

January 4, 1999

ALL AGREEMENT STATES
MINNESOTA, OHIO, OKLAHOMA, PENNSYLVANIA, AND WISCONSIN

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-99-001)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.. **XX DRAFT PART 35**
COMPATIBILITY CHART

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION.....

Supplementary information: Enclosed for your information is a draft compatibility chart for the proposed revision of 10 CFR Part 35. This draft chart was developed in accordance with the compatibility categorization criteria detailed in NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" dated February 27, 1998. The compatibility categories in the draft chart reflect revisions, in some cases, to the categories that were contained in the proposed rule that was published on August 5, 1998.

We invite your comments and suggestions relative to the compatibility designations detailed in this draft document. The closing date for receipt of comments is February 12, 1999.

If you have any questions regarding this correspondence, please contact me or the individual named below.

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Paul H. Lohaus, Deputy Director
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Enclosure:
As stated

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ALL AGREEMENT STATES
MINNESOTA, OHIO, OKLAHOMA, PENNSYLVANIA, AND WISCONSIN

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-98-)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

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COMPATIBILITY CHART**

TRAINING COURSE INFORMATION.....

TECHNICAL INFORMATION.....

OTHER INFORMATION.....

Supplementary information: Enclosed for your information is a draft compatibility chart for the proposed revision of 10 CFR Part 35. This draft chart was developed in accordance with the compatibility categorization criteria detailed in NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" dated February 27, 1998. The compatibility categories in the draft chart reflect revisions, in some cases, to the categories that were contained in the proposed rule that was published on August 5, 1998.

We invite your comments and suggestions relative to the compatibility designations detailed in this draft document. The closing date for receipt of comments is February 1, 1999.

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DATE	12/17/98	12/17/98	12/22/98	12/ /98		

OSP FILE CODE: SP-A-4



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 4, 1999

ALL AGREEMENT STATES
MINNESOTA, OHIO, OKLAHOMA, PENNSYLVANIA, AND WISCONSIN

TRANSMITTAL OF STATE AGREEMENTS PROGRAM INFORMATION (SP-99-001)

Your attention is invited to the enclosed correspondence which contains:

INCIDENT AND EVENT INFORMATION.....

PROGRAM MANAGEMENT INFORMATION.. **XX DRAFT PART 35**
COMPATIBILITY CHART

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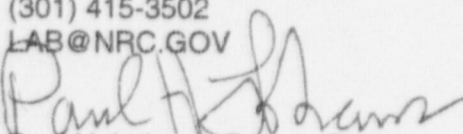
Supplementary information: Enclosed for your information is a draft compatibility chart for the proposed revision of 10 CFR Part 35. This draft chart was developed in accordance with the compatibility categorization criteria detailed in NRC Management Directive 5.9, "Adequacy and Compatibility of Agreement State Programs" dated February 27, 1998. The compatibility categories in the draft chart reflect revisions, in some cases, to the categories that were contained in the proposed rule that was published on August 5, 1998.

We invite your comments and suggestions relative to the compatibility designations detailed in this draft document. The closing date for receipt of comments is February 12, 1999.

