10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
PART 35--MEDICAL USE OF BYPRODUCT MATERIAL	PART 35--MEDICAL USE OF BYPRODUCT MATERIAL	PART 35--MEDICAL USE OF BYPRODUCT MATERIAL
Subpart A--General Information	Subpart A--General Information	Subpart A--General Information
Sec.	Sec.	
35.1 Purpose and scope.	35.1 Purpose and scope.	35.1 Purpose and scope.
35.2 Definitions.	35.2 Definitions.	35.2 Definitions.
35.5 Maintenance of records.	35.5 Maintenance of records.	35.5 Maintenance of records.
35.6 Provisions for research involving human subjects.	35.6 Provisions for research involving human subjects.	35.6 Provisions for the protection of human research subjects.
35.7 FDA, other Federal, and State requirements.	35.7 FDA, other Federal, and State requirements.	35.7 FDA, other Federal, and State requirements.
35.8 Information collection requirements: OMB approval.	35.8 Information collection requirements: OMB approval.	35.8 Information collection requirements: OMB approval.
	35.10 Implementation.	35.10 Implementation.
35.11 License required.	35.11 License required.	35.11 License required.
35.12 Application for license, amendment, or renewal.	35.12 Application for license, amendment, or renewal.	35.12 Application for license, amendment, or renewal.
35.13 License amendments.	35.13 License amendments.	35.13 License amendments.
35.14 Notifications.	35.14 Notifications.	35.14 Notifications.
35.15 Exemptions regarding Type A specific licenses of broad scope.	35.15 Exemptions regarding Type A specific licenses of broad scope.	35.15 Exemptions regarding Type A specific licenses of broad scope.
35.18 License issuance.	35.18 License issuance.	35.18 License issuance.
35.19 Specific exemptions.	35.19 Specific exemptions.	35.19 Specific exemptions.

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CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart B--General Administrative Requirements	Subpart B--General Administrative Requirements	Subpart B--General Administrative Requirements
35.20 ALARA program.[20.1101]		
35.21 Radiation Safety Officer.		
35.22 Radiation Safety Committee.[35.24]		
35.23 Statements of authority and responsibilities.[35.24]		
	35.24 Authority and responsibilities for the radiation protection program.	35.24 Authority and responsibilities for the radiation protection program.
35.25 Supervision.		
35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service.	35.26 Radiation protection program changes.	35.26 Radiation protection program changes.
35.31 Radiation safety program changes.	35.27 Supervision.	35.27 Supervision.
35.32 Quality management program.		
35.33 Notifications, reports, and records of misadministrations.		
	35.40 Written directives.	35.40 Written directives.
	35.41 Procedures for administrations requiring a written directive.	35.41 Procedures for administrations requiring a written directive.
35.49 Suppliers for sealed sources or devices for medical use.	35.49 Suppliers for sealed sources or devices for medical use.	35.49 Suppliers for sealed sources or devices for medical use.
	35.50 Training for Radiation Safety Officer.	35.50 Training for Radiation Safety Officer.
	35.51 Training for an authorized medical physicist.	35.51 Training for an authorized medical physicist.
	35.55 Training for an authorized nuclear pharmacist.	35.55 Training for an authorized nuclear pharmacist.
	35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.	35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
	35.59 Recentness of training.	35.59 Recentness of training.

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CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart C--General Technical Requirements	Subpart C--General Technical Requirements	Subpart C--General Technical Requirements
35.50 Possession, use, calibration, and check of dose calibrators.	35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.	35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.
35.51 Calibration and check of survey instruments.	35.61 Calibration and check of survey instruments.	35.61 Calibration of survey instruments.
35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.	35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.	
35.53 Measurement of dosages of unsealed byproduct material for medical use.	35.63 Determination of dosages of unsealed byproduct material for medical use.	35.63 Determination of dosages of unsealed byproduct material for medical use.
35.57 Authorization for calibration and reference sources.	35.65 Authorization for calibration and reference sources.	35.65 Authorization for calibration, transmission, and reference sources.
35.59 Requirements for possession of sealed sources and brachytherapy sources.	35.67 Requirements for possession of sealed sources and brachytherapy sources.	35.67 Requirements for possession of sealed sources and brachytherapy sources.
35.60 Syringe shields and labels.	35.69 Labeling and shielding of vials and syringes.	35.69 Labeling of vials and syringes.
35.61 Vial shields and labels.		
35.70 Surveys for contamination and ambient radiation exposure rate.	35.70 Surveys for ambient radiation exposure rate.	35.70 Surveys of ambient radiation exposure rate.
35.75 Release of patients or human research subjects containing radiopharmaceuticals or permanent implants.	35.75 Release of individuals containing radiopharmaceuticals or implants.	35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.
35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.	35.80 Provision of mobile service.	35.80 Provision of mobile medical service.
35.90 Storage of volatiles and gases.		
35.92 Decay-in-storage.	35.92 Decay-in-storage.	35.92 Decay-in-storage.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart D--Uptake, Dilution, and Excretion	Subpart D--Unsealed Byproduct Material--Low Dose	Subpart D--Unsealed Byproduct Material - Written Directive Not Required
35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.	35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
35.120 Possession of survey instrument.		
		35.190 Training for uptake, dilution, and excretion studies.
Subpart E--Imaging and Localization		
35.200 Use of unsealed byproduct material for imaging and localization studies.	35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.
35.204 Permissible molybdenum-99 concentration.	35.204 Permissible molybdenum-99 concentration.	35.204 Permissible molybdenum-99 concentration.
35.205 Control of aerosols and gases.		
35.220 Possession of survey instruments.		
	35.290 Training for uptake, dilution, and excretion studies.	35.290 Training for imaging and localization studies.
	35.292 Training for imaging and localization studies.	

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart F--Radiopharmaceuticals for Therapy	Subpart E--Unsealed Byproduct Material--High Dose	Subpart E--Unsealed Byproduct Material -Written Directive Required
35.300 Use of unsealed byproduct material for therapeutic administration. 35.310 Safety instruction. 35.315 Safety precautions. 35.320 Possession of survey instruments.	35.300 Use of unsealed byproduct material for which a written directive is required. 35.310 Safety instruction. 35.315 Safety precautions.	35.300 Use of unsealed byproduct material for which a written directive is required. 35.310 Safety instruction. 35.315 Safety precautions.
	35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive.	35.390 Training for use of unsealed byproduct material for which a written directive is required. 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). 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).

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart G--Sources for Brachytherapy	Subpart F--Manual Brachytherapy	Subpart F-- Manual Brachytherapy
35.400 Use of sources for brachytherapy.	35.400 Use of sources for manual brachytherapy.	35.400 Use of sealed sources for manual brachytherapy.
35.404 Release of patients or human research subjects treated with temporary implants.	35.404 Radiation surveys of patients or human research subjects treated with implants.	35.404 Surveys after source implant and removal.
35.406 Brachytherapy sources inventory.	35.406 Brachytherapy sources inventory.	35.406 Brachytherapy sources accountability.
35.410 Safety instruction.	35.410 Safety instruction.	35.410 Safety instruction.
35.415 Safety precautions.	35.415 Safety precautions.	35.415 Safety precautions.
35.420 Possession of survey instrument.		
	35.432 Full calibration measurements of brachytherapy sources.	35.432 Calibration measurements of brachytherapy sealed sources.
		35.433 Decay of strontium-90 sources for ophthalmic treatments.
		35.457 Therapy-related computer systems.
	35.490 Training for use of manual brachytherapy sources.	35.490 Training for use of manual brachytherapy sources.
		35.491 Training for ophthalmic use of strontium-90.
Subpart H--Sealed Sources for Diagnosis	Subpart G--Sealed Sources for Diagnosis	Subpart G--Sealed Sources for Diagnosis
35.500 Use of sealed sources for diagnosis.	35.500 Use of sealed sources for diagnosis.	35.500 Use of sealed sources for diagnosis.
35.520 Availability of survey instrument.		
	35.590 Training for use of sealed sources for diagnosis.	35.590 Training for use of sealed sources for diagnosis.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart I--Teletherapy	Subpart H--Therapeutic Medical Devices	Subpart H--Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
35.600 Use of a sealed source in a teletherapy unit.	35.600 Use of a sealed source in a device for therapeutic medical uses.	35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
	35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.	35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.
35.605 Maintenance and repair restrictions.	35.605 Installation, maintenance, and repair.	35.605 Installation, maintenance, adjustment, and repair.
35.606 License amendments.		
35.610 Safety instruction.	35.610 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.	35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.615 Safety precautions.	35.615 Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.	35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
35.620 Possession of survey instrument.		
35.630 Dosimetry equipment.	35.630 Dosimetry equipment.	35.630 Dosimetry equipment.
35.632 Full calibration measurements.	35.632 Full calibration measurements on teletherapy units.	35.632 Full calibration measurements on teletherapy units.
	35.633 Full calibration measurements on remote afterloaders.	35.633 Full calibration measurements on remote afterloader units.
	35.635 Full calibration measurements on gamma stereotactic radiosurgery units.	35.635 Full calibration measurements on gamma stereotactic radiosurgery units.
35.634 Periodic spot-checks.	35.642 Periodic spot-checks for teletherapy units.	35.642 Periodic spot-checks for teletherapy units.
35.636 Safety checks for teletherapy facilities.		
35.641 Radiation surveys for teletherapy facilities.	35.643 Periodic spot-checks	35.643 Periodic spot-checks for

CURRENT RULE	PROPOSED RULE	FINAL RULE
35.643 Modification of teletherapy unit or room before beginning a treatment program.	for high dose-rate and pulsed dose-rate remote afterloaders.	remote afterloader units.
	35.644 Periodic spot-checks for low dose-rate remote afterloaders.	
35.645 Reports of teletherapy surveys, checks, tests, and measurements.	35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.	35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.
35.647 Five-year inspection.	35.647 Additional technical requirements for mobile remote afterloaders.	35.647 Additional technical requirements for mobile remote afterloader units.
	35.652 Radiation surveys.	35.652 Radiation surveys.
	35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.	35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
	35.657 Therapy-related computer systems.	35.657 Therapy-related computer systems.
	35.690 Training for use of therapeutic medical devices.	35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
	Subpart I--Reserved	Subpart I--Reserved

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart J--Training and Experience Requirements	Subpart J--Training and Experience Requirements	Subpart J--Reserved
35.900 Radiation Safety Officer.[35.50, 900]	35.900 Radiation Safety Officer.	
35.901 Training for experienced Radiation Safety Officer.		
35.910 Training for uptake, dilution, and excretion studies.	35.910 Training for uptake, dilution, and excretion studies.	
35.920 Training for imaging and localization studies.	35.920 Training for imaging and localization studies.	
35.930 Training for therapeutic use of unsealed byproduct material.	35.930 Training for therapeutic use of unsealed byproduct material.	
35.932 Training for treatment of hyperthyroidism.	35.932 Training for treatment of hyperthyroidism.	
35.934 Training for treatment of thyroid carcinoma.	35.934 Training for treatment of thyroid carcinoma.	
35.940 Training for use of brachytherapy sources.	35.940 Training for use of brachytherapy sources.	
35.941 Training for ophthalmic use of strontium-90.	35.941 Training for ophthalmic use of strontium-90.	
35.950 Training for use of sealed sources for diagnosis.	35.950 Training for use of sealed sources for diagnosis.	
35.960 Training for teletherapy.	35.960 Training for use of therapeutic medical devices.	
35.961 Training for teletherapy physicist.	35.961 Training for an authorized medical physicist.	
35.970 Training for experienced authorized users.		
35.971 Physician training in a three month program.		
35.972 Recentness of training.[35.57]		
35.980 Training for an authorized nuclear pharmacist.	35.980 Training for an authorized nuclear pharmacist.	
35.981 Training for experienced nuclear pharmacists.	35.981 Training for experienced nuclear pharmacists.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material	Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material
	35.1000 Other medical uses of byproduct material or radiation from byproduct material.	35.1000 Other medical uses of byproduct material or radiation from byproduct material.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Subpart L--Records	Subpart L--Records
	35.2024 Records of authority and responsibilities for radiation protection programs.	35.2024 Records of authority and responsibilities for radiation protection programs.
	35.2026 Records of radiation program safety changes.	35.2026 Records of radiation protection program changes.
	35.2040 Records of written directives.	35.2040 Records of written directives.
	35.2045 Records of medical events.	35.2045 Records of medical events.
		35.2047 Record of a dose to an embryo/fetus or a nursing child.
	35.2060 Records of instrument calibrations.	35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct materials.
	35.2061 Records of radiation survey instrument calibrations.	35.2061 Records of radiation survey instrument calibrations.
	35.2063 Records of dosages of unsealed byproduct material for medical use.	35.2063 Records of dosages of unsealed byproduct material for medical use.
	35.2067 Records for possession of sealed sources and brachytherapy sources.	35.2067 Records of possession of sealed sources and brachytherapy sources.
	35.2070 Records of surveys for ambient radiation exposure rate.	35.2070 Records of surveys for ambient radiation exposure rate.
	35.2075 Records of the release of individuals containing radiopharmaceuticals or implants.	35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material.
	35.2080 Records of administrative and technical requirements that apply to the provision of mobile services.	35.2080 Records of administrative and technical requirements that apply to the provision of mobile medical services.
	35.2092 Records of waste disposal.	35.2092 Records of decay-in-storage.
	35.2204 Records of molybdenum-99 concentration.	35.2204 Records of molybdenum-99 concentrations.
	35.2310 Records of instruction and training.	35.2310 Records of safety instruction.
	35.2404 Records of radiation surveys of patients and human research subjects.	35.2404 Records of surveys after source implant and removal.
	35.2406 Records of brachytherapy source	35.2406 Records of brachytherapy source

CURRENT RULE	PROPOSED RULE	FINAL RULE
	inventory.	accountability.
	35.2432 Records of full calibrations on brachytherapy sources.	35.2432 Records of calibration measurements of brachytherapy sealed sources.
		35.2433 Records of decay of strontium-90 sources for ophthalmic treatments.
	35.2605 Records of installation, maintenance, and repair.	35.2605 Records of installation, maintenance, adjustment, and repair.
	35.2630 Records of dosimetry equipment.	35.2630 Records of dosimetry equipment.
	35.2632 Records of teletherapy full calibrations.	35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations.
	35.2633 Records of remote afterloader full calibrations.	
	35.2635 Records of gamma stereotactic radiosurgery unit full calibrations.	
	35.2642 Records of periodic spot-checks for teletherapy units.	
	35.2643 Records of periodic spot-checks for remote afterloaders.	35.2642 Records of periodic spot-checks for teletherapy units.
	35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.	35.2643 Records of periodic spot-checks for remote afterloader units.
	35.2647 Records of additional technical requirements for mobile remote afterloaders.	35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units.
	35.2652 Records of surveys of therapeutic treatment units.	35.2647 Records of additional technical requirements for mobile remote afterloader units.
	35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.	35.2652 Records of surveys of therapeutic treatment units.
		35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Subpart M--Reports	Subpart M--Reports
	35.3045 Reports of medical events. 35.3047 Report of a dose to an embryo/fetus or a nursing child. 35.3067 Reports of leaking sources.	35.3045 Report and notification of a medical event. 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child. 35.3067 Report of a leaking source.
Subpart K--Enforcement	Subpart N--Enforcement	Subpart N--Enforcement
35.990 Violations. 35.991 Criminal penalties. 35.999 Resolution of conflicting requirements during transition period.	35.4001 Violations. 35.4002 Criminal penalties.	35.4001 Violations. 35.4002 Criminal penalties.
	Appendix A to 10 CFR Part 35--Examining Organization or Entity	
Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).	Authority: Secs. 81, 161, 182, 183, 68 Stat. 935, 948, 953, 954, as amended (42 U.S.C. 2111, 2201, 2232, 2233); sec. 201, 88 Stat. 1242, as amended (42 U.S.C. 5841).	
Source: 51 FR 36951, Oct. 16, 1986, unless otherwise noted.		

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart A--General Information	Subpart A--General Information	Subpart A--General Information
Section 35.1 Purpose and scope.	Sec. 35.1 Purpose and scope.	§ 35.1 Purpose and scope.
This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the protection of the public health and safety. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, and 170 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.	This part prescribes requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.	This part contains the requirements and provisions for the medical use of byproduct material and for issuance of specific licenses authorizing the medical use of this material. These requirements and provisions provide for the radiation safety of workers, the general public, patients, and human research subjects. The requirements and provisions of this part are in addition to, and not in substitution for, others in this chapter. The requirements and provisions of parts 19, 20, 21, 30, 71, 170, and 171 of this chapter apply to applicants and licensees subject to this part unless specifically exempted.
Section 35.2 Definitions.	Sec. 35.2 Definitions.	§ 35.2 Definitions.
Address of use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.	Address of use means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.	*Address of use* means the building or buildings that are identified on the license and where byproduct material may be received, used, or stored.
Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.	Agreement State means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.	*Agreement State* means any State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

CURRENT RULE	PROPOSED RULE	FINAL RULE
ALARA (as low as reasonably achievable) means making every reasonable effort to maintain exposures to radiation as far below the dose limits as is practical: (1) Consistent with the purpose for which the licensed activity is undertaken, (2) Taking into account the state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and (3) In relation to utilization of nuclear energy in the public interest.		
Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.	Area of use means a portion of an address of use that has been set aside for the purpose of receiving, using, or storing byproduct material.	*Area of use* means a portion of an address of use that has been set aside for the purpose of receiving, preparing, using, or storing byproduct material.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Authorized medical physicist means a physicist who-- (1) Meets the requirements in Secs. 35.51(a) and 35.59 or Secs. 35.961 and 35.59; or (2) Is identified as a medical physicist on a Commission or Agreement State license; or (3) Is identified as a medical physicist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material.	*Authorized medical physicist* means an individual who -- (1) Meets the requirements in §§ 35.51(a) and 35.59; or (2) Is identified as an authorized medical physicist on -- (i) A specific license issued by the Commission or Agreement State license; (ii) A permit issued by a Commission master material licensee; (iii) A permit issued by a Commission or Agreement State broad scope licensee; or (iv) A permit issued by a Commission master material license broad scope permittee where that permittee has been given authorization to issue permits designating authorized medical physicists.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Authorized nuclear pharmacist means a pharmacist who is:	Authorized nuclear pharmacist means a pharmacist who--	*Authorized nuclear pharmacist* means a pharmacist who --
(1) Board certified as a nuclear pharmacist by the Board of Pharmaceutical Specialties;	(1) Meets the requirements in Secs. 35.55(a) and 35.59 or Secs. 35.980(a) and 35.59; or	(1) Meets the requirements in §§ 35.55(a) and 35.59; or
(2) Identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or	(2) Is identified as an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in the practice of nuclear pharmacy; or	(2) Is identified as an authorized nuclear pharmacist on -- (i) A specific license issued by the Commission or Agreement State license; (ii) A permit issued by a Commission master material licensee; (iii) A permit issued by a Commission or Agreement State broad scope licensee; or (iv) A permit issued by a Commission master material license broad scope permittee where that permittee has been given authorization to issue permits designating authorized nuclear pharmacists; or
(3) Identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy.	(3) Is identified as an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in the practice of nuclear pharmacy; or (4) Is approved as an authorized nuclear pharmacist by a nuclear pharmacy authorized by the Commission to approve authorized nuclear pharmacists.	(3) Is designated as an authorized nuclear pharmacist in accordance with § 32.72(b)(4).

CURRENT RULE	PROPOSED RULE	FINAL RULE
Authorized user means a physician, dentist, or podiatrist who is: (1) Board certified by at least one of the boards listed in Paragraph (a) of Sections 35.910, 35.920, 35.930, 35.940, 35.950, or 35.960;	Authorized user means a physician, dentist, or podiatrist who-- (1) Meets the requirements in Secs. 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and Sec. 35.59, or Secs. 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and Sec. 35.59; or	*Authorized user* means a physician, dentist, or podiatrist who -- (1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.491, 35.590(a), or 35.690(a); or
(2) Identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or	(2) Is identified as an authorized user on a Commission or Agreement State license that authorizes the medical use of byproduct material; or	(2) Is identified as an authorized user on -- (i) A specific license issued by the Commission or Agreement State license; (ii) A permit issued by a Commission master material licensee;
(3) Identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.	(3) Is identified as an authorized user on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material.	(iii) A permit issued by a Commission or Agreement State broad scope licensee; or (iv) A permit issued by a Commission master material license broad scope permittee where that permittee has been given authorization to issue permits designating authorized users.
		Brachytherapy means a method of radiation therapy in which sealed sources are used to deliver a radiation dose at a distance of up to a few centimeters by surface, intracavitary, intraluminal, or interstitial application.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Brachytherapy source means an individual sealed source or a manufacturer-assembled source train that is not designed to be disassembled by the user.	Brachytherapy source means a radioactive sealed source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.	*Brachytherapy source* means a radioactive source or a manufacturer-assembled source train or a combination of these sources that is designed to deliver a therapeutic dose within a distance of a few centimeters.
		Client's address means the area of use or a temporary jobsite for the purpose of providing mobile medical service in accordance with § 35.80.
Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.	Dedicated check source means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.	*Dedicated check source* means a radioactive source that is used to assure the constant operation of a radiation detection or measurement device over several months or years.
Dental use means the intentional external administration of the radiation from byproduct material to human beings in the practice of dentistry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.		
Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.	Dentist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.	*Dentist* means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice dentistry.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.	Diagnostic clinical procedures manual means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical, dosage, and route of administration.	
	High dose-rate remote afterloader, as used in this part, means a device that remotely delivers a dose rate in excess of 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.	*High dose-rate remote afterloader*, as used in this part, means a device that remotely delivers a dose rate in excess of 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.
	Low dose-rate remote afterloader as used in this part, means a device that remotely delivers a dose rate of less than 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.	*Low dose-rate remote afterloader*, as used in this part, means a device that remotely delivers a dose rate of less than or equal to 2 gray (200 rads) per hour at the point or surface where the dose is prescribed.
Management means the chief executive officer or that person's delegate or delegates.	Management means the chief executive officer or that person's delegate or delegates.	*Management* means the chief executive officer or other individual having the authority to manage, direct, or administer the licensee’s activities, or those persons’ delegate or delegates.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Manual brachytherapy, as used in this part, means a type of brachytherapy in which the radioactive sources (e.g., seeds, ribbons) are manually inserted either into the body cavities that are in close proximity to a treatment site or directly into the tissue volume.
	Medical event means an event that meets the criteria in Sec. 35.3045(a).	*Medical event* means an event that meets the criteria in § 35.3045(a).
Medical Institution means an organization in which several medical disciplines are practiced.	Medical institution means an organization in which several medical disciplines are practiced.	*Medical institution* means an organization in which several medical disciplines are practiced.
Medical use means the intentional internal or external administration of byproduct material or the radiation therefrom to patients or human research subjects under the supervision of an authorized user.	Medical use means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.	*Medical use* means the intentional internal or external administration of byproduct material or the radiation from byproduct material to patients or human research subjects under the supervision of an authorized user.
Ministerial change means a change that is made, after ascertaining the applicable requirements, by persons in authority in conformance with the requirements and without making a discretionary judgment about whether those requirements should apply in the case at hand.		

