnecessary patient contact with members of the public, and to assure that proper notifications are made if the patient dies.</p> <p>The H&S two or fewer failure test scenario: If the safety precautions are not taken, then hospital personnel could be overexposed and persons visiting the patient could be overexposed. Contaminated material could also be released into the public domain, and public overexposures could occur. In addition, if the proper persons are not notified if a patient dies or, if a medical emergency occurs, other personnel could be overexposed.</p>
§35.390	Training for use of unsealed byproduct material for which a written directive is required	B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§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	o be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§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	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§35.400	Use of sealed sources for manual brachytherapy	[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires the use of sealed sources in the SS&D Registry by all specific licensees. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.404	Surveys after source implant and removal	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event, and overexposures in excess of Part 20 limits. The essential objective of this requirement is to assure that patient and area surveys are performed immediately after removal of sources from the patient or human research subject.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform a patient radiation survey after implanting sources, sources could be misplaced and the public and workers could be exposed to radiation in excess of basic radiation protection limits in Part 20 and a medical event could occur.</p>
§35.406	Brachytherapy sources accountability	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a lost source, medical event, public and worker overexposure. The essential objective of this requirement is to assure the accountability of sources after use.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not maintain source accountability a source may be misplaced and the public and workers could be overexposed and a medical event could occur.</p>
§35.410	Safety instruction	H&S, except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of exposure to members of the public. The essential objective of this requirement is to assure that personnel caring for a patient receive proper radiation safety instruction.</p> <p>The H&S two or fewer failure test scenario: If the personnel caring for patients are not properly instructed, then the personnel could be overexposed and persons visiting the patient could be overexposed.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.415	Safety precautions	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of worker and public exposure. The essential objective of these requirements is to limit patient contact with members of the public, to assure the availability of emergency response equipment and to assure that proper notifications are made if the patient dies.</p> <p>The H&S two or fewer failure test scenario: If the safety precautions are not taken, then hospital personnel could be overexposed and persons visiting the patient could be overexposed. In addition, if the proper persons are not notified if a patient dies or, if a medical emergency occurs, other hospital personnel could be overexposed and material could be released into the public domain, and public overexposures could occur.</p>
§35.432	Calibration measurements of brachytherapy sources	H&S, except paragraph (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that full calibration measurements on sources are performed before the first use of the source or source/applicator configuration.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform full calibration measurements of brachytherapy sources, a medical event could occur.</p>
§35.433	Decay of strontium-90 sources for ophthalmic treatments	H&S- (a), except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the source is properly decayed to identify the correct source strength.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not properly decay the source and it's strength is not accurately determined, a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.457	Therapy-related computer systems	H&S	<p>Based upon Handbook 5.9 Part paragraphs (a) and (b) was designated II, "Categorization Criteria," Section E, this provision was designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood a medical event. The essential objective of this requirement is to assure that therapy related computer systems are functioning properly and testing is done in accordance with national protocols.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not verify that computerized treatment planning systems are operating properly, and a medical event occurs.</p>
§35.490	Training for use of manual brachytherapy sources	B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>
§35.491	Training for ophthalmic use of strontium-90	B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.500	Use of sealed sources for diagnosis	[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires the use of sealed sources in the SS&D Registry by all specific licensees. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.
§35.590	Training for use of sealed sources for diagnosis	B	To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.