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Enclosure:
As stated

COMPATIBILITY DESIGNATIONS FOR DRAFT 10 CFR PART 35 - MEDICAL USE OF BYPRODUCT MATERIAL

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.1	Purpose and scope	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2	Definitions		
	Address of use	D	Does not meet any of the criteria of Category A, B, C, or D/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.
	Area of use	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Authorized medical physicist	C	<p>Based upon Handbook 5.9 Part Ii, "Categorization Criteria," Section (C), paragraph (2)(e), this definition was identified as a Category C because its absence could potentially impair effective communication. This definition impacts effective communication because it is used to delineate that the individual is legally vested with the authority to function as an authorized medical physicist. This definition is also needed because of its impact on the establishment of a nationwide training and certification program in the medical use area. The essential objective of this definition is to establish that the medical physicist is a person identified on a license issued by the Commission or by an Agreement State, or meets the minimum requirements in 35.59 and 35.961.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Authorized nuclear pharmacist	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(e), this definition was identified as a Category C because its absence could potentially impair effective communication. This definition impacts effective communication because it is used to delineate that the individual is legally vested with the authority to function as an authorized nuclear pharmacist. This definition is also needed because of its impact on the establishment of a nationwide training and certification program in the medical use area. The essential objective of this definition is to establish that the nuclear pharmacist is a person identified on a license issued by the Commission or by an Agreement State, or meets the minimum requirements in 35.59 and 35.980.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Authorized user	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(e), this definition was identified as a Category C because its absence could potentially impair effective communication. This definition impacts effective communication because it is used to delineate that the individual is legally vested with the authority to function as an authorized user. This definition is also needed because of its impact on the establishment of a nationwide training and certification program in the medical use area. The essential objective of this definition is to establish that an authorized user is a person identified on a license issued by the Commission or by an Agreement State, or meets the minimum requirements in this part.
	Brachytherapy source	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Dedicated check source	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Dentist	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Diagnostic clinical procedures manual	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	High dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Low dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Management	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Medical event	D	Does not meet any of the criteria of Category A, B, C, or D/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 D/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.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Mobile service	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Output	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Pharmacist	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Physician	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Podiatrist	D	Does not meet any of the criteria of Category A, B, C, or D/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.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	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.
	Pulsed dose-rate remote afterloader	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Radiation safety officer	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraph (2)(e), this definition was identified as a Category C because its absence could potentially impair effective communication. This definition impacts effective communication because it is used to delineate that the individual is legally vested with the authority to function as radiation safety officer, especially since there is no longer a radiation safety committee provision. This definition is also needed because of its impact on the establishment of a nationwide training and certification program in the medical use area. The essential objective of this definition is to establish that the RSO is identified on a license issued by the Commission or by an Agreement State, or meets the minimum requirements in 35.59 and 35.900.</p>
	Sealed source	[B]	<p>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.</p>
	Sealed source and device registry	D	<p>Does not meet any of the criteria of Category A, B, C, or D/H&S.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
	Stereotactic radiosurgery	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Structured educational program	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Temporary jobsite	D	Does not meet any of the criteria of Category A, B, C, or D/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.
	Unit dosage	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
	Written directive	D	Does not meet any of the criteria of Category A, B, C, or D/H&S since the term was not defined in this section, but is defined in 35.40.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.5	Maintenance of records	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.6	Provisions for research involving human 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 D/H&S.
§35.8	Information collection requirements: OMB Approval	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.10	Implementation	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§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 D/H&S.
§35.13	License amendments	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.14	Notifications	D	Does not meet any of the criteria of Category A, B, C, or D/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 D/H&S.
§35.18	License issuance	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.19	Specific exemptions	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.24	Authority and responsibilities for the radiation protection program	<p>D - paragraphs (a) (1), (a) (2), (a)(3), (b), (d) and (f)</p> <p>D/H&S- paragraph (c) and (e)</p>	<p>Paragraphs (a)(1), (a)(2), (a)(3)(b), (d) and (f), do not meet any of the criteria of Category A, B, C, or D/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 (c) and (e) were designated Category D/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 (c) is to assure that the RSO agrees to implement the radiation safety program. The essential objective of paragraph (e) 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 limits in Parts 20 and 35 and a medical event could occur.</p>