Misadministration means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:

(i) Involving the wrong individual, or wrong radiopharmaceutical; or

(ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:

(i) Involving the wrong individual, wrong radiopharmaceutical, or wrong route of administration; or

(ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose:

(i) Involving the wrong individual, or wrong treatment site; or

(ii) When the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose.

(4) A teletherapy radiation dose:

(i) Involving the wrong individual, wrong mode of treatment, or wrong treatment site;

(ii) When the treatment consists of three or fewer fractions and the calculated total administered dose differs from the total prescribed dose by more than 10 percent of the total prescribed dose;

(iii) When the calculated weekly administered dose exceeds the weekly prescribed dose by 30 percent or more of the weekly prescribed dose; or

(iv) When the calculated total administered dose differs from the total prescribed dose by more than 20 percent of the total prescribed dose.

(5) A brachytherapy radiation dose:

(i) Involving the wrong individual, wrong radioisotope, or wrong treatment site (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);

(ii) Involving a sealed source that is leaking;

(iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or

(iv) When the calculated administered dose differs from the prescribed dose by more than 20 percent of the prescribed dose.

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I - 125 or I - 131, both:

(i) Involving the wrong individual, wrong radiopharmaceutical, wrong

CURRENT RULE	PROPOSED RULE	FINAL RULE
route of administration, or when the administered dosage differs from the prescribed dosage; and (ii) When the dose to the individual exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.		
		Medium dose-rate remote afterloader, as used in this part, means a device that remotely delivers a dose rate of greater than 2 gray (200 rads), but less than 12 gray (1200 rads) per hour at the point or surface where the dose is prescribed.
Mobile nuclear medicine service means the transportation and medical use of byproduct material.	Mobile service means the transportation and medical use of byproduct material by the same licensee at temporary jobsites.	*Mobile medical service* means the transportation of byproduct material to and its medical use at the client's address.
Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.	Output means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a teletherapy unit for a specified set of exposure conditions.	*Output* means the exposure rate, dose rate, or a quantity related in a known manner to these rates from a brachytherapy source or a teletherapy, remote afterloader, or gamma stereotactic radiosurgery unit for a specified set of exposure conditions.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.	Pharmacist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.	*Pharmacist* means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice pharmacy.
Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.	Physician means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.	*Physician* means a medical doctor or doctor of osteopathy licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.
Podiatric use means the intentional external administration of the radiation from byproduct material to human beings in the practice of podiatry in accordance with a license issued by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.		
Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.	Podiatrist means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.	*Podiatrist* means an individual licensed by a State or Territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to practice podiatry.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Preceptor means an individual who provides or directs the training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, or a Radiation Safety Officer.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Prescribed dosage means the quantity of radiopharmaceutical activity as documented: (1) In a written directive; or (2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.	Prescribed dosage means the quantity of radiopharmaceutical activity as documented– (1) In a written directive; or (2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.	*Prescribed dosage* means the specified activity or range of activity of unsealed byproduct material as documented -- (1) In a written directive; or (2) In accordance with the directions of the authorized user for procedures performed pursuant to §§ 35.100 and 35.200.
Prescribed dose means: (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; or (3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.	Prescribed dose means-- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; (3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or (4) For remote afterloaders, the total dose as documented in the written directive.	*Prescribed dose* means -- (1) For gamma stereotactic radiosurgery, the total dose as documented in the written directive; (2) For teletherapy, the total dose and dose per fraction as documented in the written directive; (3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive; or (4) For remote afterloaders, the total dose and dose per fraction as documented in the written directive.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Pulsed dose-rate remote afterloader means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the ``high dose rate'' range, but is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.	*Pulsed dose-rate remote afterloader*, as used in this part, means a special type of remote afterloading device that uses a single source capable of delivering dose rates in the “high dose-rate” range, but -- (1) Is approximately one-tenth of the activity of typical high dose-rate remote afterloader sources; and (2) Is used to simulate the radiobiology of a low dose rate treatment by inserting the source for a given fraction of each hour.
Radiation Safety Officer means the individual identified as the Radiation Safety Officer on a Commission license.	Radiation Safety Officer means the individual identified as the Radiation Safety Officer on a Commission license who– (1) Meets the requirements in Secs. 35.50 and 35.59 or Secs. 35.900 and 35.59; or (2) Is identified as a Radiation Safety Officer on a Commission or Agreement State license.	*Radiation Safety Officer* means an individual who -- (1) Meets the requirements in §§ 35.50(a) and 35.59; or (2) Is identified as a Radiation Safety Officer on -- (i) A specific license issued by the Commission or Agreement State license; (ii) A permit issued by a Commission master material licensee; (iii) A permit issued by a Commission or Agreement State broad scope licensee; or (iv) A permit issued by a Commission master material license broad scope permittee where that permittee has been given authorization to issue permits designating Radiation Safety Officers.

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Recordable event means the administration of:

(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;

(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;

(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:

(i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and

(ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;

(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

(5) A teletherapy radiation dose when the calculated weekly administered dose exceeds the weekly prescribed dose by 15 percent or more of the weekly prescribed dose; or

(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed

CURRENT RULE	PROPOSED RULE	FINAL RULE
dose by more than 10 percent of the prescribed dose.		
Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.	Sealed source means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.	*Sealed source* means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.
	Sealed Source and Device Registry means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.	*Sealed Source and Device Registry* means the national registry that contains all the registration certificates, generated by both NRC and the Agreement States, that summarize the radiation safety information for the sealed sources and devices and describe the licensing and use conditions approved for the product.
	Stereotactic radiosurgery means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.	*Stereotactic radiosurgery* means the use of external radiation in conjunction with a stereotactic guidance device to very precisely deliver a dose to a tissue volume.
	Structured educational program means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.	*Structured educational program* means an educational program designed to impart particular knowledge and practical education through interrelated studies and supervised training.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Teletherapy physicist means the individual identified as the teletherapy physicist on a Commission license.		*Teletherapy*, as used in this part, means a method of radiation therapy in which collimated gamma rays are delivered at a distance from the patient or human research subject.
	Temporary jobsite means a location where mobile services are conducted other than those location(s) of use authorized on the license.	*Temporary jobsite* means a location where mobile medical services are conducted other than those location(s) of use authorized on the license.
		Therapeutic dosage means a dosage of an unsealed byproduct material that is intended to deliver a radiation dose to a patient or human research subject for palliative or curative treatment.
		Therapeutic dose means a radiation dose delivered from a source containing byproduct material to a patient or human research subject for palliative or curative treatment.
	Treatment site means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.	*Treatment site* means the anatomical description of the tissue intended to receive a radiation dose, as described in a written directive.
		Type of use means use of byproduct material under §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, or 35.1000.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Unit dosage means a dosage intended for medical use in a single patient or human research subject that has been obtained from a manufacturer or preparer licensed pursuant to Sec. 32.72 of this chapter or equivalent Agreement State requirements.	*Unit dosage* means a dosage prepared for medical use for administration as a single dosage to a patient or human research subject without any further manipulation of the dosage after it is initially prepared.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Written directive means an order in writing for a specific patient or human research subject, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information: (1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or 1-131: the dosage; (2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration; (3) For gamma stereotactic radiosurgery: target coordinates, collimator size, plug pattern, and total dose; (4) For teletherapy: the total dose, dose per fraction, treatment site, and overall treatment period; (5) For high-dose-rate remote afterloading brachytherapy: the radioisotope, treatment site, and total dose; or (6) For all other brachytherapy: (i) Prior to implantation: the radioisotope, number of sources, and source strengths; and (ii) After implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength and exposure time (or, equivalently, the total dose).	Written directive means an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in Sec. 35.40.	*Written directive* means an authorized user’s written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject, as specified in § 35.40.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.5 Maintenance of records. Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.	Sec. 35.5 Maintenance of records. Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original or a reproduced copy or a microform provided that the copy or microform is authenticated by authorized personnel and that the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications, must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.	§ 35.5 Maintenance of records. Each record required by this part must be legible throughout the retention period specified by each Commission regulation. The record may be the original, a reproduced copy, or a microform provided that the copy or microform is authenticated by authorized personnel and the microform is capable of producing a clear copy throughout the required retention period. The record may also be stored in electronic media with the capability for producing legible, accurate, and complete records during the required retention period. Records such as letters, drawings, and specifications must include all pertinent information such as stamps, initials, and signatures. The licensee shall maintain adequate safeguards against tampering with and loss of records.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.6 Provisions for research involving human subjects. A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an "Institutional Review Board" in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects,	Sec. 35.6 Provisions for research involving human subjects. A licensee may conduct research involving human subjects using byproduct material provided that the research is conducted, funded, supported, or regulated by another Federal Agency which has implemented the Federal Policy for the Protection of Human Subjects. Otherwise, a licensee shall apply for and receive approval of a specific amendment to its NRC license before conducting such research. Both types of licensees shall, at a minimum, obtain informed consent from the human subjects and obtain prior review and approval of the research activities by an ``Institutional Review Board'' in accordance with the meaning of these terms as defined and described in the Federal Policy for the Protection of Human Subjects.	§ 35.6 Provisions for the protection of human research subjects. (a) A licensee may conduct research involving human research subjects only if using the byproduct materials specified on its license for the uses authorized on its license. (b) If the research is conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy for the Protection of Human Subjects (Federal Policy), the licensee shall, prior to conducting research -- (1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal Policy; and (2) Obtain “informed consent,” as defined and described in the Federal Policy, from the human research subject. (c) If the research will not be conducted, funded, supported, or regulated by another Federal agency that has implemented the Federal Policy, the license shall, prior to conducting research, apply for and receive a specific amendment to its NRC medical use license. The amendment request must include a written commitment that the licensee will, prior to conducting research -- (1) Obtain review and approval of the research from an “Institutional Review Board,” as defined and described in the Federal

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Policy; and (2) Obtain “informed consent”, as defined and described in the Federal Policy, from the human research subject. (d) Nothing in this section relieves licensees from complying with the other requirements in this part.
Section 35.7 FDA, other Federal, and State requirements. Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.	Sec. 35.7, FDA, other Federal, and State requirements. Nothing in this part relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.	§ 35.7 FDA, other Federal, and State requirements. Licensees are required to comply with applicable FDA, other Federal, and State requirements governing radioactive drugs or devices.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.8 Information collection requirements: OMB approval.	Sec. 35.8 Information collection requirements: OMB approval.	§ 35.8 Information collection requirements: OMB approval.
(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number 3150-0010.	(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.	(a) The Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements in this part under control number 3150-0010.
(b) The approved information collection requirements contained in this part appear in Sections 35.6, 35.12, 35.13, 35.14, 35.20, 35.21, 35.22, 35.23, 35.29, 35.31, 35.50, 35.51, 35.52, 35.53, 35.59, 35.60, 35.61, 35.70, 35.75, 35.80, 35.92, 35.204, 35.205, 35.310, 35.315, 35.404, 35.406, 35.410, 35.415, 35.606, 35.610, 35.615, 35.630, 35.632, 35.634, 35.636, 35.641, 35.643, 35.645, 35.647, 35.980, 35.981.	(b) The approved information collection requirements contained in this part appear in Secs. 35.6, 35.12, 35.13, 35.14, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.60, 35.61, 35.62, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.204, 35.290, 35.292, 35.310, 35.315, 35.390, 35.404, 35.406, 35.410, 35.415, 35.432, 35.490, 35.590, 35.604, 35.605, 35.610, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645, 35.647, 35.652, 35.655, 35.690, 35.900, 35.910, 35.920, 35.930, 35.940, 35.950, 35.960, 35.961, 35.980, 35.981, 35.2024, 35.2026, 35.2040, 35.2045, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204,	(b) The approved information collection requirements contained in this part appear in §§ 35.6, 35.12, 35.13, 35.14, 35.19, 35.24, 35.26, 35.27, 35.40, 35.41, 35.50, 35.51, 35.55, 35.57, 35.60, 35.61, 35.63, 35.67, 35.69, 35.70, 35.75, 35.80, 35.92, 35.190, 35.204, 35.290, 35.310, 35.315, 35.390, 35.392, 35.394, 35.404, 35.406, 35.410, 35.415, 35.432, 35.490, 35.491, 35.590, 35.604, 35.605, 35.610, 35.615, 35.630, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, 35.647, 35.652, 35.655, 35.690, 35.2024, 35.2026, 35.2040, 35.2045, 35.2047, 35.2060, 35.2061, 35.2063, 35.2067, 35.2070, 35.2075, 35.2080, 35.2092, 35.2204, 35.2310, 35.2404, 35.2406, 35.2432, 35.2433,

CURRENT RULE	PROPOSED RULE	FINAL RULE
	35.2310, 35.2404, 35.2406, 35.2432, 35.2605, 35.2630, 35.2632, 35.2633, 35.2635, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, 35,3067, and Appendix A.	35.2605, 35.2630, 35.2632, 35.2642, 35.2643, 35.2645, 35.2647, 35.2652, 35.2655, 35.3045, 35.3047, and 35.3067.
(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:	(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved as follows:	(c) This part contains information collection requirements in addition to those approved under the control number specified in paragraph (a) of this section. These information collection requirements and the control numbers under which they are approved are as follows:
(1) In Section 35.12, Form NRC-313 is approved under control number 3150-0120.	(1) In Sec. 35.12, NRC Form 313, including NRC Forms 313A, and 313B which licensees may use to provide supplemental information, is approved under control number 3150-0120.	(1) In § 35.12, NRC Form 313, including NRC Forms 313A and 313B, which licensees may use to provide supplemental information, is approved under control number 3150-0120.
(2) [Reserved]	(2) [Reserved]	(2) [Reserved]
(d) OMB has assigned control number 3150-0171 for the information collection requirements contained in Sections 35.32 and 35.33.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.10 Implementation. (a) A licensee shall implement the provisions in this part on or before [date 6 months from publication of the Final Rule], with the exception of the requirements listed in paragraph (b) of this section. (b) A licensee shall implement the training requirements in Secs. 35.50(a), 35.51(a), 35.55(a), 35.59, 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), and 35.690(a) on or before [date--2 years from publication of the Final Rule]. (c) Prior to [date--2 years from publication of the Final Rule], a licensee shall satisfy the training requirements of this part for a Radiation Safety Officer, an authorized medical physicist, an authorized nuclear pharmacist, or an authorized user by complying with either: (1) The appropriate training requirements in subpart J; or (2) The appropriate training requirements in subpart B or subparts D through H. (d) If the requirements of this part are more restrictive than the existing license condition, the licensee shall comply with this part unless exempted by paragraph (f) of this section. (e) Any existing license condition that is more restrictive than a requirement in this part remains in effect until there is a license amendment or license renewal.	§ 35.10 Implementation. (a) A licensee shall implement the provisions in this part on or before [insert date 6 months from publication of the Final Rule].

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	(f) If a license condition exempted a licensee from a provision of part 35 on [date--6 months from publication of the Final Rule], it will continue to exempt a licensee from the corresponding provision in this part. (g) If a license condition cites provisions in part 35 that will be deleted on [date--6 months from publication of the Final Rule], then the license condition remains in effect until there is a license amendment or license renewal that modifies or removes this condition.	
		(b) If a license condition exempted a licensee from a provision of Part 35 on [insert date--6 months from publication of the Final Rule], then the license condition continues to exempt the licensee from the requirements in the corresponding provision until there is a license amendment or license renewal that modifies or removes the license condition. (c) When a requirement in this part differs from the requirement in an existing license condition, the requirement in this part shall govern. (d) Licensees shall continue to comply with any license conditions that require it to implement procedures required by §§ 35.610, 35.642, 35.643, and 35.645 until ther is a license amendment or renewal that modifies the license condition.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.11 License required.	Sec. 35.11 License required.	§ 35.11 License required.
(a) A person shall not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.	(a) A person may not manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use except in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.	(a) A person may manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.
(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in Section 35.25, unless prohibited by license condition.	(b) An individual may receive, possess, use, or transfer byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in Sec. 35.27, unless prohibited by license condition.	(b) A specific license is not needed for an individual who-- (1) Receives, possesses, uses, or transfers byproduct material in accordance with the regulations in this chapter under the supervision of an authorized user as provided in § 35.27, unless prohibited by license condition; and
(c) An individual may prepare unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in Section 35.25, unless prohibited by license condition.	(c) An individual may prepare unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in Sec. 35.27, unless prohibited by license condition.	(2) Prepares unsealed byproduct material for medical use in accordance with the regulations in this chapter under the supervision of an authorized nuclear pharmacist or authorized user as provided in § 35.27, unless prohibited by license condition.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.12 Application for license, amendment, or renewal.	Sec. 35.12 Application for license, amendment, or renewal.	§ 35.12 Application for license, amendment, or renewal.
(a) If the application is for medical use sited in a medical institution, only the institution's management may apply. If the application is for medical use not sited in a medical institution, any person may apply.	(a) An application must be signed by the management of the facility.	(a) An application must be signed by the applicant's or licensee's management.
(b) An application for a license for medical use of byproduct material as described in Sections 35.100, 35.200, 35.300, 35.400, and 35.500 of this part must be made by filing an original and one copy of Form NRC-313, "Application for Materials License." For guidance in completing the form, refer to the instructions in the most current versions of the appropriate Regulatory Guides. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.	(b) An application for a license for medical use of byproduct material as described in Secs. 35.100, 35.200, 35.300, 35.400, and 35.500, and for medical use of remote afterloaders in Sec. 35.600, must be made by filing an original and one copy of NRC Form 313, ``Application for Material License.'' A request for a license amendment or renewal may be submitted as an original and one copy in letter format.	(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by -- (1) Filing an original and one copy of NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and (2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.
(c) An application for a license for medical use of byproduct material as described in Section 35.600 of this part must be made by filing an original and one copy of Form NRC-313. For guidance in completing the form, refer to the instructions in the most current version of the appropriate Regulatory Guide. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.	(c) Except for medical use of remote afterloaders, a separate license application must be filed for each medical use of byproduct material as described in Sec. 35.600 by filing an original and one copy of NRC Form 313. A request for a license amendment or renewal may be submitted as an original and one copy in letter format.	(c) A request for a license amendment or renewal must be made by -- (1) Submitting an original and one copy in letter format; and (2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.
	(d) An application for a license for medical use of byproduct material as described in Sec. 35.1000	(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or

CURRENT RULE	PROPOSED RULE	FINAL RULE
(d) For copies of regulatory guides, application forms, or to submit an application or an amendment request, refer to Section 30.6 of this chapter.	must be made by filing an original and one copy of NRC Form 313. (1) In addition to the information required in NRC Form 313, the application must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in subparts A through C of this part, as well as any specific information necessary for-- (i) Radiation safety precautions and instructions; (ii) Training and experience of proposed users; (iii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (iv) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. (2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.	amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part. (1) The applicant shall also provide specific information on -- (i) Radiation safety precautions and instructions; (ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and (iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety. (2) The applicant or licensee shall also provide any other information requested by the Commission in its review of the application.
(e) An applicant that satisfies the requirements specified in 10 CFR 33.13 may apply for a Type A specific license of broad scope.	(e) An applicant that satisfies the requirements specified in Sec. 33.13 may apply for a Type A specific license of broad scope.	(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.13 License amendments.	Sec. 35.13 License amendments.	§ 35.13 License amendments.
A licensee shall apply for and must receive a license amendment:	A licensee shall apply for and must receive a license amendment--	A licensee shall apply for and must receive a license amendment --
(a) Before it receives or uses byproduct material for a clinical procedure permitted under this part but not permitted by the license issued pursuant to this part;	(a) Before it receives or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued pursuant to this part;	(a) Before it receives or uses byproduct material for a type of use that is permitted under this part, but that is not authorized on the licensee's current license issued under this part;
(b) Before it permits anyone to work as an authorized user or authorized nuclear pharmacist under the license, except an individual who is:	(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except an individual who is--	(b) Before it permits anyone to work as an authorized user, authorized nuclear pharmacist, or authorized medical physicist under the license, except --
(1) An authorized user certified by the organizations specified in paragraph (a) of Section 35.910, Section 35.920, Section 35.930, Section 35.940, Section 35.950, or Section 35.960;	(1) An authorized user who meets the requirements Secs. 35.290(a), 35.292(a), 35.390(a), 35.490(a), 35.590(a), or 35.690(a) and Sec. 35.59, or Secs. 35.910, 35.920, 35.930, 35.932, 35.934, 35.940, 35.941, 35.950, 35.960 and Sec. 35.59;	(1) For an authorized user, an individual who meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.491, 35.590(a), or 35.690(a);
(2) An authorized nuclear pharmacist certified by the organization specified in paragraph (a) of Section 35.980;	(2) An authorized nuclear pharmacist who meets the requirements in Sec. 35.55(a) and Sec. 35.59; or Secs. 35.980 and 35.59;	(2) For an authorized nuclear pharmacist, an individual who meets the requirements in §§ 35.55(a) and 35.59;
	(3) An authorized medical physicist who meets the requirements in Sec. 35.51(a) and Sec. 35.59; or Secs. 35.961 and 35.59;	(3) For an authorized medical physicist, an individual who meets the requirements in §§ 35.51(a)and 35.59;
(3) Identified as an authorized user or an authorized nuclear pharmacist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy,	(4) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a Commission or Agreement State license that authorizes the use of byproduct material in medical use or in the practice of nuclear pharmacy,	(4) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on--
		(i) A Commission or Agreement State license or other equivalent permit or license recognized by NRC that authorizes the use of