§35.600	Use of a sealed sources in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit	[C]	This section is a bracketed Category C, because it is already required by 10 CFR § 30.32 (g) and § 32.74. Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(f), 10 CFR § 30.32 (g) was designated a Category C. This section requires the use of sealed sources in the SS&D Registry by all specific licensees. In addition, 10 CFR § 32.74, "Manufacture and distribution of sources or devices containing byproduct material for medical use," is designated a Category B. This designation was based upon Handbook 5.9 Part II, "Categorization Criteria," Section (B), paragraph (b), requirements for approval of products that are distributed nationwide. If an Agreement State has adopted 10 CFR § 30.32 (g) and 10 CFR § 32.74, it is not necessary to adopt this section since the requirements are covered by these provisions.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.604	Surveys of patients and human research subjects treated with a remote afterloader unit	H&S, except paragraph (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated H&S. This provision assists in establishing a minimum level of safety for the medical use of agreement materials on a nationwide basis by reducing the likelihood of a lost source, medical event, and public/worker overexposure. The essential objective of this requirement is to assure that a survey is conducted on the patient and the device after source(s) removal from the patient or human research subject.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform a patient radiation survey after implanting sources, sources could be misplaced and the public and workers could be exposed to radiation in excess of radiation protection limits in Parts 20 and 35 and a medical event could occur.</p>
§35.605	Installation, maintenance, adjustment and repair	H&S, except paragraph (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event and public and worker overexposure. The essential objective of these requirements is to assure that installation, maintenance, and adjustments are performed by a person specifically licensed by the Commission or an Agreement State.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not use a person who is specifically licensed to install and service devices and an equipment failure occurs, the person servicing the device could become overexposed. In addition, the public and workers could receive exposures in excess of the radiation protection limits in Part 20, if the device is not serviced properly.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.610	Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S, except paragraphs (f) & (g) are D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for agreement materials by reducing the likelihood of a medical event and public and worker overexposure. The essential objective of these requirements is to assure the establishment and use of safety procedures and instructions for remote afterloaders, teletherapy units and gamma stereotactic radiosurgery units.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not develop and implement safety procedures and instructions, and radioactive material is mishandled, workers and the public could receive radiation exposures in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>
§35.615	Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event, worker and public exposure. The essential objective of these requirements is to assure that controls are implemented, to require the physical presence of the authorized user and/or authorized medical physicist during the use of the device, and to assure the accessibility of emergency equipment.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not control access to therapy equipment and treatment rooms, and an equipment failure occurs, the public and workers could receive exposures in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.630	Dosimetry equipment	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure the use of a dosimetry system that has been calibrated in accordance with national standards.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not calibrate and check dosimetry equipment in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of radiation limits in Part 20 and a medical event could occur.</p>
§35.632	Full calibration measurements on teletherapy units	H&S, except paragraph (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&S. These provisions assist in establishing a minimum level of safety basis by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform full calibration measurements on teletherapy units in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>
§35.633	Full calibration measurements on remote afterloader units	H&S, except paragraph (i) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform full calibration measurements on remote afterloaders in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.635	Full calibration measurements on gamma stereotactic radiosurgery units	H&S, except paragraph (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform full calibration measurements on gamma stereotactic radiosurgery units in accordance with industry standards, and an equipment failure occurs, the public and workers could be exposed to radiation in excess of the radiation protection limits in Part 20 and a medical event could occur.</p>
§35.642	Periodic spot-checks for teletherapy units	H&S, except paragraph (f) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (e) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement material by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform periodic spot checks of teletherapy units, and an equipment failure occurs, the public and workers could receive exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>
§35.643	Periodic spot-checks for remote afterloader units	H&S, except paragraph (f) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (e) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform periodic spot checks of high dose-rate and pulsed dose-rate remote afterloaders, and an equipment failure occurs, the public and workers could receive exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.645	Periodic spot-checks for gamma stereotactic radiosurgery units	H&S, except paragraph (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a medical event by checking instrument performance between maintenance and full calibrations. The essential objective of this requirement is to assure that the medical device is performing properly.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform periodic spot checks of gamma stereotactic radiosurgery units, and an equipment failure occurs, then the public and workers could receive exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>
§35.647	Additional technical requirements for mobile remote afterloader units	<p>H&S - paragraphs (a) through (d) for those States which authorize this activity, except (e) is D.</p> <p>D - for other States.</p>	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a H&S those Agreement States which authorize this service. This provision assists in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of a public exposure. The essential objective of this requirement is to assure that the appropriate radiation surveys are performed and that the proper administrative controls are utilized.</p> <p>The H&S two or fewer failure test scenario: If these requirements are not adopted, a mobile remote afterloader licensee would not be required to check survey instruments and verify sources after use, then sources could be misplaced and the public and workers could be exposed to radiation in excess of radiation protection limits in Part 20 and a medical event could occur.</p>
§35.652	Radiation surveys	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood of public and worker overexposures. The essential objective of this requirement is to assure that exposure to the source(s) in the shielded position does not exceed the levels stated in the SS&D registry.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not perform these radiation surveys, and the radiation safety of the device is compromised, then the public and workers could receive exposures in excess of radiation protection limits in Part 20.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.655	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units	H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood a medical event, and public and worker exposure. The essential objective of this requirement is to assure that the inspection and servicing of teletherapy and gamma stereotactic radiosurgery units during source replacements or at intervals not to exceed 5 years and this inspection and servicing is performed by a person specifically licensed by the Commission or an Agreement State.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not have their teletherapy and gamma stereotactic radiosurgery units inspected and serviced at 5-year intervals and an equipment failure occurs, the public and workers could receive radiation exposures in excess of radiation protection limits in Part 20 and a medical event could occur.</p>
§35.657	Therapy-related computer systems	H&S	<p>Based upon Handbook 5.9 Part paragraphs (a) and (b) was designated II, "Categorization Criteria," Section E, this provision was designated H&S. These provisions assist in establishing a minimum level of safety for the medical use of agreement materials by reducing the likelihood a medical event. The essential objective of this requirement is to assure that therapy related computer systems are functioning properly and testing is done in accordance with national protocols.</p> <p>The H&S two or fewer failure test scenario: If a licensee does not verify that computerized treatment planning systems are operating properly, and a medical event occurs.</p>
§35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	B	<p>To be included in Category B, an NRC program element is to be one that applies to activities that have direct and significant effects in multiple jurisdictions. The Commission directed the staff to revise the compatibility level assigned to the training and experience requirements for all categories of physician authorized users and other individuals from "C" to "B" to ensure that the training and experience requirements for the medical use of byproduct material are consistent between NRC and Agreement States.</p>

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
Subpart J - Retained for 2-year Transition Period	Training & Experience Requirements	No compatibility category changes	A two year "Transition Period" has been established starting on the effective date of the revised Part 35. The current Subpart J addressing training and experience requirements will be accepted along with the revised requirements.