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 D/H&S.
§35.27	Supervision	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.40	Written directives	D/H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.41	Procedures for administrations requiring a written directive	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.49	Suppliers for sealed sources or devices for medical use	[C]	<p>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.</p>
§35.50	Training for Radiation Safety Officer	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that only persons qualified by training and experience shall be authorized as a Radiation Safety Officer.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.51	Training for authorized medical physicist	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that only persons qualified by training and experience shall be authorized as a medical physicist.
§35.55	Training for an authorized nuclear pharmacist	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that only persons qualified by training and experience shall be authorized as a nuclear pharmacist.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to exempt experienced authorized users, including Radiation Safety Officers, who are named on a license from the training requirements in §35.50, §35.51 and Subparts C through H.
§35.59	Recentness of training	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that applicants requesting authorized user status are familiar with current medical practice in this area.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.60	Possession, use, calibration, and check of instruments to measure activity of photon-emitting radionuclides	D/H&S, except paragraph (e) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.61	Calibration and check of survey instruments	D/H&S, except paragraph (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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. The requirement 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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.62	Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides	D/H&S, except paragraph (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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>
§35.63	Determination of dosages of unsealed byproduct material for medical use	D/H&S, except paragraph (e) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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 determination of 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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.65	Authorization for calibration and reference sources	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.67	Requirements for possession of sealed sources and brachytherapy sources	D/H&S, except paragraph (e) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.69	Labeling and shielding of vials and syringes	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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 the worker could be overexposed.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.70	Surveys for ambient radiation exposure rate	D/H&S, except paragraph (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this requirement was designated a D/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 limits in Part 20.</p>
§35.75	Release of individuals containing radiopharmaceuticals or implants	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 to individuals who are breast-feeding an infant/child when the dose to the infant/child could exceed 0.1 rem TEDE.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.80	Provision of mobile service	D - except paragraph (a) is D/H&S for those States which authorize this service.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a D/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 client management is aware that byproduct material will be used onsite, that instruments are possessed, used, calibrated and checked as described in §35.60 and §35.62, 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: Paragraph (a) requires that the requirements in §35.60 and §35.62 be applied to mobile services. 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. If radiation levels are not measured with properly operating instruments, the radiation protection limits in Part 20 for workers and the public could be exceeded.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.92	Decay-in-storage	<p>D/H&S - for those States which authorize this activity.</p> <p>D - for other States</p>	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) and (b) are designated as D/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 radioactive materials with less than 120 day half-life and to assure that surveys will be performed on the material before disposal in ordinary trash.</p> <p>The H&S two or fewer failure test scenario: If the radioactive material is not required to decay-in-storage properly before placing in ordinary trash, radioactive material of a high activity could be released into the public domain and overexposure of members of the public could occur. In addition, if the material is not properly surveyed before placing in ordinary trash, workers and members of the public could be overexposed.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies (written directive not required)	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this provision was designated a D/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>
§35.200	Use of unsealed byproduct material for imaging and localization studies (including any dosages of sodium I-131 in quantities less than or equal to 30 microcuries)	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, this section was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.204	Permissible molybdenum-99 concentration	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.290	Training for uptake, dilution, and excretion studies	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), these requirements were designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that properly trained physicians use the radioactive material in this section.
§35.292	Training for imaging and localization studies	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), these requirements were designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that properly trained physicians use the radioactive material in this section.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.300	Use of unsealed byproduct material for therapeutic administration (including any dosage of sodium I-131 in quantities greater than 30 microcuries)	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.310	Safety instruction	D/H&S, except (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a D/H&S. These provision 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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.315	Safety precautions	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a D/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 therapeutic use of unsealed byproduct material (including any dosages of sodium I-131 in quantities greater than 30 microcuries)	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that properly trained physicians use the radioactive material in this section.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.400	Use of sources for manual brachytherapy	[C]	<p>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.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.404	Radiation surveys of individuals with therapy implants	D/H&S, except (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) and (b) were designated D/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 Parts 20 and a medical event could occur.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.406	Brachytherapy sources inventory	D/H&S, except (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) and (b) were designated D/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	D/H&S, except (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.415	Safety precautions	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.432	Full calibration measurements of brachytherapy sources	D/H&S, except (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated D/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>
§35.490	Training for use of manual brachytherapy sources	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2)(b) and (2)(f), these requirements were designated a Category C by relieving an undue burden on interstate commerce by establishing a minimum level of training for the medical use of agreement materials. The essential objective of this requirement is to assure that properly trained physicians handle sealed sources for human use in this section.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.500	Use of sealed sources for diagnosis	[C]	<p>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.</p>
§35.590	Training for use of sealed sources for diagnosis	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that properly trained physicians handle sealed sources for human use in this section.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.600	Use of a sealed source in a device for therapeutic medical uses	[C]	<p>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.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.604	Radiation Surveys of individuals treated with remote afterloaders	D/H&S, except (b) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.605	Installation, maintenance and repair	D/H&S, except (d) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated D/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 be 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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.610	Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units	D/H&S except (e) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.615	Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units	D/H&S	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, these provisions were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.630	Dosimetry equipment	D/H&S except (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.632	Full calibration measurements on teletherapy units	D/H&S, except (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated D/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 radiation limits in Part 20 and a medical event could occur.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.633	Full calibration measurements on remote afterloaders	D/H&S, except (h) is D	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated D/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 radiation limits in Part 20 and a medical event could occur.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.635	Full calibration measurements on gamma stereotactic radiosurgery units	D/H&S, except (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated D/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 radiation limits in Part 20 and a medical event could occur.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.642	Periodic spot-checks for teletherapy units	D/H&S, except (f) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (e) were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.643	Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders	D/H&S, except (h) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (g) were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.644	Periodic spot-check for low dose-rate remote afterloaders	D/H&S, except (e) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (d) were designated D/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 requiring the checking of instrument performance between maintenance and full calibrations are performed. 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 low 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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.645	Periodic spot-checks for gamma stereotactic radiosurgery units	D/H&S, except (g) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) through (f) were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.647	Additional technical requirements for mobile remote afterloaders	D - except paragraphs (a) through (d) are a D/H&S those States which authorize this service.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraph (a) was designated a D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.652	Radiation surveys	D/H&S, except (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.655	Five-year inspection for teletherapy and gamma stereotactic radiosurgery units	D/H&S, except (c) is D.	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section E, paragraphs (a) and (b) were designated D/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>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.657	Therapy-related computer systems	D/H&S	<p>Based upon Handbook 5.9 Part paragraphs (a) and (b) was designated II, "Categorization Criteria," Section E, this provision was designated D/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, a medical event could occur.</p>
§35.690	Training for use of therapeutic medical devices	C	<p>Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (2) (b) and (2)(f), this requirement was designated a Category C because they relieve undue burdens on interstate commerce by establishing a minimum level of training for the medical use of agreement materials on a nationwide basis. The essential objective of this requirement is to assure that properly trained physicians use therapeutic medical devices.</p>
§35.900	Radiation safety officer	[C]	<p>This section is a bracketed Category C, because it is already required by 10 CFR §35.50. If an Agreement State has adopted 10 CFR §35.50, the State should not adopt this section.</p>