CURRENT RULE	PROPOSED RULE	FINAL RULE
respectively; or	respectively; or	byproduct material in medical use or in the practice of nuclear pharmacy, respectively; or
(4) Identified as an authorized user or an authorized nuclear pharmacist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.	(5) Identified as an authorized user, an authorized nuclear pharmacist, or authorized medical physicist on a permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.	(ii) A permit issued by a Commission or Agreement State specific license of broad scope that is authorized to permit the use of byproduct material in medical use or in the practice of nuclear pharmacy, respectively.
(c) Before it changes Radiation Safety Officers or Teletherapy Physicists;	(c) Before it changes Radiation Safety Officers;	(c) Before it changes Radiation Safety Officers, except as provided in § 35.24(c);
(d) Before it orders byproduct material in excess of the amount, or radionuclide or form different than authorized on the license; and	(d) Before it orders byproduct material in excess of the amount, or radionuclide or form that is different than the radionuclide or form authorized on the license;	(d) Before it receives byproduct material in excess of the amount or in a different form, or receives a different radionuclide than is authorized on the license;
(e) Before it adds to or changes the areas of use or address or addresses of use identified in the application or on the license.	(e) Before it adds to or changes the areas identified in the application or on the license, except for areas where byproduct material is used in accordance with Secs. 35.100 and 35.200; and	(e) Before it adds to or changes the areas identified in the application or on the license, except for areas where byproduct material is used only in accordance with §§ 35.100 and 35.200; and
	(f) Before it changes the address(es) of use identified in the application or on the license.	(f) Before it changes the address(es) of use identified in the application or on the license.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.14 Notifications.	Sec. 35.14 Notifications.	§ 35.14 Notifications.
(a) A licensee shall provide to the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user or an authorized nuclear pharmacist pursuant to Section 35.13 (b)(1) through (b)(4).	(a) A licensee shall provide to the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, an authorized medical physicist, pursuant to Sec. 35.13 (b)(1) through (b)(5).	(a) A licensee shall provide the Commission a copy of the board certification, the Commission or Agreement State license, or the permit issued by a licensee of broad scope for each individual no later than 30 days after the date that the licensee permits the individual to work as an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist, under § 35.13 (b)(1) through (b)(4).
(b) A licensee shall notify the Commission by letter no later than 30 days after:	(b) A licensee shall notify the Commission by letter no later than 30 days after:	(b) A licensee shall notify the Commission by letter no later than 30 days after:
(1) An authorized user, an authorized nuclear pharmacist, Radiation Safety Officer, or teletherapy physicist permanently discontinues performance of duties under the license or has a name change; or	(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;	(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;
(2) The licensee's mailing address changes.	(2) The licensee's mailing address changes;	(2) The licensee's mailing address changes;
	(3) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in Sec. 30.34(b) of this chapter; or	(3) The licensee’s name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; or
	(4) The licensee has added to or changed the areas where byproduct material is used in accordance with Secs. 35.100 and 35.200.	(4) The licensee has deleted or otherwise changed the areas where byproduct material is used in accordance with §§ 35.100 and 35.200.
(c) The licensee shall mail the documents required in this section to the appropriate address identified in Section 30.6 of this chapter.	(c) The licensee shall mail the documents required in this section to the appropriate address identified in Sec. 30.6 of this chapter.	(c) The licensee shall mail the documents required in this section to the appropriate address identified in § 30.6 of this chapter.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.15 Exemptions regarding Type A specific licenses of broad scope.	Sec. 35.15 Exemptions regarding Type A specific licenses of broad scope.	§ 35.15 Exemptions regarding Type A specific licenses of broad scope.
A licensee possessing a Type A specific license of broad scope for medical use is exempt from the following:	A licensee possessing a Type A specific license of broad scope for medical use is exempt from--	A licensee possessing a Type A specific license of broad scope for medical use, issued under Part 33, is exempt from --
(a) The provisions of Section 35.13(b);	(a) The provisions of Sec. 35.13(b);	(a) The provisions of § 35.12(d) regarding the need to file an amendment to the license for medical uses of byproduct material, as described in § 35.1000;
(b) The provisions of Section 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;	(b) The provisions of Sec. 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;	(b) The provisions of § 35.13(b);
(c) The provisions of Section 35.14(a); and	(c) The provisions of Sec. 35.14(a);	(c) The provisions of § 35.13(e) regarding additions to or changes in the areas of use only at the addresses specified in the license;
(d) The provisions of Section 35.14(b)(1) for an authorized user or an authorized nuclear pharmacist.	(d) The provisions of Sec. 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist; and	(d) The provisions of § 35.14(a);
	(e) The provisions of Sec. 35.49(a).	(e) The provisions of § 35.14(b)(1) for an authorized user, an authorized nuclear pharmacist, or an authorized medical physicist;
		(f) The provisions of § 35.49(a).

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.18 License issuance.	Sec. 35.18 License issuance.	§ 35.18 License issuance.
The Commission shall issue a license for the medical use of byproduct material if:	(a) The Commission shall issue a license for the medical use of byproduct material if--	(a) The Commission shall issue a license for the medical use of byproduct material if --
(a) The applicant has filed Form NRC-313 "Application for Materials License" in accordance with the instructions in Section 35.12;	(1) The applicant has filed Form NRC-313 ``Application for Materials License'' in accordance with the instructions in Sec. 35.12;	(1) The applicant has filed Form NRC-313 "Application for Material License" in accordance with the instructions in § 35.12;
(b) The applicant has paid any applicable fee as provided in Part 170 of this chapter;	(2) The applicant has paid any applicable fee as provided in part 170 of this chapter;	(2) The applicant has paid any applicable fee as provided in Part 170 of this chapter;
(c) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and	(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this chapter for the protection of the public health and safety; and	(3) The Commission finds the applicant equipped and committed to observe the safety standards established by the Commission in this Chapter for the protection of the public health and safety; and
(d) The applicant meets the requirements of part 30 of this chapter.	(4) The applicant meets the requirements of part 30 of this chapter.	(4) The applicant meets the requirements of Part 30 of this chapter.
	(b) The Commission shall issue a license for mobile services if the applicant:	(b) The Commission shall issue a license for mobile medical services if the applicant:
	(1) Meets the requirements in paragraph (a) of this section; and	(1) Meets the requirements in paragraph (a) of this section; and
	(2) Assures that individuals or human research subjects to whom radiopharmaceuticals or radiation from implants will be administered may be released following treatment in accordance with Sec. 35.75.	(2) Assures that individuals or human research subjects to whom unsealed byproduct material or radiation from implants containing byproduct material will be administered may be released following treatment in accordance with § 35.75.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.19 Specific exemptions.	Sec. 35.19 Specific exemptions.	§ 35.19 Specific exemptions.
The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest. The Commission will review requests for exemptions from training and experience requirements with the assistance of its Advisory Committee on the Medical Uses of Isotopes.	The Commission may, upon application of any interested person or upon its own initiative, grant such exemptions from the regulations in this part as it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.	The Commission may, upon application of any interested person or upon its own initiative, grant exemptions from the regulations in this part that it determines are authorized by law and will not endanger life or property or the common defense and security and are otherwise in the public interest.

Subpart B--General Administrative Requirements
Subpart B--General Administrative Requirements

Section 35.20 ALARA program.

(a) Each licensee shall develop and implement a written radiation protection program that includes provisions for keeping doses ALARA.

(b) To satisfy the requirement of paragraph (a) of this section:

(1) At a medical institution, management, the Radiation Safety Officer, and all authorized users must participate in the program as requested by the Radiation Safety Committee.

(2) For licensees that are not medical institutions, management and all authorized users must participate in the program as requested by the Radiation Safety Officer.

(c) The program must include notice to workers of the program's existence and workers' responsibility to help keep dose equivalents ALARA, a review of summaries of the types and amounts of byproduct material used, occupational doses, changes in radiation safety procedures and safety measures, and continuing education and training for all personnel who work with or in the vicinity of byproduct material. The purpose of the review is to ensure that licensees make a reasonable effort to maintain individual and collective occupational doses ALARA.

Sec. 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of Sec. 20.1101 of this chapter, a licensee's management must approve in writing--

(1) Requests for license application, renewal, or amendments before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under Sec. 35.26;

(b) A licensee with multiple modalities or multiple users shall also develop, implement, and maintain written administrative procedures for interdepartmental/interdisciplinary coordination of the licensee's radiation protection program.

§ 35.24 Authority and responsibilities for the radiation protection program.

(a) In addition to the radiation protection program requirements of § 20.1101 of this chapter, a licensee's management shall approve in writing --

(1) Requests for a license application, renewal, or amendment before submittal to the Commission;

(2) Any individual before allowing that individual to work as an authorized user, authorized nuclear pharmacist, authorized medical physicist; and

(3) Radiation protection program changes that do not require a license amendment and are permitted under § 35.26;

Section 35.21 Radiation Safety Officer.	§ 35.24 Authority and responsibilities for the radiation protection program.	§ 35.24 Authority and responsibilities for the radiation protection program.
(a) A licensee shall appoint a Radiation Safety Officer responsible for implementing the radiation safety program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program.	(c) A licensee's management shall appoint a Radiation Safety Officer, who agrees in writing to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements in the daily operation of the licensee's radiation protection program.	(b) A licensee's management shall appoint a Radiation Safety Officer, who agrees, in writing, to be responsible for implementing the radiation protection program. The licensee, through the Radiation Safety Officer, shall ensure that radiation safety activities are being performed in accordance with licensee-approved procedures and regulatory requirements. (c) For up to 60 days each year, a licensee may permit an authorized user or an individual qualified to be a Radiation Safety Officer to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer, as provided in paragraph (g) of this section, if the licensee takes the actions required in paragraphs (b), (e), (g), and (h) of this section. (d) A licensee may simultaneously appoint more than one temporary Radiation Safety Officer in accordance with paragraph (c) of this section, if needed to ensure that the licensee has a temporary Radiation Safety Officer that satisfies the requirements to be a Radiation Safety Officer for each of the different uses of byproduct material permitted by the license.
(b) The Radiation Safety Officer shall: (1) Investigate overexposures, accidents, spills, losses, thefts, unauthorized receipts, uses, transfers, disposals,		

misadministrations, and other deviations from approved radiation safety practice and implement corrective actions as necessary;

(2) Establish, collect in one binder or file, and implement written policy and procedures for:

(i) Authorizing the purchase of byproduct material;

(ii) Receiving and opening packages of byproduct material;

(iii) Storing byproduct material;

(iv) Keeping an inventory record of byproduct material;

(v) Using byproduct material safely;

(vi) Taking emergency action if control of byproduct material is lost;

(vii) Performing periodic radiation surveys;

(viii) Performing checks of survey instruments and other safety equipment;

(ix) Disposing of byproduct material;

(x) Training personnel who work in or frequent areas where byproduct material is used or stored;

(xi) Keeping a copy of all records and reports required by the Commission regulations, a copy of these regulations, a copy of each licensing request and license and amendments, and the written policy and procedures required by the regulations.

(3) Brief management once each year on the byproduct material program;

(4) Establish personnel exposure investigational levels that, when exceeded, will initiate an investigation by the

Radiation Safety Officer of the cause of the exposure;

(5) Establish personnel exposure investigational levels that, when exceeded, will initiate a prompt investigation by the Radiation Safety Officer of the cause of the exposure and a consideration of actions that might be taken to reduce the probability of recurrence;

(6) For medical use not at a medical institution, approve or disapprove minor changes in radiation safety procedures that are not potentially important to safety with the advice and consent of management; and

(7) For medical use at a medical institution, assist the Radiation Safety Committee in the performance of its duties.

Section 35.22 Radiation Safety Committee.

Each medical institution licensee shall establish a Radiation Safety Committee to oversee the use of byproduct material.

(a) Each Committee must meet the following administrative requirements:

(1) Membership must consist of at least three individuals and must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. Other members may be included as the licensee deems appropriate.

(2) The Committee must meet at least quarterly.

(3) To establish a quorum and to conduct business, at least one-half of the Committee's membership must be present, including the Radiation Safety Officer and the management's representative.

(4) The minutes of each Radiation Safety Committee meeting must include:

(i) The date of the meeting;

(ii) Members present;

(iii) Members absent;

(iv) Summary of deliberations and discussions;

(v) Recommended actions and the numerical results of all ballots; and

(vi) ALARA program reviews described in Section 35.20(c).

(5) The Committee

(f) Licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, or two or more types of units under Subpart H shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer. The Committee may include other members the licensee considers appropriate.

must promptly provide each member with a copy of the meeting minutes, and retain one copy for the duration of the license.

(b) To oversee the use of licensed material, the Committee must:

(1) Review recommendations on ways to maintain individual and collective doses ALARA;

(2)(i) Review, on the basis of safety and with regard to the training and experience standards in subpart J of this part, and approve or disapprove any individual who is to be listed as an authorized user, an authorized nuclear pharmacist, the Radiation Safety Officer, or a teletherapy physicist before submitting a license application or request for amendment or renewal; or

(ii) Review, pursuant to Section 35.13 (b)(1) through (b)(4), on the basis of the board certification, the license, or the permit identifying an individual, and approve or disapprove any individual prior to allowing that individual to work as an authorized user or authorized nuclear pharmacist;

(3) Review on the basis of safety, and approve with the advice and consent of the Radiation Safety Officer and the management representative, or disapprove minor changes in radiation safety procedures that are not potentially important to safety and are permitted under Section 35.31 of this part;

(4) Review quarterly, with the assistance of the Radiation Safety Officer, a summary of the occupational radiation dose records of all personnel working with

byproduct material;

(5) Review quarterly, with the assistance of the Radiation Safety Officer, all incidents involving byproduct material with respect to cause and subsequent actions taken; and

(6) Review annually, with the assistance of the Radiation Safety Officer, the radiation safety program.

Section 35.23 Statements of authority and responsibilities.

(a) A licensee shall provide the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, sufficient authority, organizational freedom, and management prerogative, to:

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions; and

(3) Verify implementation of corrective actions.

(b) A licensee shall establish and state in writing the authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Officer, and at a medical institution the Radiation Safety Committee, and retain the current edition of these statements as a record until the Commission terminates the license.

(e) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to--

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(d) A licensee shall establish in writing the authority, duties, and responsibilities of the Radiation Safety Officer.

(f) A licensee shall retain a record of actions taken pursuant to paragraphs (a), (c), and (d) of this section in accordance with Sec. 35.2024.

(g) A licensee shall provide the Radiation Safety Officer sufficient authority, organizational freedom, time, resources, and management prerogative, to --

(1) Identify radiation safety problems;

(2) Initiate, recommend, or provide corrective actions;

(3) Stop unsafe operations; and,

(4) Verify implementation of corrective actions.

(e) A licensee shall establish the authority, duties, and responsibilities of the Radiation Safety Officer in writing.

(h) A licensee shall retain a record of actions taken under paragraphs (a), (b), and (e) of this section in accordance with § 35.2024.

Sec. 35.26 Radiation protection program changes.	§ 35.26 Radiation protection program changes.
(a) A licensee may revise its radiation protection program without Commission approval if--	(a) A licensee may revise its radiation protection program without Commission approval if --
(1) The revisions do not require an amendment under Sec. 35.13;	(1) The revision does not require an amendment under § 35.13;
(2) The revisions do not reduce radiation safety;	(2) The revision is in compliance with the regulations and the license ;
(3) The revisions have been reviewed and approved by the Radiation Safety Officer and licensee management; and	(3) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and
(4) The affected individuals are instructed on the revised program before the changes are implemented.	(4) The affected individuals are instructed on the revised program before the changes are implemented.
(b) A licensee shall retain a record of each change in accordance with Sec. 35.2026.	(b) A licensee shall retain a record of each change in accordance with § 35.2026.

Section 35.25 Supervision.	Sec. 35.27 Supervision.	§ 35.27 Supervision.
(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by Section 35.11(b) of this part shall:	(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by Sec. 35.11(b) shall--	(a) A licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user or as allowed by § 35.11(b)(1) shall --
(1) Instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material and in the licensee's written quality management program;	(1) Instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and	(1) In addition to the requirements in § 35.12, instruct the supervised individual in the licensee's written radiation protection procedures, written directive procedures, regulations of this chapter, and license conditions with respect to the use of byproduct material; and
(2) Require the supervised individual to follow the instructions of the supervising authorized user, follow the written radiation safety and quality management procedures established by the licensee, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and	(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of radioactive material, written radiation protection procedures established by the licensee, regulations of this chapter; and license conditions with respect to the medical use of byproduct material.	(2) Require the supervised individual to follow the instructions of the supervising authorized user for medical uses of byproduct material, written radiation protection procedures established by the licensee, regulations of this chapter, and license conditions with respect to the medical use of byproduct material.
(3) Periodically review the supervised individual's use of byproduct material and the records kept to reflect this use.		
(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Section 35.11(c), shall:	(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by Sec. 35.11(c), shall--	(b) A licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall --
(1) Instruct the supervised individual in the preparation of byproduct material for medical use and the principles of and procedures for radiation safety and in the licensee's written	(1) Instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's	(1) In addition to the requirements in § 35.12, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to

quality management program, as appropriate to that individual's use of byproduct material;	use of byproduct material; and	that individual's involvement with byproduct material; and
(2) Require the supervised individual to follow the instructions given pursuant to paragraph (b)(1) of this section and to comply with the regulations of this chapter and license conditions; and	(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures established by the licensee and the regulations of this chapter, and license conditions.	(2) Require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, the written radiation protection procedures established by the licensee and the regulations of this chapter, and license conditions.
(3) Require the supervising authorized nuclear pharmacist or physician who is an authorized user to periodically review the work of the supervised individual as it pertains to preparing byproduct material for medical use and the records kept to reflect that work.		
	(c) A licensee shall establish, implement, and maintain a policy for all supervised individuals to request clarification, as needed, from-- (1) The authorized user, before initiating or continuing any procedure that requires a written directive, if the supervised individual has any question about what should be done or how it should be done; and (2) The authorized user or authorized nuclear pharmacist about the instructions and requirements provided to the supervised individual in accordance with paragraphs (a) and (b) of this section.	
(c) A licensee that supervises an individual is		

responsible for the acts and omissions of the supervised individual.	(d) A licensee that permits supervised activities under paragraph (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.	(c) A licensee that permits supervised activities under paragraphs (a) and (b) of this section is responsible for the acts and omissions of the supervised individual.
Section 35.29 Administrative requirements that apply to the provision of mobile nuclear medicine service. (a) The Commission will license mobile nuclear medicine service only in accordance with subparts D, E and H of this part and Section 31.11 of this chapter. (b) Mobile nuclear medicine service licensees shall obtain a letter signed by the management of each client for which services are rendered that authorizes use of byproduct material at the client's address of use. The mobile nuclear medicine service licensee shall retain the letter for three years after the last provision of service. (c) If a mobile nuclear medicine service provides services that the client is also authorized to provide, the client is responsible for assuring that services are conducted in accordance with the regulations in this chapter while the mobile nuclear medicine service is under the client's direction. (d) A mobile nuclear medicine service may not order byproduct material to be delivered directly from the manufacturer or distributor to the client's address of use.		Cross Reference to proposed and final § 35.80

Section 35.31 Radiation safety program changes. (a) A licensee may make minor changes in radiation safety procedures that are not potentially important to safety, i.e., ministerial changes, that were described in the application for license, renewal, or amendment except for those changes in Sections 35.13 and 35.606 of this part. Examples of such ministerial changes include: editing of procedures for clarity or conformance with local drafting policy or updating names, telephone numbers, and addresses; adoption of model radiation safety procedures published in NRC Regulatory Guides; replacement of equipment; reassignment of tasks among employees; or assignment of service contracts for services such as personnel dosimetry, radiation safety equipment repair or calibration, waste disposal, and safety surveys. A licensee is responsible for assuring that any change made is in compliance with the requirements of the regulations and the license. (b) A licensee shall retain a record of each change until the license has been renewed or terminated. The record must include the effective date of the change, a copy of the old and new radiation safety procedures, the reason for the change, a summary of radiation safety matters that were considered before making the change, the signature of the Radiation Safety Officer, and the signatures of the affected authorized users and of	Cross Reference proposed and final § 35.26

management or, in a medical institution, the Radiation Safety Committee's chairman and the management representative.

Section 35.32 Quality management program.