§35.900	Radiation Safety Officer	D	
§35.910	Training for uptake, dilution, and excretion studies	D	
§35.920	Training for imaging and localization studies	D	
§35.930	Training for Therapeutic use of unsealed byproduct material	D	
§35.932	Training for treatment of hyperthyroidism	D	
§35.934	Training for treatment of thyroid carcinoma	D	
§35.940	Training for use of brachytherapy sources	D	
§35.941	Training for ophthalmic use of strontium-90	D	
§35.950	Training for use of sealed sources for diagnosis	D	
§35.960	Training for use of therapeutic medical devices	D	

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.961	Training for authorized medical physicist	D	
§35.980	Training for an authorized nuclear pharmacist	D	
§35.981	Training for experienced nuclear pharmacist	D	
§35.1000	Other medical uses of byproduct material or radiation from byproduct material	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2024	Records of authority and responsibilities for radiation protection programs	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2026	Records of radiation protection program changes	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2040	Records of written directives	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2041	Records for procedures for administrations requiring a written directive	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2060	Records of calibrations of instruments used to measure the activity of unsealed byproduct materials	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2061	Records of radiation survey instrument calibrations	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.2063	Records of dosage of unsealed byproduct material for medical use	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2067	Records of leak test and inventory of sealed sources and brachytherapy sources	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2070	Records of surveys for ambient radiation exposure rate	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2075	Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2080	Records of mobile medical services	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2092	Records of decay-in-storage	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2204	Records of molybdenum-99 concentrations	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2310	Records of safety instruction	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2404	Records of surveys after source implant and removal	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2406	Records of brachytherapy source accountability	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2432	Records of calibration measurements of brachytherapy sources	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.2433	Records of decay of strontium-90 sources for ophthalmic treatments	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2605	Records of installation, maintenance, adjustment and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2610	Records of safety procedures	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2630	Records of dosimetry equipment used for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2632	Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2642	Records of periodic spot-checks for teletherapy units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2643	Records of periodic spot-checks for remote afterloader units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2645	Records of periodic spot-checks for gamma stereotactic radiosurgery units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2647	Records of additional technical requirements for mobile remote afterloader units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.2652	Records of surveys of therapeutic treatment units	D	Does not meet any of the criteria of Category A, B, C, or H&S.

* This definition provides information that is essential to the common understanding beyond the plain dictionary meaning.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.2655	Records of 5-year inspection of teletherapy and gamma stereotactic radiosurgery units	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.3045	Report and notification of a medical event	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(c), this requirement was designated a Category C because absent this provision there could be a potential preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. The essential objective of this requirement is to assure that medical events are reported to the radiation control program and in order to assess the effectiveness of the national program for control of Atomic Energy Act materials.
§35.3047	Report and notification of a dose to an embryo/fetus or a nursing child	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(c), this requirement was designated a Category C because absent this provision there could be a potential preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. The essential objective of this requirement is to assure that doses to the embryo/fetus or nursing child are reported to the radiation control program.
§35.3067	Report of a leaking source	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(c), this requirement was designated a Category C because absent this provision there could be a potential preclusion of an effective review or evaluation by the Commission and Agreement State programs for agreement material with respect to protection of public health and safety. The essential objective of this requirement is to assure that leaking sources are reported to the radiation control program.
§35.4001	Violations	D	Does not meet any of the criteria of Category A, B, C, or H&S.
§35.4002	Criminal penalties	D	Does not meet any of the criteria of Category A, B, C, or H&S.

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* This definition provides information that is essential to the common understanding beyond the plain dictionary meaning.