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.910	Training for uptake, dilution, and excretion studies	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.290. If an Agreement State has adopted 10 CFR §35.290, the State should not adopt this section.
§35.920	Training for imaging and localization studies	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.292. If an Agreement State has adopted 10 CFR §35.292, the State should not adopt this section.
§35.930	Training for therapeutic use of unsealed byproduct material	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.390. If an Agreement State has adopted 10 CFR §35.390, the State should not adopt this section.
§35.932	Training for treatment of hyperthyroidism	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.390. If an Agreement State has adopted 10 CFR §35.390, the State should not adopt this section.
§35.934	Training for treatment of thyroid carcinoma	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.390. If an Agreement State has adopted 10 CFR §35.390, the State should not adopt this section.
§35.940	Training for use of brachytherapy sources	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.490. If an Agreement State has adopted 10 CFR §35.490, the State should not adopt this section.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.941	Training for ophthalmic use of strontium-90	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.490. If an Agreement State has adopted 10 CFR §35.490, the State should not adopt this section.
§35.950	Training for use of sealed sources for diagnosis	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.590. If an Agreement State has adopted 10 CFR §35.590, the State should not adopt this section.
§35.960	Training for use of therapeutic medical devices	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.690. If an Agreement State has adopted 10 CFR §35.690, the State should not adopt this section.
§35.961	Training for authorized medical physicist	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.51. If an Agreement State has adopted 10 CFR §35.51, the State should not adopt this section.
§35.980	Training for an authorized nuclear pharmacist	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.55. If an Agreement State has adopted 10 CFR §35.55, the State should not adopt this section.
§35.981	Training for experienced nuclear pharmacists	[C]	This section is a bracketed Category C, because it is already required by 10 CFR §35.57. If an Agreement State has adopted 10 CFR §35.57, the State should not adopt this section.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.1000	Other medical uses of byproduct material or radiation therefrom	D	Does not meet any of the criteria of Category A, B, C, or D/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 D/H&S.
§35.2026	Records of radiation protection program safety changes	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2040	Records of written directives	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2045	Records of medical events	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2060	Records of instrument calibrations	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2061	Records of radiation survey instrument calibrations	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§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 D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.2067	Records of possession of sealed sources and brachytherapy sources	D	Does not meet any of the criteria of Category A, B, C, or D/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 D/H&S.
§35.2075	Records of the release of individuals containing radiopharmaceuticals or implants	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2080	Records of administrative and technical requirements that apply to the provision of mobile services	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2092	Records of waste disposal	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2204	Records of molybdenum-99 concentration	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2310	Records of instruction and training	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.2404	Records of radiation surveys of patients and human research subjects	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2406	Records of brachytherapy source inventory	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2432	Records of full calibrations on brachytherapy sources	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2605	Records of installation, maintenance, and repair	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2630	Records of dosimetry equipment	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2632	Records of teletherapy full calibrations	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2633	Records of remote afterloader full calibrations	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2635	Records of gamma stereotactic radiosurgery unit full calibrations	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.2642	Records of periodic spot-checks for teletherapy units	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
§35.2643	Records of periodic spot-checks for remote afterloaders	D	Does not meet any of the criteria of Category A, B, C, or D/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 D/H&S.
§35.2647	Records of additional technical requirements for mobile remote afterloaders	D	Does not meet any of the criteria of Category A, B, C, or D/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 D/H&S.
§35.2655	Records of five-year inspection of teletherapy and gamma stereotactic radiosurgery units	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.3045	Reports of medical events	C, except paragraphs (b) and (f) are D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (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.
§35.3047	Reports of a dose to an embryo/fetus or a nursing child	C, except paragraph (c) is D.	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (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.

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§35.3069	Reports of leaking sources	C	Based upon Handbook 5.9 Part II, "Categorization Criteria," Section (C), paragraphs (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 D/H&S.
§35.4002	Criminal penalties	D	Does not meet any of the criteria of Category A, B, C, or D/H&S.
Appendix A	Examining Organization or Entity	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 provides the requirements for the establishment of a nationwide training program in the area of medical use of agreement materials, which would have direct and significant effects in multiple jurisdiction.
§20.1301 (a)(3)	Dose limits for individual members of the public	A	

REGULATION SECTION	SECTION TITLE	COMPATIBILITY CATEGORY	COMMENTS
§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	B	