(a) Each applicant or licensee under this part, as applicable, shall establish and maintain a written quality management program to provide high confidence that byproduct material or radiation from byproduct material will be administered as directed by the authorized user. The quality management program must include written policies and procedures to meet the following specific objectives:

(1) That, prior to administration, a written directive 1_/ is prepared for:

1_/ If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also, a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the

patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(i) Any teletherapy radiation dose;

(ii) Any gamma stereotactic radiosurgery radiation dose;

(iii) Any brachytherapy radiation dose;

(iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or

(v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

(2) That, prior to each administration, the patient's or human research subject's identity is verified by more than one method as the individual named in the written directive;

(3) That final plans of treatment and related calculations for brachytherapy, teletherapy, and gamma stereotactic radiosurgery are in accordance with the respective written directives;

(4) That each administration is in accordance with the written

directive; and

(5) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(b) The licensee shall:

(1) Develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation of:

(i) A representative sample of patient and human research subject administrations,

(ii) All recordable events, and

(iii) All misadministrations

to verify compliance with all aspects of the quality management program; these reviews shall be conducted at intervals no greater than 12 months;

(2) Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of paragraph (a) of this section; and

(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

(c) The licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;

(2) Identifying what, if any, corrective action is required to prevent recurrence; and

(3) Retaining a record,

in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

(d) The licensee shall retain:

(1) Each written directive; and

(2) A record of each administered radiation dose or radiopharmaceutical dosage where a written directive is required in paragraph (a)(1) above, in an auditable form, for three years after the date of administration.

(e) The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional Office within 30 days after the modification has been made.

(f)(1) Each applicant for a new license, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 a quality management program as part of the application for a license and implement the program upon issuance of the license by the NRC.

(2) Each existing licensee, as applicable, shall submit to the appropriate NRC Regional Office in accordance with 10 CFR 30.6 by January 27, 1992 a written certification that the quality management program has been implemented along with a copy of the program.

Sec. 35.40 Written directives.	§ 35.40 Written directives.
(a) A written directive must be prepared, dated, and signed by an authorized user prior to administration of I-131 sodium iodide greater than 1.11 Megabequerels (Mbq) (30 microcuries (<greek-m>Ci)), any therapeutic dosage of a radiopharmaceutical, or any therapeutic dose of radiation from byproduct material.\1\	(a) A written directive must be dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 Megabequerels (MBq) (30 microcuries (µCi)), any therapeutic dosage of unsealed byproduct material or any therapeutic dose of radiation from byproduct material.

\1\ If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in writing in the patient's record a written directive is prepared within 48 hours of the oral directive. If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision. Also, a written revision to an existing written directive may be made by any diagnostic or	(1) If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive is acceptable. The information contained in the oral directive must be documented as soon as possible in writing in the patient's record. A written directive must be prepared within 48 hours of the oral directive.

therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.	

(b) The written directive must contain the patient or human research subject's name and the following:	(b) The written directive must contain the patient or human research subject's name and the following information--
(1) For any administration of quantities greater than 1.11 MBq (30 <greek-m>Ci) of sodium iodide I-131: the dosage;	(1) For any administration of quantities greater than 1.11 MBq (30 µCi) of sodium iodide I-131: the dosage;
(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-131: the radiopharmaceutical, dosage, and route of administration;	(2) For an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131: the radioactive drug, dosage, and route of administration;
(3) For gamma stereotactic radiosurgery: target coordinates (including gamma angle), collimator size, plug pattern, total dose for the treatment, and the total treatment volume;	(3) For gamma stereotactic radiosurgery: the total dose, treatment site, and number of target coordinate settings per treatment for each anatomically distinct treatment site;
(4) For teletherapy: the total dose, dose per fraction, number of fractions, treatment site, and overall treatment period;	(4) For teletherapy: the total dose, dose per fraction, number of fractions, and treatment site;
(5) For remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or	(5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; or
(6) For all other brachytherapy:	(6) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:
(i) Prior to implantation:	(i) Before implantation: treatment site, the radionuclide, and dose; and

treatment site, the radionuclide, number of sources and source strengths or dose; and

(ii) After implantation but prior to completion of the procedure: the radionuclide, treatment site, and total source strength and exposure time (or, equivalently, the total dose).

(c) The licensee shall retain the written directive in accordance with Sec. 35.2040.

(ii) After implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, and total source strength and exposure time (or, equivalently, the total dose).

(c) A written revision to an existing written directive may be made if the revision is dated and signed by an authorized user before the administration of the dosage of unsealed byproduct material, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.

(1) If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive is acceptable. The oral revision must be documented as soon as possible in the patient's record. A revised written directive must be signed by the authorized user within 48 hours of the oral revision.

(d) The licensee shall retain the written directive in accordance with § 35.2040.

Sec. 35.41 Procedures for administrations requiring a written directive.	§ 35.41 Procedures for administrations requiring a written directive.
(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:	(a) For any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that:
(1) The patient's or human research subject's identity is verified before each administration; and	(1) The patient's or human research subject's identity is verified before each administration; and
(2) Each administration is in accordance with the written directive.	(2) Each administration is in accordance with the written directive.
(b) The procedures required by paragraph (a) of this section must, at a minimum, address--	(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material--
(1) Verifying the identity of the patient or human research subject;	(1) Verifying the identity of the patient or human research subject;
(2) Verifying that the specific details of the administration are in accordance with the written directive and treatment plan;	(2) Verifying that the administration is in accordance with the treatment plan, if applicable, and the written directive;
(3) Checking both manual and computer-generated dose calculations; and	(3) Checking both manual and computer-generated dose calculations; and
(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical devices authorized by Sec. 35.600.	(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

Section 35.33 Notifications, reports, and records of misadministrations.

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center 2_/ no later than the next calendar day after discovery of the misadministration.

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2_/ The commercial telephone number of the NRC Operations Center is (301) 816-5100.

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(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that

individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall

retain a record of each misadministration for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

Section 35.49 Suppliers for sealed sources or devices for medical use.	Sec. 35.49 Suppliers for sealed sources or devices for medical use.	§ 35.49 Suppliers for sealed sources or devices for medical use.
A licensee may use for medical use only:	A licensee may use for medical use only--	For medical use, a licensee may only use --
(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and 10 CFR 32.74 or the equivalent requirements of an Agreement State; or	(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR part 30 and Sec. 32.74 of this chapter or the equivalent requirements of an Agreement State; or	(a) Sealed sources or devices initially manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR Part 30 and 10 CFR 32.74 of this chapter or the equivalent requirements of an Agreement State; or
(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or the equivalent requirements of an Agreement State.	(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR part 30 or the equivalent requirements of an Agreement State.	(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR Part 30 or the equivalent requirements of an Agreement State.

Sec. 35.50 Training for Radiation Safety Officer

Except as provided in Sec. 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer (RSO) as provided in Sec. 35.24 to be an individual who--

(a) Is certified by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission or;

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the RSO on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following;

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and instruments used to measure radionuclides;

§ 35.50 Training for Radiation Safety Officer.

Except as provided in § 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in § 35.24 to be an individual who --

(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed a structured educational program consisting of both:

(i) 200 hours of didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Radiation biology; and

(E) Radiation dosimetry; and

(ii) One year of full-time radiation safety experience under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes similar type(s) of use(s) of byproduct material involving the following--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the

(C) Securing and controlling byproduct material;	activity of dosages, survey meters, and instruments used to measure radionuclides;
(D) Using administrative controls to avoid mistakes in the administration of byproduct material;	(C) Securing and controlling byproduct material;
(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and	(D) Using administrative controls to avoid mistakes in the administration of byproduct material;
(F) Disposing of byproduct material; and	(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and
(2) Has obtained written certification, signed by a preceptor RSO, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an RSO for medical uses of byproduct material; and	(F) Disposing of byproduct material; and
(3) Following completion of the requirements in paragraph (b) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part; or	(2) Has obtained written certification, signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; or
(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has RSO responsibilities.	(c) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee's license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer

responsibilities.

Sec. 35.51 Training for authorized medical physicist.	§ 35.51 Training for an authorized medical physicist.
The licensee shall require the authorized medical physicist to be an individual who--	The licensee shall require the authorized medical physicist to be an individual who --
(a) Is certified by a speciality board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or	(a) Is certified by a specialty board whose certification process includes all of the training and experience requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or
(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics, or an equivalent training program approved by the NRC, and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time practical experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in Secs. 35.67, 35.632, 35.633, 35.635, 35.642, 35.643, 35.644, 35.645 and 35.652, as applicable; and	(b)(1) Holds a master's or doctor's degree in physics, biophysics, radiological physics, medical physics, or health physics and has completed one year of full-time training in therapeutic radiological physics and an additional year of full-time work experience under the supervision of a medical physicist at a medical institution that includes the tasks listed in §§ 35.67, 35.433, 35.632, 35.633, 35.635, 35.642, 35.643, 35.645, and 35.652, as applicable; and
(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the requirements in paragraph (b)(1) in this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized medical physicist; and,	(2) Has obtained written certification, signed by a preceptor authorized medical physicist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized medical physicist.
(3) Following completion of the requirements in paragraph	

(b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.

Sec. 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who--

(a) Is certified as a nuclear pharmacist by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas--

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving--

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

§ 35.55 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who --

(a) Is certified as a nuclear pharmacist by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas --

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised practical experience in a nuclear pharmacy involving --

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of instruments used to determine the activity of dosages, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the requirements in paragraph (b)(1) have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.

patients or human research subjects;

(D) Using administrative controls to avoid medical events in the administration of byproduct material; and

(E) Using procedures to prevent or minimize radioactive contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.

Sec. 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.	§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist.
(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license before [date--6 months from publication of the Final Rule] need not comply with the training requirements of Secs. 35.50 and 35.51, respectively.	(a) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license before [insert date 6 months from publication of the Final Rule] need not comply with the training requirements of §§ 35.50, 35.51, or 35.55, respectively.
(b) Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before [date--6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of subparts C through H.	(b) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a Commission or Agreement State license issued before [insert date 6 months from publication of the Final Rule] who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D -H.
Sec. 35.59 Recentness of training.	§ 35.59 Recentness of training.
The training and experience specified in subparts B, D, E, F, G, H, and J must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.	The training and experience specified in Subparts B, D, E, F, G, and H must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart C--General Technical Requirements	Subpart C--General Technical Requirements	Subpart C--General Technical Requirements
Section 35.50 Possession, use, calibration, and check of dose calibrators.	Sec. 35.60 Possession, use, calibration, and check of instruments to measure the activity of photon-emitting radionuclides.	§ 35.60 Possession, use, and calibration of instruments to measure the activity of unsealed byproduct material.
(a) A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.	(a) For other than unit dosages, a licensee shall possess and use instrumentation to measure the activity of photon-emitting radionuclides prior to administration to each patient or human research subject.	(a) For direct measurements performed in accordance with § 35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.
(b) A licensee shall:	(b) If a licensee uses instrumentation to measure the activity of dosages of photon-emitting radionuclides, including unit dosages, it shall develop, implement, and maintain written procedures for proper operation of the instrumentation. At aminimum, a licensee shall--	(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer's instructions.
(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any	(1) Perform tests, before initial use and following repair, on each instrument for accuracy, linearity, and geometry dependence; (2) Perform an accuracy test annually; (3) Perform a linearity test annually over the range of	

CURRENT RULE	PROPOSED RULE	FINAL RULE
other photon-emitting radionuclide; (2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV; (3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and (4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose	medical use; and (4) Check each instrument for constancy and proper operation at the beginning of each day of use. (c) Accuracy tests must be performed with source(s) with a principal photon energy of between 100 and 500 keV whose activity is traceable to the National Institute of Standards and Technology (NIST) or by a supplier who has compared the source to a source that was calibrated by NIST.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
calibrator. (c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator. (d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent. (e) A licensee shall retain a record of each check and test required by this section for three years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include: (1) For paragraph (b)(1) of this section, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check; (2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the	(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 1.11 MBq (30 <greek-m>Ci) and shall repair or replace the instrumentation if the accuracy or constancy error exceeds 10 percent. (e) A licensee shall retain a record of each check and test required by this section in accordance with Sec. 35.2060.	(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with § 35.2060.

model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test.

(3) For paragraph (b)(3) of this section, the model and serial number of the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test.

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.51 Calibration and check of survey instruments. (a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall: (1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source; (2) Calibrate two separated readings on each scale that must be calibrated; and (3) Conspicuously note on the instrument the apparent exposure rate from a dedicated check source as determined at the time of calibration, and the date of calibration. (b) When calibrating a survey instrument, the licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and shall conspicuously attach a correction chart or graph to the instrument.	Sec. 35.61 Calibration and check of survey instruments. (a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR part 20 before first use, annually, and following repair. A licensee shall-- (1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source; (2) Calibrate two separated readings on each scale that will be used to show compliance with this part; and (3) Conspicuously note on the instrument the date of calibration. (b) A licensee shall consider a point as calibrated if the indicated exposure rate differs from the calculated exposure rate by not more than 20 percent, and conspicuously attach a correction chart or graph to the instrument if the indicated exposure rate differs from the calculated exposure rate by more than 10 percent.	§ 35.61 Calibration of survey instruments. (a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR Part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall -- (1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source; (2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and (3) Conspicuously note on the instrument the date of calibration. (b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

CURRENT RULE	PROPOSED RULE	FINAL RULE
(c) A licensee shall check each survey instrument for proper operation with the dedicated check source each day of use. A licensee is not required to keep records of these checks.	(c) Survey instruments must be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent.	
(d) A licensee shall retain a record of each survey instrument calibration for three years. The record must include:	(d) A licensee shall retain a record of each survey instrument calibration in accordance with Sec. 35.2061.	(c) A licensee shall retain a record of each survey instrument calibration in accordance with § 35.2061.
(1) A description of the calibration procedure; and		
(2) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the signature of the individual who performed the calibration.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.52 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.	Sec. 35.62 Possession, use, calibration, and check of instruments to measure dosages of alpha- or beta-emitting radionuclides.	
(a) This section does not apply to unit dosages of alpha- or beta- emitting radionuclides that are obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements.	(a) For other than unit dosages, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. A licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-or beta-emitting radionuclides prior to administration to each patient or human research subject.	
	(b) A licensee shall develop, implement, and maintain written procedures for use of the instrumentation. At a minimum, a licensee shall--	
(b) For other than unit dosages obtained pursuant to paragraph (a) of this section, a licensee shall possess and use instrumentation to measure the radioactivity of alpha- or beta-emitting radionuclides. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha- or beta-emitting radionuclides prior to administration to each patient or human research subject. In addition, the licensee shall:	(1) Perform tests before initial use, and following repair, on each instrument for accuracy, linearity, and geometry dependence, unless it is not appropriate for the use of the instrument; and make adjustments when necessary; (2) Perform accuracy annually; (3) Perform linearity tests annually over the range of medical use; and (4) Check each instrument for constancy and proper operation at the beginning of each day of use. (c) Accuracy tests must be performed with source(s) that are traceable to NIST or by a supplier who has compared the source to a source that was calibrated by NIST. (d) A licensee shall retain a	

CURRENT RULE	PROPOSED RULE	FINAL RULE
(1) Perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary; and (2) Check each instrument for constancy and proper operation at the beginning of each day of use.	record of each check and test required by this section in accordance with Sec. 35.2060.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.53 Measurement of dosages of unsealed byproduct material for medical use. A licensee shall: (a) Measure the activity of each dosage of a photon-emitting radionuclide prior to medical use. (b) Measure, by direct measurement or by combination of measurements and calculations, the activity of each dosage of an alpha- or a beta-emitting radionuclide prior to medical use, except for unit dosages obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; (c) Retain a record of the measurements required by this section for three years. To satisfy this requirement, the record must contain the: (1) Generic name, trade name, or abbreviation of the radiopharmaceutical, its lot number, and expiration dates and the radionuclide; (2) Patient's or human research subject's name, and identification number if one has been assigned; (3) Prescribed dosage and activity of the dosage at the time of measurement, or a notation that the total activity is less than 1.1 megabecquerels (30 microcuries); (4) Date and time of the measurement; and (5) Initials of the individual who made the record.	Sec. 35.63 Determination of dosages of unsealed byproduct material for medical use. (a) A licensee shall determine and record the activity of each dosage prior to medical use. (b) For a unit dosage of an alpha-, beta-, or photon-emitting radionuclide, this determination must be made either by direct measurement or by a decay correction, based on the measurement made by a manufacturer or preparer licensed pursuant to Sec. 32.72 of this chapter or equivalent Agreement State requirements. (c) For a dosage of a alpha-, beta-, or photon-emitting radionuclide prepared by the licensee, this determination must be made by direct measurement or by combination of measurements and calculations. (d) Unless otherwise directed by the authorized user, a licensee shall not use a dosage if the dosage does not fall within the prescribed dosage range or if the dosage differs from the prescribed dosage by more than 20 percent. (e) A licensee shall retain a record of the dosage	§ 35.63 Determination of dosages of unsealed byproduct material for medical use. (a) A licensee shall determine and record the activity of each dosage before medical use. (b) For a unit dosage, this determination must be made by-- (1) A decay correction, based on the activity or activity concentration determined by -- (i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA. (c) For other than unit dosages, this determination must be made by-- (1) Direct measurement of radioactivity; (2) Combination of direct measurement of radioactivity and mathematical calculations; or (3) Combination of volumetric measurements and mathematical calculations, based on the measurement made by a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements. (e) A licensee shall retain a record of the dosage

CURRENT RULE	PROPOSED RULE	FINAL RULE
	determination required by this section in accordance with Sec. 35.2063.	determination required by this section in accordance with § 35.2063.
Section 35.57 Authorization for calibration and reference sources. Any person authorized by Section 35.11 of this part for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use: (a) Sealed sources manufactured and distributed by a person licensed pursuant to Section 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 15 millicuries each; (b) Any byproduct material listed in Sections 35.100 or 35.200 with a half-life not longer than 100 days in individual amounts not to exceed 15 millicuries; (c) Any byproduct material listed in Sections 35.100 or 35.200 with a half-life longer than 100 days in individual amounts not to exceed 200 microcuries each; and (d) Technetium-99m in individual amounts not to exceed 50 millicuries.	Sec. 35.65 Authorization for calibration and reference sources. Any person authorized by Sec. 35.11 for medical use of byproduct material may receive, possess, and use the following byproduct material for check, calibration, and reference use: (a) Sealed sources manufactured and distributed by a person licensed pursuant to Sec. 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 1.11 kBq (30 mCi) each; (b) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.555 MBq (15 mCi); (c) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed 7.4 MBq (200 <greek-l>Ci) each and not to exceed 1000 times the quantities in appendix B of Part 30 of this chapter whichever is more limiting; and (d) Technetium-99m in amounts as needed.	§ 35.65 Authorization for calibration, transmission, and reference sources. Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use. (a) Sealed sources manufactured and distributed by a person licensed under §§ 32.72 and 32.74 of this chapter or equivalent Agreement State regulations and that do not exceed 1.11GBq (30 mCi) each. (b) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.555 GBq (15 mCi). (c) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 µCi) or 1000 times the quantities in Appendix B of Part 30 of this chapter. (d) Technetium-99m in amounts as needed.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.59 Requirements for possession of sealed sources and brachytherapy sources.	Sec. 35.67 Requirements for possession of sealed sources and brachytherapy sources.	§ 35.67 Requirements for possession of sealed sources and brachytherapy sources.
(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.	(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer, and shall maintain the instructions for the duration of source use in a legible form convenient to users.	(a) A licensee in possession of any sealed source or brachytherapy source shall follow the radiation safety and handling instructions supplied by the manufacturer.
(b) A licensee in possession of a sealed source shall:	(b) A licensee in possession of a sealed source shall--	(b) A licensee in possession of a sealed source shall --
(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within six months before transfer to the licensee; and	(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and	(1) Test the source for leakage before its first use unless the licensee has a certificate from the supplier indicating that the source was tested within 6 months before transfer to the licensee; and
(2) Test the source for leakage at intervals not to exceed six months or at other intervals approved by the Commission or an Agreement State and described in the label or brochure that accompanies the source.	(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.	(2) Test the source for leakage at intervals not to exceed 6 months or at other intervals approved by the Commission or an Agreement State in the Sealed Source and Device Registry.
(c) To satisfy the leak test requirements of this section, the licensee must:	(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leakage test can detect the presence of 185 Bq (0.005 <greek-m>Ci) of radioactive material on the sample.	(c) To satisfy the leak test requirements of this section, the licensee shall measure the sample so that the leak test can detect the presence of 185 Bq (0.005 µCi) of radioactive material in the sample.
(1) Take a wipe sample from the sealed source or from the surfaces of the device in which the sealed source is mounted or stored on which radioactive contamination might be expected to accumulate or wash the source in a small volume of detergent solution and treat the entire volume as the sample;		
(2) Take teletherapy and other device source test samples when the source is in		

CURRENT RULE	PROPOSED RULE	FINAL RULE
the "off" position; and (3) Measure the sample so that the leakage test can detect the presence of 0.005 microcuries of radioactive material on the sample.		
(d) A licensee shall retain leakage test records for five years. The records must contain the model number, and serial number if assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample expressed in microcuries, a description of the method used to measure each test sample, the date of the test, and the signature of the Radiation Safety Officer.	(d) A licensee shall retain leakage test records in accordance with Sec. 35.2067.	(d) A licensee shall retain leak test records in accordance with § 35.2067.
(e) If the leakage test reveals the presence of 0.005 microcurie or more of removable contamination, the licensee shall: (1) Immediately withdraw the sealed source from use and store it in accordance with the requirements in parts 20 and 30 of this chapter; and (2) File a report within five days of the leakage test with the appropriate NRC Office listed in Section 30.6 of this chapter, with a copy to Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555, describing the equipment involved, the test results, and the action taken.	(e) If the leakage test reveals the presence of 185 Bq (0.005 <greek-m>Ci) or more of removable contamination, the licensee shall-- (1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and (2) File a report within 5 days of the leakage test in accordance with Sec. 35.3067.	(e) If the leak test reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination, the licensee shall -- (1) Immediately withdraw the sealed source from use and store, dispose, or cause it to be repaired in accordance with the requirements in parts 20 and 30 of this chapter; and (2) File a report within 5 days of the leak test in accordance with § 35.3067.
(f) A licensee need not perform a leakage test on the following sources:	(f) A licensee need not perform a leakage test on the	(f) A licensee need not perform a leak test on the

CURRENT RULE	PROPOSED RULE	FINAL RULE
(1) Sources containing only byproduct material with a half-life of less than 30 days;	following sources: (1) Sources containing only byproduct material with a half-life of less than 30 days;	following sources: (1) Sources containing only byproduct material with a half-life of less than 30 days;
(2) Sources containing only byproduct material as a gas;	(2) Sources containing only byproduct material as a gas;	(2) Sources containing only byproduct material as a gas;
(3) Sources containing 100 microcuries or less of beta or gamma-emitting material or 10 microcuries or less of alpha-emitting material;	(3) Sources containing 3.7 MBq (100 <greek-m>Ci) or less of beta or gamma-emitting material or 0.37 MBq (10 <greek-m>Ci) or less of alpha-emitting material;	(3) Sources containing 3.7 MBq (100 µCi) or less of beta or gamma-emitting material or 0.37 MBq (10 µCi) or less of alpha-emitting material;
(4) Sources stored and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within six months before the date of use or transfer; and	(4) Sources stored for less than a 10-year period and not being used. The licensee shall, however, test each such source for leakage before any use or transfer unless it has been leakage-tested within 6 months before the date of use or transfer; and	
(5) Seeds of iridium-192 encased in nylon ribbon.	(5) Seeds of iridium-192 encased in nylon ribbon.	(4) Seeds of iridium-192 encased in nylon ribbon; and (5) Sources stored and not being used. However, the licensee shall test each such source for leakage before any use or transfer unless it has been leak tested within 6 months before the date of use or transfer.
(g) A licensee in possession of a sealed source or brachytherapy source shall conduct a quarterly physical inventory of all such sources in its possession. The licensee shall retain each inventory record for five years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the signature of the Radiation Safety Officer.	(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with Sec. 35.2067.	(g) A licensee in possession of sealed sources or brachytherapy sources, except for gamma stereotactic radiosurgery sources, shall conduct a semi-annual physical inventory of all such sources in its possession. The licensee shall retain each inventory record in accordance with § 35.2067.
(h) A licensee in		

possession of a sealed source or brachytherapy source shall measure the ambient dose rates quarterly in all areas where such sources are stored. This does not apply to teletherapy sources in teletherapy units or sealed sources in diagnostic devices.

(i) A licensee shall retain a record of each survey required in paragraph (h) of this section for three years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the survey instrument used, and the signature of the Radiation Safety Officer.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.60 Syringe shields and labels. (a) A licensee shall keep syringes that contain byproduct material to be administered in a radiation shield. (b) To identify its contents, a licensee shall conspicuously label each syringe or syringe radiation shield that contains a syringe with a radiopharmaceutical. The label must show the radiopharmaceutical name or its abbreviation, the clinical procedure to be performed, or the patient's or the human research subject's name. (c) A licensee shall require each individual who prepares a radiopharmaceutical kit to use a syringe radiation shield when preparing the kit and shall require each individual to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient or human research subject. Section 35.61 Vial shields and labels. (a) A licensee shall require each individual preparing or handling a vial that contains a radiopharmaceutical to keep the vial in a vial radiation shield. (b) To identify its contents, a licensee shall conspicuously label each vial radiation shield that contains a vial of a radiopharmaceutical.	Sec. 35.69 Labeling and shielding of vials and syringes. (a) A licensee shall develop, implement, and maintain written procedures for-- (1) Labeling each syringe, syringe shield, or vial shield that contains a radiopharmaceutical to identify the radiopharmaceutical name, or its abbreviation, and to ensure that the contents are conspicuously identified as containing radioactive material; and (2) Shielding vials and syringes containing radiopharmaceuticals. (b) A licensee shall instruct individuals, commensurate with the individual's assigned duties, in the procedures required by paragraph (a) of this section.	§ 35.69 Labeling of vials and syringes. Each syringe and vial that contains unsealed byproduct material must be labeled to identify the radioactive drug. Each syringe shield and vial shield must also be labeled unless the label on the syringe or vial is visible when shielded.

CURRENT RULE	PROPOSED RULE	FINAL RULE
The label must show the radiopharmaceutical name or its abbreviation.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.70 Surveys for contamination and ambient radiation exposure rate. (a) A licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered. (b) A licensee shall survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored. (c) A licensee shall conduct the surveys required by paragraphs (a) and (b) of this section so as to be able to detect dose rates as low as 0.1 millirem per hour. (d) A licensee shall establish radiation dose rate trigger levels for the surveys required by paragraphs (a) and (b) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if a dose rate exceeds a trigger level. (e) A licensee shall survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored. (f) A licensee shall conduct the surveys required by paragraph (e) of this section so as to be able to detect contamination on each wipe sample of 2000 disintegrations per minute.	Sec. 35.70 Surveys for ambient radiation exposure rate. (a) Except as provided in paragraph (b) of this section, a licensee shall survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals requiring a written directive were prepared for use or administered. (b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects can not be released pursuant to Sec. 35.75. (c) A licensee shall retain a record of each survey in accordance with Sec. 35.2070.	§ 35.70 Surveys of ambient radiation exposure rate. (a) In addition to the surveys required by Part 20 of this chapter, a licensee shall survey with a radiation detection survey instrument at the end of each day of use. A licensee shall survey all areas where unsealed byproduct material requiring a written directive was prepared for use or administered. (b) A licensee does not need to perform the surveys required by paragraph (a) of this section in an area(s) where patients or human research subjects are confined when they cannot be released under § 35.75. (c) A licensee shall retain a record of each survey in accordance with § 35.2070.

CURRENT RULE	PROPOSED RULE	FINAL RULE
(g) A licensee shall establish removable contamination trigger levels for the surveys required by paragraph (e) of this section. A licensee shall require that the individual performing the survey immediately notify the Radiation Safety Officer if contamination exceeds the trigger level.		
(h) A licensee shall retain a record of each survey for three years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the initials of the individual who performed the survey.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Sec. 35.75 Release of individuals containing radiopharmaceuticals or Implants.	Sec. 35.75 Release of individuals containing radiopharmaceuticals or implants.	§ 35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material.
(a) The licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or permanent implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 millisieverts (0.5 rem).1/	(a) A licensee may authorize the release from its control of any individual who has been administered radiopharmaceuticals or implants containing radioactive material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).\2\	(a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).[1]
1/ Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials," describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 millisieverts (0.5 rem).	\2\ Regulatory Guide 8.39, ``Release of Patients Administered Radioactive Materials,'' describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).	
(b) The licensee shall provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 millisievert (0.1 rem). If the dose to a breast-feeding infant or child could exceed 1 millisievert (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include:	(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a breast-feeding infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions shall also include--	(b) A licensee shall provide the released individual, or the individual's parent or guardian, with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (0.1 rem). If the total effective dose equivalent to a nursing infant or child could exceed 1 mSv (0.1 rem) assuming there were no interruption of breast-feeding, the instructions must also include --
(1) Guidance on the	(1) Guidance on the	(1) Guidance on the

CURRENT RULE	PROPOSED RULE	FINAL RULE
interruption or discontinuation of breast-feeding and (2) Information on the consequences of failure to follow the guidance. (c) The licensee shall maintain a record of the basis for authorizing the release of an individual, for 3 years after the date of release, if the total effective dose equivalent is calculated by: (1) Using the retained activity rather than the activity administered, (2) Using an occupancy factor less than 0.25 at 1 meter, (3) Using the biological or effective half-life, or (4) Considering the shielding by tissue. (d) The licensee shall maintain a record, for 3 years after the date of release, that instructions were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 millisieverts (0.5 rem).	interruption or discontinuation of breast-feeding; and (2) Information on the potential consequences, if any, of failure to follow the guidance. (c) A licensee shall maintain a record of the basis for authorizing the release of an individual, in accordance with Sec. 35.2075(a). (d) The licensee shall maintain a record of instructions provided to breast-feeding women in accordance with Sec. 35.2075(c).	interruption or discontinuation of breast-feeding; and (2) Information on the potential consequences, if any, of failure to follow the guidance. (c) A licensee shall maintain a record of the basis for authorizing the release of an individual in accordance with § 35.2075(a). (d) The licensee shall maintain a record of instructions provided to a breast-feeding female in accordance with § 35.2075(b).

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE PROPOSED RULE FINAL RULE

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.80 Technical requirements that apply to the provision of mobile nuclear medicine service.	Sec. 35.80 Provision of mobile service.	§ 35.80 Provision of mobile medical service.
A licensee providing mobile nuclear medicine service shall:	(a) A licensee providing mobile service shall--	(a) A licensee providing mobile medical service shall --
(a) Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals or radiopharmaceuticals that are intended for reconstitution of radiopharmaceutical kits;	(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address of use and clearly delineates the authority and responsibility of each entity;	(1) Obtain a letter signed by the management of each client for which services are rendered that permits the use of byproduct material at the client's address and clearly delineates the authority and responsibility of the licensee and the client;
(b) Bring into each address of use all byproduct material to be used and, before leaving, remove all unused byproduct material and all associated waste;	(2) Check instruments as described in Secs. 35.60 and 35.62 for proper function before medical use at each address of use or on each day of use, whichever is more frequent;	(2) Check instruments used to measure the activity of unsealed byproduct materials for proper function before medical use at each client's address or on each day of use, whichever is more frequent. At a minimum, the check for proper function required by this paragraph must include a constancy check;
(c) Secure or keep under constant surveillance and immediate control all byproduct material when in transit or at an address of use;		
(d) Check survey instruments and dose calibrators as described in Sections 35.50 and 35.51, and check all other transported equipment for proper function before medical use at each address of use;	(3) Check survey instruments for proper operation with a dedicated check source before use at each address of use;	(3) Check survey instruments for proper operation with a dedicated check source before use at each client's address; and
(e) Carry a radiation detection survey meter in each vehicle that is being used to transport byproduct material, and, before leaving a client address of use, survey all radiopharmaceutical areas of use with a radiation detection survey meter to ensure that all radiopharmaceuticals and all associated waste have been removed;	(4) Before leaving a client's address of use, survey all areas of use to ensure compliance with the requirements in part 20 of this chapter; and	(4) Before leaving a client's address, survey all areas of use to ensure compliance with the requirements in Part 20 of this chapter.
(f) Retain a record of each survey required in paragraph (e) of this section for three years. The record	(b) A mobile nuclear medicine service may not have byproduct material delivered from the manufacturer or the distributor to the client's address of use, unless the client has a license allowing possession of the byproduct material.	(b) A mobile medical service may not have byproduct material delivered from the manufacturer or the distributor to the client unless the client has a license allowing possession of the byproduct material. Byproduct material delivered to the client

CURRENT RULE	PROPOSED RULE	FINAL RULE
must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who performed the survey.	Radioactive material delivered to the client's address of use must be received and handled in conformance with the client's license.	must be received and handled in conformance with the client's license.
	(c) A licensee providing mobile nuclear services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with Sec. 35.2080.	(c) A licensee providing mobile medical services shall retain the letter required in paragraph (a)(1) and the record of each survey required in paragraph (a)(4) of this section in accordance with § 35.2080.
Section 35.90 Storage of volatiles and gases. A licensee shall store volatile radiopharmaceuticals and radioactive gases in the shipper's radiation shield and container. A licensee shall store a multi-dose container in a fume hood after drawing the first dosage from it.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.92 Decay-in-storage.	Sec. 35.92 Decay-in-storage.	§ 35.92 Decay-in-storage.
(a) A licensee may hold byproduct material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash and is exempt from the requirements of Section 20.2001 of this chapter if it:	(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal in ordinary trash if it--	(a) A licensee may hold byproduct material with a physical half-life of less than 120 days for decay-in-storage before disposal without regard to its radioactivity if it --
(1) Holds byproduct material for decay a minimum of ten half-lives;		
(2) Monitors byproduct material at the container surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding;	(1) Monitors byproduct material at the surface before disposal as ordinary trash and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and	(1) Monitors byproduct material at the surface before disposal and determines that its radioactivity cannot be distinguished from the background radiation level with an appropriate radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
(3) Removes or obliterates all radiation labels; and	(2) Removes or obliterates all radiation labels;	(2) Removes or obliterates all radiation labels except for material that will be handled as biomedical waste after it has been released from the licensee.
(4) Separates and monitors each generator column individually with all radiation shielding removed to ensure that it has decayed to background radiation level before disposal.		
(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section for three years. The record must include the date of the disposal, the date on which the byproduct material was placed in storage, the radionuclides disposed, the survey instrument used, the back-ground dose rate, the dose rate measured at the surface of each waste container, and	(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with Sec. 35.2092.	(b) A licensee shall retain a record of each disposal permitted under paragraph (a) of this section in accordance with § 35.2092.

the name of the individual who performed the disposal.

1. NUREG-1556, Vol. 9, “Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses,” describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 0.5 rem (5 mSv).

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart D--Uptake, Dilution, and Excretion	Subpart D--Unsealed Byproduct Material--Low Dose	Subpart D--Unsealed Byproduct Material - Written Directive Not Required
Section 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies.	Sec. 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	§ 35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.
A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material prepared for medical use that is either:	A licensee may use for uptake, dilution, or excretion studies any unsealed byproduct material, except in quantities that require a written directive pursuant to Sec. 35.40, prepared for medical use that is either--	Except for quantities that require a written directive pursuant to § 35.40(b)(2), a licensee may use any unsealed byproduct material prepared for medical use for uptake, dilution, or excretion studies that is --
(a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or	(a) Obtained from a manufacturer or preparer licensed pursuant to Sec. 32.72 of this chapter or equivalent Agreement State requirements; or	(a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or
(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 35.920, or an individual under the supervision of either as specified in Section 35.25.	(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Sec. 35.292, or an individual under the supervision of either as specified in Sec. 35.27.	(b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or
		(c) Obtained from an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or (d) Prepared by the licensee for use in research in accordance with a Radioactive Drug Research Committee-approved application or an Investigational New Drug (IND) protocol accepted by FDA.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.120 Possession of survey instrument. A licensee authorized to use byproduct material for uptake, dilution, and excretion studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.190 Training for uptake, dilution, and excretion studies. Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.100 to be a physician who -- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b) Is an authorized user under §§ 35.290 or 35.390 or equivalent Agreement State requirements; or (c)(1) Has completed 60 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies; the training and experience must include -- (i) Classroom and laboratory training in the following areas -- (A) Radiation physics and instrumentation;

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(B) Radiation protection;
(C) Mathematics pertaining to the use and measurement of radioactivity;
(D) Chemistry of byproduct material for medical use; and
(E) Radiation biology; and
(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.190, § 35.290, or § 35.390 or equivalent Agreement State requirements, involving --
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;
(C) Calculating, measuring, and safely preparing patient or human research subject dosages;
(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;
(E) Using procedures to contain spilled byproduct

material safely and using proper decontamination procedures; and

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.190, 35.290, or 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required. A licensee may use for imaging and localization studies any unsealed byproduct material, except in quantities that require a written directive pursuant to Sec. 35.40, prepared for medical use that is either-- (a) Obtained from a manufacturer or preparer licensed pursuant to Sec. 32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Sec. 35.292, or an individual under the supervision of either as specified in Sec. 35.27.	§ 35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required. Except for quantities that require a written directive under § 35.40(b)(2), a licensee may use any unsealed byproduct material prepared for medical use for imaging and localization studies that is -- (a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or (c) Obtained from an NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA.

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CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.204 Permissible molybdenum-99 concentration. (a) A licensee may not administer to humans a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m). (b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section. (c) If a licensee is required to measure the molybdenum-99 concentration, the licensee shall retain a record of each measurement in accordance with § 35.2204.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.290 Training for imaging and localization studies. Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who -- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b) Is an authorized user under § 35.390 or equivalent Agreement State requirements; or (c)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies; the training and experience must include, at a minimum, -- (i) Classroom and laboratory training in the following areas -- (A) Radiation physics and instrumentation;

CURRENT RULE	PROPOSED RULE	FINAL RULE
		(B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; (D) Chemistry of byproduct material for medical use; (E) Radiation biology; and (ii) Work experience, under the supervision of an authorized user, who meets the requirements in §§ 35.290 or 35.390 or equivalent Agreement State requirements, involving -- (A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (E) Using procedures to safely contain spilled radioactive material

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and using proper decontamination procedures;

(F) Administering dosages of radioactive drugs to patients or human research subjects; and

(G) Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.290 or § 35.390 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Subpart E--Unsealed Byproduct Material - Written Directive Required § 35.300 Use of unsealed byproduct material for which a written directive is required. A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is -- (a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or (c) Obtained from an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) application accepted by FDA; or (d) Prepared by the licensee for use in accordance with an Investigational New

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart E--Imaging and Localization		Drug (IND) protocol accepted by FDA.
Section 35.200 Use of unsealed byproduct material for imaging and localization studies. A licensee may use for imaging and localization studies any unsealed byproduct material prepared for medical use that is either: (a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 35.920, or an individual under the supervision of either as specified in Section 35.25.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.204 Permissible molybdenum-99 concentration.	Sec. 35.204 Permissible molybdenum-99 concentration.	
(a) A licensee may not administer to humans a radiopharmaceutical containing more than 0.15 microcurie of molybdenum-99 per millicurie of technetium-99m.	(a) A licensee may not administer to humans a radiopharmaceutical containing more than 5.55 kBq (0.15 <greek-m>Ci) of molybdenum-99 per millicurie of technetium-99m.	
(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration in each eluate or extract.	(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.	
(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement for three years. The record must include, for each elution or extraction of technetium-99m, the measured activity of the technetium expressed in millicuries, the measured activity of the molybdenum expressed in microcuries, the ratio of the measures	(c) A licensee that must measure molybdenum concentration shall retain a record of each measurement in accordance with Sec. 35.2204.	

expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the initials of the individual who made the measurement.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.205 Control of aerosols and gases. (a) A licensee that administers radioactive aerosols or gases shall do so in a room with a system that will keep airborne concentrations low enough so as not to exceed the limits prescribed by Sections 20.1201 and 20.1301 of this chapter. The system must either be directly vented to the atmosphere through an air exhaust or provide for collection and decay or disposal of the aerosol or gas in a shielded container. (b) A licensee shall administer radioactive gases only in rooms that are at negative pressure compared to surrounding rooms. (c) Before receiving, using, or storing a radioactive gas, the licensee shall calculate the amount of time needed after a spill to reduce the concentration in the room low enough so as not to exceed the limits prescribed by Section 20.1201 of this chapter. The calcula-tion must be based on the highest activity of gas handled in a single container, the air volume of the room, and the measured available air exhaust		

rate.

(d) A licensee shall make a record of the calculations required in paragraph (c) of this section that includes the assumptions, measurements, and calculations made and shall retain the record for the duration of use of the area. A licensee shall also post the calculated time and safety measures to be instituted in case of a spill at the area of use.

(e) A licensee shall check the operation of reusable collection systems each month, and measure the ventilation rates available in areas of radioactive gas use each six months.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.220 Possession of survey instruments. A licensee authorized to use byproduct material for imaging and localization studies shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range of 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.290 Training for uptake, dilution, and excretion studies. Except as provided in Secs. 35.57, the licensee shall require the authorized user of a radiopharmaceutical for uses authorized under Sec. 35.100 to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission or–	
	(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of diagnostic radiopharmaceuticals, consisting of both-- (i) 40 hours of didactic training in the following areas-- (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	measurement of radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology; and (ii) 20 hours of supervised practical experience under the supervision of an authorized user involving–	
	(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and (F) Administering dosages to patients or human research subjects; and (2) Has obtained written	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	certification, signed by a preceptor authorized user, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of a diagnostic radiopharmaceutical for the uses listed in Sec. 35.100; and (3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.292 Training for imaging and localization studies. Except as provided in Secs. 35.57, the licensee shall require the authorized user of radiopharmaceuticals and generators for the uses authorized under Sec. 35.200 to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or (b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of diagnostic radiopharmaceuticals and generators, consisting of both-- (i) 80 hours of didactic training in the following areas-- (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology; and (ii) 40 hours of supervised practical experience under the supervision of an authorized user involving--	
	(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;	
	(F) Eluting technetium-99m from generator systems, measuring and testing	

the eluate for molybdenum-99, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and

(G) Administering dosages to patients or human research subjects; and

(2) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraph (b)(1) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of diagnostic radiopharmaceuticals and generators for the uses listed in Sec. 35.200; and

(3) Following completion of the requirements in paragraph (b)(1) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

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§ 35.310 Safety instruction.

In addition to the requirements of § 19.12 of this chapter,

(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material and cannot be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --

(1) Patient or human research subject control;

(2) Visitor control, including --

(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and

(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;

(3) Contamination control;

(4) Waste control; and

(5) Notification of the Radiation Safety Officer, or his or her designee, and the authorized user if the

CURRENT RULE	PROPOSED RULE	FINAL RULE
		patient or the human research subject has a medical emergency or dies. (b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.315 Safety precautions. (a) For each patient or human research subject that cannot be released in accordance with § 35.75, a licensee shall -- (1) Quarter the patient or the human research subject either in -- (i) A private room with a private sanitary facility; or (ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released pursuant to § 35.75; (2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign. (3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and (4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be

distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.

(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.390 Training for use of unsealed byproduct material for which a written directive is required. Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who -- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive; the training and experience must include -- (i) Classroom and laboratory training in the following areas -- (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and

measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a) or § 35.390(b)(1)(G)(1), (2), (3), or (4), as appropriate, or equivalent Agreement State requirements, involving --

(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

(C) Calculating, measuring, and safely preparing patient or human research subject dosages;

(D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material;

(E) Using procedures to contain spilled byproduct material safely and using proper decontamination

procedures;

(F) Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and

(G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status--

(1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131;

(2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[1];

(3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or

(4) Parenteral administration of any other radionuclide; and

(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §

CURRENT RULE	PROPOSED RULE	FINAL RULE
		35.390(a) or § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4), as appropriate, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300(a) or § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4), as appropriate.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 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). Except as provided in § 35.57, the licensee shall require an authorized user 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), to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b) Is an authorized user under §§ 35.390(a), 35.390(b)(1)(ii)(G)(1) or (2), or 35.394 or equivalent Agreement State requirements; or (c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the

training must include --

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

(iii) Mathematics pertaining to the use and measurement of radioactivity;

(iv) Chemistry of byproduct material for medical use; and

(v) Radiation biology; and

(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(b)(1)(ii)(G)(1) or (2) or 35.392 or equivalent Agreement State requirements, involving --

(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;

(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;

(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;

(iv) Using administrative controls to prevent a medical

event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.390(b)(1)(ii)(G)(1), 35.390(b)(1)(ii)(G)(2), 35.392, or 35.394, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 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). Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b) Is an authorized user under § 35.390(a), 35.390(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; or (c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the

CURRENT RULE	PROPOSED RULE	FINAL RULE
		training must include -- (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Chemistry of byproduct material for medical use; and (v) Radiation biology; and (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b)(1)(ii)(G)(2) or 35.394 or equivalent Agreement State requirements, involving -- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters; (iii) Calculating, measuring, and safely preparing patient or human research

CURRENT RULE	PROPOSED RULE	FINAL RULE
		subject dosages; (iv) Using administrative controls to prevent a medical event involving the use of byproduct material; (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and (vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and (3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b)(1)(ii)(G)(2) or 35.394 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131.

1.Experience with at least 3 cases in Category (2) also satisfies the requirement in Category (1).

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart F--Radiopharmaceuticals for Therapy	Subpart E--Unsealed Byproduct Material--High Dose	Subpart E--Unsealed Byproduct Material - Written Directive Required
Section 35.300 Use of unsealed byproduct material for therapeutic administration. A licensee may use for therapeutic administration any unsealed byproduct material prepared for medical use that is either: (a) Obtained from a manufacturer or preparer licensed pursuant to 10 CFR 32.72 or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Section 35.920, or an individual under the supervision of either as specified in Section 35.25.	Sec. 35.300 Use of unsealed byproduct material for which a written directive is required. A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is either-- (a) Obtained from a manufacturer or preparer licensed pursuant to Sec. 32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in Sec. 35.292, or an individual under the supervision of either as specified in Sec. 35.27.	§ 35.300 Use of unsealed byproduct material for which a written directive is required. A licensee may use any unsealed byproduct material prepared for medical use and for which a written directive is required that is -- (a) Obtained from a manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (b) Prepared by an authorized nuclear pharmacist, a physician who is an authorized user and who meets the requirements specified in §§ 35.290 or 35.390, or an individual under the supervision of either as specified in § 35.27; or (c) Obtained from an NRC or Agreement State licensee for use in research in accordance with an Investigational New Drug (IND) application accepted by FDA; or (d) Prepared by the licensee for use in accordance with an

CURRENT RULE	PROPOSED RULE	FINAL RULE
		Investigational New Drug (IND) protocol accepted by FDA.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.310 Safety instruction.	Sec. 35.310 Safety instruction.	§ 35.310 Safety instruction.
	In addition to the requirements of Sec. 19.12 of this chapter,	In addition to the requirements of § 19.12 of this chapter,
(a) A licensee shall provide radiation safety instruction for all personnel caring for the patient or the human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with Section 35.75 of this chapter. To satisfy this requirement, the instruction must describe the licensee's procedures for:	(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received radiopharmaceutical therapy and can not be released in accordance with Sec. 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include–	(a) A licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that have received therapy with unsealed byproduct material and cannot be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include --
(1) Patient or human research subject control;	(1) Patient or human research subject control;	(1) Patient or human research subject control;
(2) Visitor control;	(2) Visitor control, including--	(2) Visitor control, including --
	(i) Routine visitation to hospitalized individuals in accordance with Sec. 20.1301(a)(1) of this chapter; and	(i) Routine visitation to hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and
	(ii) Visitation authorized in accordance with Sec. 20.1301(a)(3);	(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter;
(3) Contamination control;	(3) Contamination control;	(3) Contamination control;
(4) Waste control; and	(4) Waste control; and	(4) Waste control; and
(5) Notification of the Radiation Safety Officer in case of the patient's or the human research subject's death or medical emergency.	(5) Notification of the authorized user and the Radiation Safety Officer, or his	(5) Notification of the Radiation Safety Officer, or his or her designee, and the

CURRENT RULE	PROPOSED RULE	FINAL RULE
(b) A licensee shall keep for three years a list of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.	designee, if the patient or the human research subject dies or has a medical emergency. (b) A licensee shall retain a record of individuals receiving instruction in accordance with Sec. 35.2310.	authorized user if the patient or the human research subject has a medical emergency or dies. (b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.315 Safety precautions.	Sec. 35.315 Safety precautions.	§ 35.315 Safety precautions.
(a) For each patient or human research subject receiving radiopharmaceutical therapy and hospitalized for compliance with Section 35.75 of this chapter, a licensee shall:	(a) For each patient or human research subject that cannot be released in accordance with Sec. 35.75, a licensee shall--	(a) For each patient or human research subject that cannot be released in accordance with § 35.75, a licensee shall --
(1) Provide a private room with a private sanitary facility;	(1) Provide a private room with a private sanitary facility;	(1) Quarter the patient or the human research subject either in -- (i) A private room with a private sanitary facility; or (ii) A room, with a private sanitary facility, with another individual who also has received therapy with unsealed byproduct material and who also cannot be released pursuant to § 35.75;
(2) Post the patient's or the human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room;	(2) Visibly post the patient's or the human research subject's room with a ``Radioactive Materials'' sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and	(2) Visibly post the patient's or the human research subject's room with a "Radioactive Materials" sign. (3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or the human research subject's room; and
(3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer;		

CURRENT RULE	PROPOSED RULE	FINAL RULE
(4) Promptly after administration of the dosage, measure the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey.		
(5) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle them as radioactive waste.	(3) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.	(4) Either monitor material and items removed from the patient's or the human research subject's room to determine that their radioactivity cannot be distinguished from the natural background radiation level with a radiation detection survey instrument set on its most sensitive scale and with no interposed shielding, or handle such material and items as radioactive waste.
(6)[Reserved 62 FR 4120.].		
(7) Survey the patient's or the human		

CURRENT RULE	PROPOSED RULE	FINAL RULE
research subject's room and private sanitary facility for removable contamination with a radiation detection survey instrument before assigning another patient or human research subject to the room. The room must not be reassigned until removable contamination is less than 200 disintegrations per minute per 100 square centimeters; and (8) Measure the thyroid burden of each individual who helped prepare or administer a dosage of iodine-131 within three days after administering the dosage, and retain for the period required by Section 20.1206(a) of this chapter a record of each thyroid burden measurement, its date, the name of the individual whose thyroid burden was measured, and the initials of the individual who made the measurements. (b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the human research subject dies or has a medical emergency.	(b) A licensee shall notify the authorized user and the Radiation Safety Officer, or his or her designee, as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.	(b) A licensee shall notify the Radiation Safety Officer, or his or her designee, and the authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.320 Possession of survey instruments. A licensee authorized to use byproduct material for radiopharmaceutical therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Sec. 35.390 Training for use of unsealed byproduct material for therapy or for use of unsealed byproduct material that requires a written directive. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a radiopharmaceutical for the uses authorized under Sec. 35.300 to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or (b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of unsealed byproduct material consisting of both-- (i) 80 hours of didactic training in the following areas-- (A) Radiation physics and instrumentation; (B) Radiation protection; (C)	§ 35.390 Training for use of unsealed byproduct material for which a written directive is required. Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who -- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission; or (b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive; the training and experience must include -- (i) Classroom and laboratory training in the following areas -- (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of	§ 35.390 Training for use of unsealed byproduct material for which a written directive is required. Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who -- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission; or (b)(1) Has completed 700 hours of training and experience in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive; the training and experience must include -- (i) Classroom and laboratory training in the following areas -- (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of

CURRENT RULE	PROPOSED RULE	FINAL RULE
Mathematics pertaining to the use and measurement of radioactivity; and	radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology; and	radioactivity; (D) Chemistry of byproduct material for medical use; and (E) Radiation biology; and
(D) Radiation biology; and (ii) 40 hours of supervised practical experience under the supervision of an authorized user at a medical institution involving--	(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a) or § 35.390(b)(1)(G)(1), (2), (3), or (4), as appropriate, or equivalent Agreement State requirements, involving --	(ii) Work experience, under the supervision of an authorized user who meets the requirements in § 35.390(a) or § 35.390(b)(1)(G)(1), (2), (3), or (4), as appropriate, or equivalent Agreement State requirements, involving --
(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Calibrating dose calibrators, as appropriate, and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and	(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;	(A) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Calibrating instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; (C) Calculating, measuring, and safely preparing patient or human research subject dosages; (D) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (E) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures;
(2) Has had experience, obtained		

CURRENT RULE	PROPOSED RULE	FINAL RULE
under the direct supervision of an authorized user, involving at least five cases for each procedure with radiation safety hazards similar to that use for which the individual is requesting authorized user status. This experience may be obtained concurrently with the supervised practical experience required by paragraph (b)(1)(ii) of this section;	(F) Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and (G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status-- (1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; (2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[1]; (3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or (4) Parenteral administration of any other radionuclide; and	(F) Eluting generator systems, measuring and testing the eluate for radiochemical purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; and (G) Administering dosages of radioactive drugs to patients or human research subjects involving a minimum of three cases in each of the following categories for which the individual is requesting authorized user status-- (1) Oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; (2) Oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131[2]; (3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV; and/or (4) Parenteral administration of any other radionuclide; and
(3) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraphs (b) (1) and (2) of this section have been satisfactorily completed and that the individual has achieved a level of competency sufficient to	(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.390(a) or §	(2) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.390(a) or §

CURRENT RULE	PROPOSED RULE	FINAL RULE
independently function as an authorized user of unsealed byproduct material for the uses listed in Sec. 35.300; and (4) Following completion of the requirements in paragraph (b) (1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.	35.390(b)(1)(ii)(G)(1), (2), (3), or (4), as appropriate, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300(a) or § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4), as appropriate.	35.390(b)(1)(ii)(G)(1), (2), (3), or (4), as appropriate, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300(a) or § 35.390(b)(1)(ii)(G)(1), (2), (3), or (4), as appropriate.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 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). Except as provided in § 35.57, the licensee shall require an authorized user 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), to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission; or (b) Is an authorized user under §§ 35.390(a), 35.390(b)(1)(ii)(G)(1) or (2), or 35.394 or equivalent Agreement State requirements; or (c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include --

CURRENT RULE PROPOSED RULE FINAL RULE

(i) Radiation physics and instrumentation;

(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Chemistry of byproduct material for medical use; and
(v) Radiation biology; and
(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(b)(1)(ii)(G)(1) or (2) or 35.392 or equivalent Agreement State requirements, involving --
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using administrative controls

to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of less than or equal to 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.390(b)(1)(ii)(G)(1), 35.390(b)(1)(ii)(G)(2), 35.392, or 35.394, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 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). Except as provided in § 35.57, the licensee shall require an authorized user for the oral administration of sodium iodide I-131 requiring a written directive in quantities greater than 1.22 Gigabecquerels (33 millicuries), to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (c) of this section and whose certification has been recognized by the Commission; or (b) Is an authorized user under § 35.390(a), 35.390(b)(1)(ii)(G)(2) or equivalent Agreement State requirements; or (c)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to the medical use of sodium iodide I-131 for procedures requiring a written directive; the training must include --

CURRENT RULE PROPOSED RULE FINAL RULE

(i) Radiation physics and instrumentation;

(ii) Radiation protection;
(iii) Mathematics pertaining to the use and measurement of radioactivity;
(iv) Chemistry of byproduct material for medical use; and
(v) Radiation biology; and
(2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.390(a), 35.390(b)(1)(ii)(G)(2) or 35.394 or equivalent Agreement State requirements, involving --
(i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys;
(ii) Calibrating instruments used to determine the activity of dosages and performing checks for proper operation for survey meters;
(iii) Calculating, measuring, and safely preparing patient or human research subject dosages;
(iv) Using

administrative controls to prevent a medical event involving the use of byproduct material;

(v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and

(vi) Administering dosages to patients or human research subjects, that includes at least 3 cases involving the oral administration of greater than 1.22 Gigabecquerels (33 millicuries) of sodium iodide I-131; and

(3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in §§ 35.390(a), 35.390(b)(1)(ii)(G)(2) or 35.394 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user for medical uses of unsealed byproduct material using sodium iodide I-131.

1.Experience with at least 3 cases in Category (2) also satisfies the requirement in Category (1).

2.Experience with at least 3 cases in Category (2) also satisfies the requirement in Category (1).

Subpart G--Sources for Brachytherapy	Subpart F-- Manual Brachytherapy	Subpart F-- Manual Brachytherapy
Section 35.400 Use of sources for brachytherapy.	Sec. 35.400 Use of sources for manual brachytherapy.	§ 35.400 Use of sealed sources for manual brachytherapy.
A licensee shall use the following sources in accordance with the manufacturer's radiation safety and handling instructions: (a) Cesium-137 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer; (b) Cobalt-60 as a sealed source in needles and applicator cells for topical, interstitial, and intracavitary treatment of cancer; (c) Gold-198 as a sealed source in seeds for interstitial treatment of cancer; (d) Iridium-192 as seeds encased in nylon ribbon for interstitial treatment of cancer; (e) Strontium-90 as a sealed source in an applicator for treatment of superficial eye conditions; and (f) Iodine-125 as a sealed source in seeds for interstitial treatment of cancer. (g) Palladium-103 as a sealed source in seeds for interstitial treatment of cancer.	A licensee shall use only brachytherapy sources for therapeutic medical uses as approved in the Sealed Source and Device Registry.	A licensee shall use only brachytherapy sealed sources for therapeutic medical uses: (a) As approved in the Sealed Source and Device Registry; or (b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE PROPOSED RULE FINAL RULE

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.404 Release of patients or human research subjects treated with temporary implants.	Sec. 35.404 Radiation surveys of patients or human research subjects treated with implants.	§ 35.404 Surveys after source implant and removal.
(a) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed. The licensee may not release from confinement for medical care a patient or a human research subject treated by temporary implant until all sources have been removed.	(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject and the adjacent area of use to confirm that no sources have been misplaced.	(a) Immediately after implanting sources in a patient or a human research subject, the licensee shall make a survey to locate and account for all sources that have not been implanted.
	(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a radiation survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.	(b) Immediately after removing the last temporary implant source from a patient or a human research subject, the licensee shall make a survey of the patient or the human research subject with a radiation detection survey instrument to confirm that all sources have been removed.
(b) A licensee shall retain a record of patient or human research subject surveys for three years. Each record must include the date of the survey, the name of the patient or the human research subject, the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient or the human research	(c) A licensee shall retain a record of patient or human research subject surveys in accordance with Sec. 35.2404.	(c) A licensee shall retain a record of the surveys required by paragraphs (a) and (b) of this section in accordance with § 35.2404.

subject, the survey instrument used, and the initials of the individual who made the survey.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.406 Brachytherapy sources inventory.	Sec. 35.406 Brachytherapy sources inventory.	§ 35.406 Brachytherapy sources accountability.
(a) Promptly after removing them from a patient or a human research subject, a licensee shall return brachytherapy sources to the storage area, and count the number returned to ensure that all sources taken from the storage area have been returned.	(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. (b) Promptly after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.	(a) A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use. (b) As soon as possible after removing sources from a patient or a human research subject, a licensee shall return brachytherapy sources to a secure storage area.
(b) A licensee shall make a record of brachytherapy source use which must include: (1) The names of the individuals permitted to handle the sources; (2) The number and activity of sources removed from storage, the patient's or the human research subject's name and room number, the time and date they were removed from storage, the number and activity of the sources in storage after the removal, and the initials of the individual who removed the sources from storage; (3) The number and activity of sources returned to storage, the patient's or the human	(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with Sec. 35.2406.	(c) A licensee shall maintain a record of the brachytherapy source accountability in accordance with § 35.2406.

research subject's name and room number, the time and date they were returned to storage, the number and activity of sources in storage after the return, and the initials of the individual who returned the sources to storage.

(c) Immediately after implanting sources in a patient or a human research subject the licensee shall make a radiation survey of the patient or the human research subject and the area of use to confirm that no sources have been misplaced. The licensee shall make a record of each survey.

(d) A licensee shall retain the records required in paragraphs (b) and (c) of this section for three years.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.410 Safety instruction.	Sec. 35.410 Safety instruction.	§ 35.410 Safety instruction.
	In addition to the requirements of Sec. 19.12 of this chapter,	In addition to the requirements of § 19.12 of this chapter,
(a) The licensee shall provide radiation safety instruction to all personnel caring for the patient or the human research subject undergoing implant therapy.	(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with Sec. 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the --	(a) The licensee shall provide radiation safety instruction, initially and at least annually, to personnel caring for patients or human research subjects that are undergoing implant therapy and cannot be released in accordance with § 35.75. To satisfy this requirement, the instruction must be commensurate with the duties of the personnel and include the --
To satisfy this requirement, the instruction must describe:		
(1) Size and appearance of the brachytherapy sources;	(1) Size and appearance of the brachytherapy sources;	(1) Size and appearance of the brachytherapy sources;
(2) Safe handling and shielding instructions in case of a dislodged source;	(2) Safe handling and shielding instructions;	(2) Safe handling and shielding instructions;
(3) Procedures for patient or human research subject control;	(3) Patient or human research subject control;	(3) Patient or human research subject control;
(4) Procedures for visitor control; and	(4) Visitor control, including both--	(4) Visitor control, including both:
	(i) Routine visitation of hospitalized individuals in accordance with Sec. 20.1301(a)(1) of this chapter; and	(i) Routine visitation of hospitalized individuals in accordance with § 20.1301(a)(1) of this chapter; and
	(ii) Visitation authorized in accordance with Sec. 20.1301(a)(3); and	(ii) Visitation authorized in accordance with § 20.1301(c) of this chapter; and
(5) Procedures for notification of the Radiation Safety Officer if the patient or	(5) Notification of the authorized user and	(5) Notification of the Radiation Safety

CURRENT RULE	PROPOSED RULE	FINAL RULE
the human research subject dies or has a medical emergency. (b) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (a) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.	Radiation Safety Officer, or his or her designee, if the patient or the human research subject dies or has a medical emergency. (b) A licensee shall retain a record of individuals receiving instruction in accordance with Sec. 35.2310.	Officer, or his or her designee, and an authorized user if the patient or the human research subject has a medical emergency or dies. (b) A licensee shall retain a record of individuals receiving instruction in accordance with § 35.2310.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.415 Safety precautions. (a) For each patient or human research subject receiving implant therapy and not released from licensee control pursuant to Section 35.75 of this part, a licensee shall: (1) Not quarter the patient or the human research subject in the same room with an individual who is not receiving radiation therapy. (2) Post the patient's or human research subject's door with a "Radioactive Materials" sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room; (3) Authorize visits by individuals under age 18 only on a case-by-case basis with the approval of the authorized user after consultation with the Radiation Safety Officer; and (4) Promptly after implanting the material, survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey	Sec. 35.415 Safety precautions. (a) For each patient or human research subject receiving brachytherapy and confined pursuant to Sec. 35.75, a licensee shall-- (1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving radiation therapy; and (2) Visibly post the patient's or human research subject's room with a ``Radioactive Materials'' sign and note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room.	§ 35.415 Safety precautions. (a) For each patient or human research subject that is receiving brachytherapy and cannot be released in accordance with § 35.75, a licensee shall -- (1) Not quarter the patient or the human research subject in the same room as an individual who is not receiving brachytherapy; (2) Visibly post the patient's or human research subject's room with a "Radioactive Materials" sign; and (3) Note on the door or in the patient's or human research subject's chart where and how long visitors may stay in the patient's or human research subject's room. (b) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source -- (1) Dislodged from the patient; and (2) Lodged within the patient following removal of the source applicators.

CURRENT RULE	PROPOSED RULE	FINAL RULE
instrument to demonstrate compliance with the requirements of Part 20 of this chapter, and retain for three years a record of each survey that includes the time and date of the survey, a plan of the area or list of points surveyed, the measured dose rate at several points expressed in millirem per hour, the instrument used to make the survey, and the initials of the individual who made the survey. (5) [Removed 62 FR 4120.]		(c) A licensee shall notify the Radiation Safety Officer, or his or her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.
(b) A licensee shall notify the Radiation Safety Officer immediately if the patient or the	(b) A licensee shall have available, near each treatment room, emergency response equipment. The emergency response equipment must include, as applicable-- (1) A device to assist in placing the source(s) in the shielded position; (2) A shielded source/applicator storage container; (3) Remote handling tools; and (4) Supplies necessary to surgically remove applicators or sources from a patient or human research subject treated internally with sealed sources. (c) A licensee shall notify the authorized user and the Radiation Safety Officer, or his designee, as soon as possible, if the patient or human research subject has a medical emergency and, immediately, if the patient dies.	

human research subject dies or has a medical emergency.

Section 35.420 Possession of survey instrument.

A licensee authorized to use byproduct material for implant therapy shall have in its possession a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour, and a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.432 Full calibration measurements of brachytherapy sources. (a) A licensee authorized to use brachytherapy sources for medical use shall perform full calibration measurements on brachytherapy sources before the first medical use of the source or source/applicator configuration. (b) A licensee may use calibration measurements provided by the source manufacturer that are made in accordance with the requirements of this section. (c) To satisfy the requirements of paragraphs (a) and (b) of this section, full calibration measurements must include determination of-- (1) The output or activity within +/-5 percent; and (2) Source positioning accuracy within applicators. (d) A licensee shall use the dosimetry system described in Sec. 35.630(a) to measure the output or activity of the brachytherapy source. (e) A licensee shall make full calibration measurements required by paragraph (a) of this section in	§ 35.432 Calibration measurements of brachytherapy sealed sources. (a) Before the first medical use of a brachytherapy sealed source on or after [insert date 6 months from publication of the Final Rule], a licensee shall – (1) Determine the source output or activity using a dosimetry system that meets the requirements of § 35.630(a); (2) Determine source positioning accuracy within applicators; and (3) Use published protocols accepted by nationally recognized bodies to meet the requirements of paragraphs (a)(1) and (a)(2) of this section. (b) A licensee may use measurements provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine that are made in accordance with paragraph (a) of this section. (c) A licensee shall mathematically correct the outputs or activities determined in paragraph (a) of this section for physical decay at intervals consistent with 1 percent physical decay. (d) A licensee shall retain a record of each calibration in accordance with § 35.2432.

accordance with published protocols by nationally recognized bodies.

(f) A licensee shall mathematically correct the outputs or activities determined in paragraph (c) of this section for physical decay at intervals consistent with 1 percent physical decay.

(g) A licensee shall retain a record of each calibration in accordance with Sec. 35.2432.

§ 35.433 Decay of strontium-90 sources for ophthalmic treatments.

(a) Only an authorized medical physicist shall calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments. The decay must be based on the activity determined under § 35.432.

(b) A licensee shall retain a record of the activity of each strontium-90 source in accordance with § 35.2433.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.457 Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of: (a) The source-specific input parameters required by the dose calculation algorithm; (b) The accuracy of dose, dwell time, and treatment time calculations at representative points; (c) The accuracy of isodose plots and graphic displays; and (d) The accuracy of the software used to determine radioactive source positions from radiographic images.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.490 Training for use of manual brachytherapy sources. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a manual brachytherapy source for the uses authorized under Sec. 35.400 to be a physician who-- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or (b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources consisting of both-- (i) 200 hours of didactic training in the following areas – (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; and (D) Radiation biology; (ii) 500 hours of supervised practical experience, under the supervision of an authorized user at a medical institution, involving– (A) Ordering,	§ 35.490 Training for use of manual brachytherapy sources. Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who -- (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes -- (i) 200 hours of classroom and laboratory training in the following areas -- (A) Radiation physics and instrumentation; (B) Radiation protection; (C) Mathematics pertaining to the use and measurement of radioactivity; and (D) Radiation biology; and (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements at a medical institution, involving -- (A) Ordering,

	receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Checking survey meters for proper operation; (C) Preparing, implanting, and removing sealed sources; (D) Maintaining running inventories of material on hand; (E) Using administrative controls to prevent a medical event involving the use of byproduct material; (F) Using emergency procedures to control byproduct material; and (2) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association or equivalent program approved by the NRC, and an additional two years of clinical experience under the supervision of an authorized user; and (3) Has obtained written certification, signed by a preceptor authorized user, that the requirements in paragraphs (b)(1) and (2) of this section have been satisfactorily completed and	receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (B) Checking survey meters for proper operation; (C) Preparing, implanting, and removing sealed sources; (D) Maintaining running inventories of material on hand; (E) Using administrative controls to prevent a medical event involving the use of byproduct material; (F) Using emergency procedures to control byproduct material; and (2) Has obtained three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.490 or equivalent Agreement State requirements, that the

CURRENT RULE	PROPOSED RULE	FINAL RULE
	that the individual has achieved a level of competency sufficient to independently function as an authorized user of manual brachytherapy sources for the uses listed in Sec. 35.400; and,	individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.
	(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.491 Training for ophthalmic use of strontium-90. Except as provided in § 35.57, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows -- (a) 24 hours of classroom and laboratory training that includes -- (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; (b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes -- (1) Examination of each individual to be treated; (2) Calculation of the dose to be administered; (3) Administration of the dose; and (4) Follow up and review of each individual's case history. (c) Has obtained written certification, signed by

CURRENT RULE	PROPOSED RULE	FINAL RULE
		a preceptor authorized user who meets the requirements in 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.
Subpart H--Sealed Sources for Diagnosis Section 35.500 Use of sealed sources for diagnosis. A licensee shall use the following sealed sources in accordance with the manufacturer's radiation safety and handling instructions: (a) Iodine-125, americium-241, or gadolinium-153 as a sealed source in a device for bone mineral analysis; and (b) Iodine-125 as a sealed source in a portable imaging device.	Subpart G--Sealed Sources for Diagnosis Sec. 35.500 Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.	Subpart G--Sealed Sources for Diagnosis § 35.500 Use of sealed sources for diagnosis. A licensee shall use only sealed sources for diagnostic medical uses as approved in the Sealed Source and Device Registry.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.520 Availability of survey instrument. A licensee authorized to use byproduct material as a sealed source for diagnostic purposes shall have available for use a portable radiation detection survey instrument capable of detecting dose rates over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1000 millirem per hour. The instrument must have been calibrated in accordance with Section 35.51 of this part.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.590 Training for use of sealed sources for diagnosis. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a diagnostic sealed source for the use in a device authorized under Sec. 35.500 to be a physician, dentist, or podiatrist who-- (a) Is certified by a speciality board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or (b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device that includes-- (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; (4) Radiation biology; and (5) Training in the use of the device for the uses requested.	§ 35.590 Training for use of sealed sources for diagnosis. Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who -- (a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or an Agreement State; or (b) Has had 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device; the training must include -- (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; (4) Radiation biology; and (5) Training in the use of the device for the uses requested.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart I--Teletherapy	Subpart H--Therapeutic Medical Devices	Subpart H-- Photon Emitting Remote Afterloader Units, Teletherapy Units, and Gamma Stereotactic Radiosurgery Units
Section 35.600 Use of a sealed source in a teletherapy unit.	Sec. 35.600 Use of a sealed source in a device for therapeutic medical uses.	§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.
The regulations and provisions of this subpart govern the use of teletherapy units for medical use that contain a sealed source of cobalt-60 or cesium-137.	A licensee shall use sealed sources and devices for therapy as approved in the Sealed Source and Device Registry for medical use.	A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgeryunits for therapeutic medical uses: (a) As approved in the Sealed Source and Device Registry; or (b) In research in accordance with an effective Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.604 Radiation surveys of patients and human research subjects treated with remote afterloaders.	§ 35.604 Surveys of patients and human research subjects treated with a remote afterloader unit.
	(a) Before releasing a patient or a human research subject from licensee control, a licensee shall make a survey of the patient or the human research subject and the afterloader device with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.	(a) Before releasing a patient or a human research subject from licensee control, a licensee shall survey the patient or the human research subject and the remote afterloader unit with a portable radiation detection survey instrument to confirm that the source(s) has been removed from the patient or human research subject and returned to the safe shielded position.
	(b) A licensee shall retain a record of patient or human research subject surveys in accordance with Sec. 35.2404.	(b) A licensee shall retain a record of these surveys in accordance with § 35.2404.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.605 Maintenance and repair restrictions.	Sec. 35.605 Installation, maintenance, and repair.	§ 35.605 Installation, maintenance, adjustment, and repair.
Only a person specifically licensed by the Commission or an Agreement State to perform teletherapy unit maintenance and repair shall:	(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a device that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the device or the source(s).	(a) Only a person specifically licensed by the Commission or an Agreement State shall install, maintain, adjust, or repair a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit that involves work on the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source(s), reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).
(a) Install, relocate, or remove a teletherapy sealed source or a teletherapy unit that contains a sealed source; or	(b) Except for low dose-rate remote afterloader devices, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in a device,	(b) Except for low dose-rate remote afterloader units, only a person specifically licensed by the Commission or an Agreement State shall install, replace, relocate, or remove a sealed source or source contained in other remote afterloader units, teletherapy units, or gamma stereotactic units.
(b) Maintain, adjust, or repair the source drawer, the shutter or other mechanism of a teletherapy unit that could expose the source, reduce the shielding around the source, or result in increased radiation levels.	(c) For a low dose-rate remote afterloader device, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall perform the functions listed in paragraph (b) of this section.	(c) For a low dose-rate remote afterloader unit, only a person specifically licensed by the Commission or an Agreement State or an authorized medical physicist shall install, replace, relocate, or remove a sealed source(s) contained in the unit.
	(d) A licensee shall retain a record of the installation, maintenance, and repair done on therapeutic medical devices in accordance with Sec. 35.2605.	(d) A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units in accordance with § 35.2605.

CURRENT RULE PROPOSED RULE FINAL RULE

Section 35.606 License amendments.

In addition to the changes specified in Section 35.13 of this part, a licensee shall apply for and must receive a license amendment before:

(a) Making any change in the treatment room shielding;

(b) Making any change in the location of the teletherapy unit within the treatment room;

(c) Using the teletherapy unit in a manner that could result in increased radiation levels in areas outside the teletherapy treatment room;

(d) Relocating the teletherapy unit; or

(e) Allowing an individual not listed on the licensee's license to perform the duties of the teletherapy physicist.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.610 Safety instruction.	Sec. 35.610 Safety procedures and instructions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.	§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
(a) A licensee shall post instructions at the teletherapy unit console. To satisfy this requirement, these instructions must inform the operator of:	(a) A licensee shall develop, implement, and maintain written procedures for--	(a) A licensee shall --
(1) The procedure to be followed to ensure that only the patient or the human research subject is in the treatment room before turning the primary beam of radiation on to begin a treatment or after a door interlock interruption;	(1) Securing the device, the console, the console keys, and the treatment room when not in use or unattended;	(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
	(2) Except for low dose-rate remote afterloaders, ensuring that only the patient or the human research subject is in the treatment room before initiating treatment with the source(s), unless contraindicated, or after a door interlock interruption;	(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s) ;
(2) The procedure to be followed if:	(3) Preventing dual operation of more than one radiation producing device in a treatment room if applicable; and	(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
(i) The operator is unable to turn the primary beam of radiation off with controls outside the treatment room or any other abnormal operation occurs; and	(4) Responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. This procedure must include--	(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include --
(ii) The names and telephone numbers of the authorized users and Radiation Safety Officer to be immediately contacted if the teletherapy unit or console operates abnormally.	(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;	(i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
	(ii) The process for	(ii) The process for

restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the device or console operates abnormally.

(b) A copy of the procedures required by Sec. 35.610(a) must be physically located at the unit console.

restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and

(iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of --

(1) The location of the procedures required by paragraph (a)(4) of this section; and

(2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(d) A licensee shall provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in --

(1) The procedures identified in paragraph (a)(4) of this section; and

(2) The operating procedures for the unit.

(e) A licensee shall ensure that operators, authorized medical physicists, and authorized users participate in drills of the

CURRENT RULE	PROPOSED RULE	FINAL RULE
		emergency procedures, initially and at least annually. (f) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with § 35.2310.
	(c) A licensee shall post instructions at the device console to inform the operator of-- (1) The location of the procedures required by Sec. 35.610(a); and (2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the device or console unit or console operates abnormally.	
(b) A licensee shall provide instruction in the topics identified in paragraph (a) of this section to all individuals who operate a teletherapy unit.	(d) A licensee shall provide instruction and practice drills, initially and at least annually, in the procedures identified in paragraph (a) of this section and the operating procedures to all individuals who operate the device, as appropriate to the individual's assigned duties. A licensee shall ensure that operators receive refresher training in the operation of the unit and procedures for periodic spot-checks and full calibrations; and that operators, authorized medical physicists, and authorized users participate in drills of the emergency procedures.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
(c) A licensee shall retain for three years a record of individuals receiving instruction required by paragraph (b) of this section, a description of the instruction, the date of instruction, and the name of the individual who gave the instruction.	(e) A licensee shall retain a record of individuals receiving instruction required by paragraph (d) of this section, in accordance with Sec. 35.2310.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.615 Safety precautions.	Sec. 35.615 Safety precautions for remote afterloaders, teletherapy units, and gamma stereotactic radiosurgery units.	§ 35.615 Safety precautions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
(a) A licensee shall control access to the teletherapy room by a door at each entrance.	(a) A licensee shall control access to the treatment room by a door at each entrance.	(a) A licensee shall control access to the treatment room by a door at each entrance.
(b) A licensee shall equip each entrance to the teletherapy room with an electrical interlock system that will:	(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will--	(b) A licensee shall equip each entrance to the treatment room with an electrical interlock system that will --
(1) Prevent the operator from turning the primary beam of radiation on unless each treatment room entrance door is closed;	(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;	(1) Prevent the operator from initiating the treatment cycle unless each treatment room entrance door is closed;
(2) Turn the primary beam of radiation off immediately when an entrance door is opened; and	(2) Cause the sources to be shielded immediately when an entrance door is opened; and	(2) Cause the source(s) to be shielded when an entrance door is opened; and
(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.	(3) Prevent the primary beam of radiation from being turned on following an interlock interruption until all treatment room entrance doors are closed and the beam on-off control is reset at the console.	(3) Prevent the source(s) from being exposed following an interlock interruption until all treatment room entrance doors are closed and the source(s) on-off control is reset at the console.
(c) A licensee shall equip each entrance to the teletherapy room with a beam condition indicator light.	(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.	(c) A licensee shall require any individual entering the treatment room to assure, through the use of appropriate radiation monitors, that radiation levels have returned to ambient levels.
(d) A licensee shall install in each teletherapy room a permanent radiation monitor capable of continuously monitoring beam status.		(d) Except for low-dose remote afterloader units, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation.
(1) A radiation monitor must provide visible notice of a teletherapy unit malfunction that results in an exposed or partially exposed source, and must be observable by an individual entering the teletherapy room.		(e) For licensed
(2) A radiation monitor must be equipped with a		

backup power supply separate from the power supply to the teletherapy unit. This backup power supply may be a battery system.

(3) A radiation monitor must be checked with a dedicated check source for proper operation each day before the teletherapy unit is used for treatment of patients or human research subjects.

(4) A licensee shall maintain a record of the check required by paragraph (d)(3) of this section for three years. The record must include the date of the check, notation that the monitor indicates when its detector is and is not exposed, and the initials of the individual who performed the check.

(5) If a radiation monitor is inoperable, the licensee shall require any individual entering the teletherapy room to use a survey instrument or audible alarm personal dosimeter to monitor for any malfunction of the source exposure mechanism that may result in an exposed or partially exposed source. The instrument or dosimeter must be checked with a dedicated check source for proper operation at the beginning of each day of use. The licensee shall keep a record as described in paragraph (d)(4) of this section.

(6) A licensee shall promptly repair or replace the radiation monitor if it is inoperable.

activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source.

(f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall --

(1) For medium dose-rate and pulsed dose-rate remote afterloader units, require --

(i) An authorized medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized medical physicist and either an authorized user or an individual, under the supervision of an authorized user, who has been trained to remove the source applicator(s) in the event of an emergency involving the unit, to be immediately available during continuation of all patient treatments involving the unit.

(2) For high dose-rate remote afterloader units, require --

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the unit; and

(ii) An authorized

medical physicist and either an authorized user or a physician, under the supervision of an authorized user, who has been trained in the operation and emergency response for the unit, to be physically present during continuation of all patient treatments involving the unit.

(3) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(4) Notify the Radiation Safety Officer, or his/her designee, and an authorized user as soon as possible if the patient or human research subject has a medical emergency or dies.

(g) A licensee shall have applicable emergency response equipment available near each treatment room to respond to a source --

(1) Remaining in the unshielded position; and

(2) Lodged within the patient following completion of the treatment.

CURRENT RULE	PROPOSED RULE	FINAL RULE
(e) A licensee shall construct or equip each teletherapy room to permit continuous observation of the patient or the human research subject from the teletherapy unit console during irradiation.	(d) Except for low-dose remote afterloaders, a licensee shall construct or equip each treatment room with viewing and intercom systems to permit continuous observation of the patient or the human research subject from the treatment console during irradiation. (e) For licensed activities where sources are placed within the patient's or human research subject's body, a licensee shall only conduct treatments which allow for expeditious removal of a decoupled or jammed source. (f) In addition to the requirements specified in paragraphs (a) through (e) of this section, a licensee shall-- (1) For low dose-rate remote afterloader devices, require-- (i) An authorized user or an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and (ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician trained in emergency response for the device, to be immediately available during continuation of all patient treatments involving the device. (2) For high dose-rate remote afterloader devices, require-- (i) An authorized user and an authorized medical physicist to be physically	

present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician that has been trained in emergency response for the device, to be physically present during continuation of all patient treatments involving the device.

(3) For pulsed dose-rate remote afterloader devices, require--

(i) An authorized user and an authorized medical physicist to be physically present during the initiation of all patient treatments involving the device; and

(ii) An authorized medical physicist and an authorized user or a physician, who has been designated by the authorized user and who is a radiation oncology physician that has been trained in emergency response for the device, to be immediately available during continuation of all patient treatments involving the device.

(4) For gamma stereotactic radiosurgery units, require an authorized user and an authorized medical physicist to be physically present throughout all patient treatments involving the unit.

(g) The licensee shall have emergency response equipment available near each treatment room. The emergency response equipment must include, as

applicable--

(1) A device to assist in placing the source(s) in the shielded position;

(2) A shielded source/applicator storage container;

(3) Remote handling tools; and

(4) Supplies necessary to surgically remove applicators or sources from a patient or human research subject treated internally with sealed sources.

Section 35.620 Possession of survey instrument.

A licensee authorized to use byproduct material in a teletherapy unit shall have in its possession either a portable radiation detection survey instrument capable of detecting dose rate over the range 0.1 millirem per hour to 100 millirem per hour or a portable radiation measurement survey instrument capable of measuring dose rates over the range 1 millirem per hour to 1,000 millirem per hour.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.630 Dosimetry equipment.	Sec. 35.630 Dosimetry equipment.	§ 35.630 Dosimetry equipment.
(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.	(a) A licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.	(a) Except for low dose-rate remote afterloader sources where the source output or activity is determined by the manufacturer, a licensee shall have a calibrated dosimetry system available for use. To satisfy this requirement, one of the following two conditions must be met.
(1) The system must have been calibrated by the National Institute of Standards and Technology or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous two years and after any servicing that may have affected system calibration; or	(1) The system must have been calibrated using a source traceable to the National Institute of Standards and Technology and published protocols approved by nationally recognized bodies or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or	(1) The system must have been calibrated using a system or source traceable to the National Institute of Standards and Technology (NIST) and published protocols accepted by nationally recognized bodies; or by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). The calibration must have been performed within the previous 2 years and after any servicing that may have affected system calibration; or
(2) The system must have been calibrated within the previous four years; eighteen to thirty months after that calibration, the system must have been intercompared at an intercomparison meeting with another dosimetry system that was calibrated within the past twenty-four months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The intercomparison meeting must be sanctioned by a calibration laboratory or radiologic physics center accredited by the AAPM. The results of the	(2) The system must have been calibrated within the previous 4 years; 18 to 30 months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by the National Institute of Standards and Technology or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison	(2) The system must have been calibrated within the previous 4 years. Eighteen to thirty months after that calibration, the system must have been intercompared with another dosimetry system that was calibrated within the past 24 months by NIST or by a calibration laboratory accredited by the AAPM. The results of the intercomparison must indicate that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration

intercomparison meeting must have indicated that the calibration factor of the licensee's system had not changed by more than 2 percent. The licensee may not use the intercomparison result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating cobalt-60 teletherapy units, the licensee shall use a teletherapy unit with a cobalt-60 source. When intercomparing dosimetry systems to be used for calibrating cesium-137 teletherapy units, the licensee shall use a teletherapy unit with a cesium-137 source.

result to change the calibration factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic devices, the licensee shall use a comparable device with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee's facility.

factor. When intercomparing dosimetry systems to be used for calibrating sealed sources for therapeutic units, the licensee shall use a comparable unit with beam attenuators or collimators, as applicable, and sources of the same radionuclide as the source used at the licensee’s facility.

(b) The licensee shall have a dosimetry system available for use for spot-check output measurements, if applicable. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.

(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with § 35.2630.

CURRENT RULE	PROPOSED RULE	FINAL RULE
(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.	(b) The licensee shall have available for use a dosimetry system for spot-check measurements. To satisfy this requirement, the system may be compared with a system that has been calibrated in accordance with paragraph (a) of this section. This comparison must have been performed within the previous year and after each servicing that may have affected system calibration. The spot-check system may be the same system used to meet the requirement in paragraph (a) of this section.	
(c) The licensee shall retain a record of each calibration, intercomparison, and comparison for the duration of the license. For each calibration, intercomparison, or comparison, the record must include the date, the model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of this section, the correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison, the names of the individuals who performed the calibration, intercomparison, or comparison, and evidence that the intercomparison meeting was sanctioned by a calibration laboratory or radiologic physics center accredited by AAPM	(c) The licensee shall retain a record of each calibration, intercomparison, and comparison in accordance with Sec. 35.2630.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.632 Full calibration measurements. (a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit: (1) Before the first medical use of the unit; and (2) Before medical use under the following conditions: (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and (3) At intervals not exceeding one year. (b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of: (1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use; (2) The coincidence of the radiation field and the field indicated by the light beam	Sec. 35.632 Full calibration measurements on teletherapy units. (a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit-- (1) Before the first medical use of the unit; and (2) Before medical use under the following conditions: (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and (3) At intervals not exceeding 1 year. (b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of-- (1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use; (2) The coincidence of the radiation field and the field indicated by the light beam	§ 35.632 Full calibration measurements on teletherapy units. (a) A licensee authorized to use a teletherapy unit for medical use shall perform full calibration measurements on each teletherapy unit -- (1) Before the first medical use of the unit; and (2) Before medical use under the following conditions: (i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay; (ii) Following replacement of the source or following reinstallation of the teletherapy unit in a new location; (iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and (3) At intervals not exceeding 1 year. (b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of -- (1) The output within +/-3 percent for the range of field sizes and for the distance or range of distances used for medical use; (2) The coincidence of the radiation field and the field indicated by the light beam

localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in Section 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with either the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine that are described in Physics in Medicine and Biology Vol. 16, No. 3, 1971, pp. 379-396, or by Task Group 21 of the Radiation Therapy Committee of the American Association of Physicists in Medicine that are described in Medical Physics Vol. 10, No. 6, 1983, pp. 741-771, and Vol. 11, No. 2, 1984, p. 213. (Both of these references have been approved for incorporation by reference by the Director of the Federal Register. Copies of the documents are available for

localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer accuracy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in Sec. 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.

localizing device;

(3) The uniformity of the radiation field and its dependence on the orientation of the useful beam;

(4) Timer constancy and linearity over the range of use;

(5) On-off error; and

(6) The accuracy of all distance measuring and localization devices in medical use.

(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.

(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.

(g) A licensee shall

inspection at the NRC Library, 11545 Rockville Pike, Rockville, Maryland 20852-2738. Copies of the documents are also on file at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC. A notice of any change in the material will be published in the Federal Register.)

retain a record of each calibration in accordance with § 35.2632.

CURRENT RULE	PROPOSED RULE	FINAL RULE
(e) A licensee shall correct mathematically the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding one month for cobalt-60 or six months for cesium-137.	(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay for intervals not exceeding 1 month for cobalt-60, 6 months for cesium-137, or at intervals consistent with 1 percent decay for all other nuclides.	
(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the licensee's teletherapy physicist.	(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (e) of this section must be performed by the authorized medical physicist.	
(g) A licensee shall retain a record of each calibration for the duration of use of the teletherapy unit source. The record must include the date of the calibration, the manufacturer's name, model number, and serial number for both the teletherapy unit and the source, the model numbers and serial numbers of the instruments used to calibrate the teletherapy unit, tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, an assessment of timer linearity and constancy, the calculated on-off error, the estimated accuracy of each distance measuring or localization device, and the signature of the teletherapy physicist.	(g) A licensee shall retain a record of each calibration in accordance with Sec. 35.2632.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.633 Full calibration measurements on remote afterloaders.	§ 35.633 Full calibration measurements on remote afterloader units.
	(a) A licensee authorized to use a remote afterloader for medical use shall perform full calibration measurements on each unit–	(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit --
	(1) Before the first medical use of the unit;	(1) Before the first medical use of the unit;
	(2) Before medical use under the following conditions:	(2) Before medical use under the following conditions:
	(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;	(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and
	(ii) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and	
	(iii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and	(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and
	(3) At intervals not exceeding 120 days for high dose-rate and pulsed dose-rate remote afterloaders; and	(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and
	(4) At intervals not exceeding 1 year for low dose-rate remote afterloaders.	(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.
	(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of:	(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:
	(1) The output within	(1) The output within

CURRENT RULE	PROPOSED RULE	FINAL RULE
	+/-5 percent; (2) Source positioning accuracy to within +/-1 millimeter; (3) Source retraction with backup battery upon power failure; and (4) The operability of the electrically assisted treatment room doors with the high-dose rate remote afterloader unit electrical power turned off.	+/- 5 percent; (2) Source positioning accuracy to within +/- 1 millimeter; (3) Source retraction with backup battery upon power failure; (4) Length of the source transfer tubes; (5) Timer accuracy and linearity over the typical range of use; (6) Length of the applicators; and (7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.
	(c) In addition to the requirements for full calibrations for all remote afterloaders in paragraph (b) of this section, a licensee shall: (1) For high dose-rate and pulsed dose-rate remote afterloaders, calibrate-- (i) At intervals not exceeding one quarter: (A) The source guide tubes; (B) Timer accuracy and linearity over the typical range of use; and (C) Length of the connectors; and (ii) Annually, the function of the source tube guides and connectors. (2) For low dose-rate remote afterloaders, perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement and a spot check of the absolute timer accuracy at intervals not exceeding one quarter.	(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output. (d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies. (e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter. (f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section. (g) A licensee shall

CURRENT RULE	PROPOSED RULE	FINAL RULE
	(d) A licensee shall use the dosimetry system described in Sec. 35.630(a) to measure the output.	mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay. (h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist. (i) A licensee shall retain a record of each calibration in accordance with § 35.2632.
	(e) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.	
	(f) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay. (g) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (f) of this section must be performed by the authorized medical physicist. (h) A licensee shall retain a record of each calibration in accordance with Sec. 35.2633.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.	§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.
	(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit–	(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit --
	(1) Before the first medical use of the unit;	(1) Before the first medical use of the unit;
	(2) Before medical use under the following conditions--	(2) Before medical use under the following conditions --
	(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;	(i) Whenever spot-check measurements indicate that the output differs by more than 5 percent from the output obtained at the last full calibration corrected mathematically for radioactive decay;
	(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and	(ii) Following replacement of the sources or following reinstallation of the gamma stereotactic radiosurgery unit in a new location; and
	(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and	(iii) Following any repair of the gamma stereotactic radiosurgery unit that includes removal of the sources or major repair of the components associated with the source assembly; and
	(3) At intervals not exceeding 1 year.	(3) At intervals not exceeding 1 year.
	(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of--	(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include determination of --
	(1) The output within +/-3 percent;	(1) The output within +/-3 percent;
	(2) Relative helmet factors;	(2) Relative helmet factors;
	(3) Isocenter	(3) Isocenter

CURRENT RULE	PROPOSED RULE	FINAL RULE
	coincidence; (4) Timer accuracy and linearity over the range of use; (5) On-off error; and (6) Trunnion centricity.	coincidence; (4) Timer accuracy and linearity over the range of use; (5) On-off error; (6) Trunnion centricity; (7) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off; (8) Helmet microswitches; (9) Emergency timing circuits; and (10) Stereotactic frames and localizing devices (trunnions).
	(c) A licensee shall use the dosimetry system described in Sec. 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.	(c) A licensee shall use the dosimetry system described in § 35.630(a) to measure the output for one set of exposure conditions. The remaining radiation measurements required in paragraph (b)(1) of this section may be made using a dosimetry system that indicates relative dose rates.
	(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols approved by nationally recognized bodies.	(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.
	(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.	(e) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section at intervals not exceeding 1 month for cobalt-60 and at intervals consistent with 1 percent physical decay for all other radionuclides.
	(f) Full calibration measurements required by paragraph (a) of this section and physical decay	(f) Full calibration measurements required by paragraph (a) of this section and physical decay corrections

CURRENT RULE	PROPOSED RULE	FINAL RULE
	corrections required by paragraph (e) of this section must be performed by the authorized medical physicist. (g) A licensee shall retain a record of each calibration in accordance with Sec. 35.2635.	required by paragraph (e) of this section must be performed by the authorized medical physicist. (g) A licensee shall retain a record of each calibration in accordance with § 35.2632.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.634 Periodic spot-checks.	Sec. 35.642 Periodic spot-checks for teletherapy units.	§ 35.642 Periodic spot-checks for teletherapy units.
(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of:	(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of–	(a) A licensee authorized to use teletherapy units for medical use shall perform output spot-checks on each teletherapy unit once in each calendar month that include determination of --
(1) Timer constancy, and timer linearity over the range of use;	(1) Timer constancy, and timer linearity over the range of use;	(1) Timer constancy, and timer linearity over the range of use;
(2) On-off error;	(2) On-off error;	(2) On-off error;
(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;	(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;	(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;
(4) The accuracy of all distance measuring and localization devices used for medical use;	(4) The accuracy of all distance measuring and localization devices used for medical use;	(4) The accuracy of all distance measuring and localization devices used for medical use;
(5) The output for one typical set of operating conditions measured with the dosimetry system described in Section 35.630(b) of this part; and	(5) The output for one typical set of operating conditions measured with the dosimetry system described in Sec. 35.630(b); and	(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and
(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).	(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).	(6) The difference between the measurement made in paragraph (b)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).
(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with procedures established by the teletherapy physicist. That individual need not actually perform the spotcheck measurements.	(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements.	(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

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(c) A licensee shall have the teletherapy physicist review the results of each spot-check within 15 days. The teletherapy physicist shall promptly notify the licensee in writing of the results of each spot-check. The licensee shall keep a copy of each written notification for three years.	(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall promptly notify the licensee in writing of the results of each spot-check.	(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.
(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month that assure proper operation of:	(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of--	(d) A licensee authorized to use a teletherapy unit for medical use shall perform safety spot-checks of each teletherapy facility once in each calendar month and after each source installation to assure proper operation of --
(1) Electrical interlocks at each teletherapy room entrance;	(1) Electrical interlocks at each teletherapy room entrance;	(1) Electrical interlocks at each teletherapy room entrance;
(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);	(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);	(2) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam on-off mechanism);
(3) Beam condition indicator lights on the teletherapy unit, on the control console, and in the facility;	(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;	(3) Source exposure indicator lights on the teletherapy unit, on the control console, and in the facility;
(4) Viewing systems;	(4) Viewing and intercom systems;	(4) Viewing and intercom systems;
(5) Treatment room doors from inside and outside the treatment room; and	(5) Treatment room doors from inside and outside the treatment room; and	(5) Treatment room doors from inside and outside the treatment room; and
(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.	(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.	(6) Electrically assisted treatment room doors with the teletherapy unit electrical power turned off.
(e) A licensee shall arrange for prompt repair of any system identified in paragraph (d) of this section	(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and	(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and

CURRENT RULE	PROPOSED RULE	FINAL RULE
that is not operating properly, and shall not use the teletherapy unit following door interlock malfunction until the interlock system has been repaired.	not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.	not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section for three years. The record must include the date of the spot-check, the manufacturer's name, model number, and serial number for both the teletherapy unit and source, the manufacturer's name, model number and serial number of the instrument used to measure the output of the teletherapy unit, an assessment of timer linearity and constancy, the calculated on-off error, a determination of the coincidence of the radiation field and the field indicated by the light beam localizing device, the calculated on-off error, the determined accuracy of each distance measuring or localization device, the difference between the anticipated output and the measured output, notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system and doors, and the signature of the individual who performed the periodic spot-check.	(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d), in accordance with Sec. 35.2642	(f) A licensee shall retain a record of each spot-check required by paragraphs (a) and (d) of this section, in accordance with § 35.2642.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.636 Safety checks for teletherapy facilities. (a) A licensee shall promptly check all systems listed in Section 35.634(d) for proper function after each installation of a teletherapy source and after making any change for which an amendment is required by Section 35.606 (a) through (d). (b) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system specified in Section 35.634(d), the licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. (c) A licensee shall retain for three years a record of the facility checks following installation of a source. The record must include notations indicating the operability of each entrance door interlock, each electrical or mechanical stop, each beam condition indicator light, the viewing system, and doors, and the signature of the Radiation Safety Officer.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.643 Periodic spot-checks for high dose-rate and pulsed dose-rate remote afterloaders.	§ 35.643 Periodic spot-checks for remote afterloader units.
	(a) A licensee authorized to use high dose-rate or pulsed dose-rate remote afterloaders for medical use shall perform spot-checks on each unit: (1) At the beginning of each week of use; (2) At the beginning of each day of use; and (3) After each source installation. (b) The licensee shall have the authorized medical physicist: (1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and (2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements. (c) To satisfy the requirements of paragraphs (a)(1) of this section, spot-checks must, at a minimum-- (1) Verify source positioning accuracy; (2) Determine output with the dosimetry system described in Sec. 35.630(b); and (3) Calculate the difference between the measurement made in paragraph (c)(2) of this section and the anticipated output, expressed as a	(a) A licensee authorized to use a remote afterloader unit for medical use shall perform spot-checks of each remote afterloader facility and on each unit: (1) Prior to the first use of a high dose-rate, medium dose-rate, or pulsed dose-rate remote afterloader unit on a given day; (2) Before each patient treatment with a low dose-rate remote afterloader unit; and (3) After each source installation. (b) A licensee shall perform the measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot check measurements. (c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check. (d) To satisfy the requirements of paragraph (a) of this section, spot-checks must, at a minimum, assure proper operation of -- (1) Electrical interlocks at each remote afterloader unit room entrance; (2) Source exposure indicator lights on the remote

percentage of the anticipated output (i.e., the value obtained at last full calibration mathematically corrected for physical decay).

(d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must, at a minimum, assure proper operation of--

(1) Electrical interlocks at each remote afterloader room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer constancy; and

(7) Clock (date and time) in the unit's computer.

(e) In addition to the requirements for spot checks in paragraph (d) of this section, a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment as part of the spot-checks.

(f) A licensee shall arrange for prompt repair of any system identified in paragraph (c) of this section that is not operating.

(g) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may

afterloader unit, on the control console, and in the facility;

(3) Viewing and intercom systems in each high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader facility;

(4) Emergency response equipment;

(5) Radiation monitors used to indicate the source position;

(6) Timer accuracy;

(7) Clock (date and time) in the unit’s computer; and

(8) Decayed source(s) activity in the unit’s computer.

(e) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.

(f) A licensee shall retain a record of each check required by paragraph (d) of this section in accordance with § 35.2643.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	be necessary to repair, replace, or check the malfunctioning system. (h) A licensee shall retain a record of each check required by paragraphs (c) and (d) of this section in accordance with Sec. 35.2643.	

CURRENT RULE PROPOSED RULE FINAL RULE

Sec. 35.644 Periodic spot-checks for low dose-rate remote afterloaders.

(a) A licensee authorized to use low dose-rate remote afterloaders for medical use shall perform spot-checks on each unit prior to each patient treatment and after each source installation that include proper operation of--

(1) Electrical interlocks at each remote afterloader room entrance;

(2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility;

(3) Emergency response equipment;

(4) Radiation monitors used to indicate the source position;

(5) Timer constancy; and

(6) Clock (date and time) in the unit's computer.

(b) In addition to the requirements for spot checks in paragraph (a) of this section, a licensee shall ensure overall proper operation of the unit by conducting a simulated cycle of treatment as part of the spot-checks.

(c) The licensee shall have the authorized medical physicist--

(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and

(2) Review the results of each spot-check required by paragraph (a) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check

CURRENT RULE	PROPOSED RULE	FINAL RULE
	measurements. (d) If the results of the checks required in paragraph (a) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. (e) A licensee shall retain a record of each check required by paragraph (a) of this section in accordance with Sec. 35.2643.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.	§ 35.645 Periodic spot-checks for gamma stereotactic radiosurgery units.
	(a) A licensee authorized to use gamma stereotactic radiosurgery units for medical use shall perform spot-checks on each unit–	(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform spot-checks of each gamma stereotactic radiosurgery facility and on each unit --
	(1) Monthly,	(1) Monthly;
	(2) At the beginning of each day of use, and	(2) Prior to the first use of the unit on a given day; and
	(3) After each source installation.	(3) After each source installation.
	(b) The licensee shall have the authorized medical physicist--	(b) The licensee shall have the authorized medical physicist --
	(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and	(1) Establish written procedures for performing the spot-checks required in paragraph (a) of this section; and
	(2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.	(2) Review the results of each spot-check required by paragraph (a)(1) of this section within 15 days of the check. The authorized medical physicist need not actually perform the spot-check measurements.
	(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum--	(c) To satisfy the requirements of paragraph (a)(1) of this section, spot-checks must, at a minimum --
	(1) Assure proper operation of--	(1) Assure proper operation of --
	(i) Treatment table retraction mechanism, using backup battery power or hydraulic/electrical backups with the unit off;	(i) Treatment table retraction mechanism, using backup battery power or hydraulic backups with the unit off;
	(ii) Helmet microswitchs;	(ii) Helmet microswitches;
	(iii) Emergency timing circuits;	(iii) Emergency timing circuits; and

CURRENT RULE	PROPOSED RULE	FINAL RULE
	(iv) Emergency off buttons; and (v) Stereotactic frames and localizing devices (trunnions). (2) Determine-- (i) The output for one typical set of operating conditions measured with the dosimetry system described in Sec. 35.630(b); (ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay); (iii) Source output against computer calculation; (iv) Timer accuracy and linearity over the range of use; (v) On-off error; and (vi) Trunnion centricity. (d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of-- (1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance; (2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility; (3) Viewing and intercom systems; (4) Timer termination; (5) Radiation monitors used to indicate room exposures; and (6) Hydraulic cutoff mechanism (if applicable).	(iv) Stereotactic frames and localizing devices (trunnions). (2) Determine -- (i) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); (ii) The difference between the measurement made in paragraph (c)(2)(i) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay); (iii) Source output against computer calculation; (iv) Timer accuracy and linearity over the range of use; (v) On-off error; and (vi) Trunnion centricity. (d) To satisfy the requirements of paragraphs (a)(2) and (a)(3) of this section, spot-checks must assure proper operation of -- (1) Electrical interlocks at each gamma stereotactic radiosurgery room entrance; (2) Source exposure indicator lights on the gamma stereotactic radiosurgery unit, on the control console, and in the facility; (3) Viewing and intercom systems; (4) Timer termination; (5) Radiation monitors used to indicate room exposures; and (6) Emergency off buttons. (e) A licensee shall

CURRENT RULE	PROPOSED RULE	FINAL RULE
	(e) A licensee shall arrange for prompt repair of any system identified in paragraph (c) of this section that is not operating properly. (f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. (g) A licensee shall retain a record of each check required by paragraphs (c) and (d) of this section in accordance with Sec. 35.2645.	arrange, as soon as possible, for repair of any system identified in paragraph (c) of this section that is not operating properly. (f) If the results of the checks required in paragraph (d) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system. (g) A licensee shall retain a record of each check required by paragraphs (c) and (d) of this section in accordance with § 35.2645.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.647 Additional technical requirements for mobile remote afterloaders. (a) A licensee providing mobile remote afterloader service shall-- (1) Check survey instruments before medical use at each address of use or on each day of use, which ever is more frequent; and (2) Account for all sources before departure from a client's address of use. (b) In addition to the periodic spot-checks required by Sec. 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader before each address of use. At a minimum, checks must be made to verify the operation of-- (1) Electrical interlocks on treatment area access points; (2) Source exposure indicator lights on the remote afterloader, on the control console, and in the facility; (3) Viewing and intercom systems; (4) Applicators and connectors; (5) Radiation monitors used to indicate room exposures; (6) Source positioning (accuracy); and (7) Radiation monitors used to indicate whether the source has returned to a safe shielded position. (c) In addition to the requirements for checks in paragraph (b) of this section, a	§ 35.647 Additional technical requirements for mobile remote afterloader units. (a) A licensee providing mobile remote afterloader service shall -- (1) Check survey instruments before medical use at each address of use or on each day of use, whichever is more frequent; and (2) Account for all sources before departure from a client's address of use. (b) In addition to the periodic spot-checks required by § 35.643, a licensee authorized to use mobile afterloaders for medical use shall perform checks on each remote afterloader unit before use at each address of use. At a minimum, checks must be made to verify the operation of -- (1) Electrical interlocks on treatment area access points; (2) Source exposure indicator lights on the remote afterloader unit, on the control console, and in the facility; (3) Viewing and intercom systems; (4) Applicators, source transfer tubes, and transfer tube-applicator interfaces; (5) Radiation monitors used to indicate room exposures; (6) Source positioning (accuracy); and (7) Radiation monitors used to indicate whether the source has returned to a safe shielded position. (c) In addition to the requirements for checks in paragraph (b), a licensee shall

CURRENT RULE	PROPOSED RULE	FINAL RULE
	licensee shall ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.	ensure overall proper operation of the remote afterloader unit by conducting a simulated cycle of treatment before use at each address of use.
	(d) A licensee shall arrange for prompt repair of any system identified in paragraph (b) of this section that is not operating properly.	(d) If the results of the checks required in paragraph (b) of this section indicate the malfunction of any system, a licensee shall lock the control console in the off position and not use the unit except as may be necessary to repair, replace, or check the malfunctioning system.
	(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with Sec. 35.2647.	(e) A licensee shall retain a record of each check required by paragraph (b) of this section in accordance with § 35.2647.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.641 Radiation surveys for teletherapy facilities. (a) Before medical use, after each installation of a teletherapy source, and after making any change for which an amendment is required by Section 35.606 (a) through (d), the licensee shall perform radiation surveys with a portable radiation measurement survey instrument calibrated in accordance with Section 35.51 of this part to verify that: (1) The maximum and average dose rates at one meter from the teletherapy source with the source in the off position and the collimators set for a normal treatment field do not exceed 10 millirem per hour and 2 millirem per hour, respectively; and (2) With the teletherapy source in the on position with the largest clinically available treatment field and with a scattering phantom in the primary beam of radiation, that: (i) Radiation dose rates in restricted areas are not likely to cause any occupationally exposed individual to receive a dose in excess of the limits specified in Section 20.1201 of this chapter; and (ii) Radiation dose rates in controlled or unrestricted areas are not likely to cause any individual member of the public to receive a dose in excess of the limits specified in Section 20.1301 of this chapter. (b) If the results of the surveys required in paragraph	Sec. 35.652 Radiation surveys. (a) In addition to the survey requirement in Sec. 20.1501 of this chapter, a licensee shall make such surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position does not exceed the levels stated in the Registry. (b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce he shielding around the source(s), or compromise the radiation safety of the device or the source(s).	§ 35.652 Radiation surveys. (a) In addition to the survey requirement in § 20.1501 of this chapter, a person licensed under this subpart shall make such surveys as defined in the Sealed Source and Device Registry to assure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Registry. (b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s). (c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with § 35.2652.

CURRENT RULE	PROPOSED RULE	FINAL RULE
(a) of this section indicate any radiation dose quantity per unit time in excess of the respective limit specified in that paragraph, the licensee shall lock the control in the off position and not use the unit: (1) Except as may be necessary to repair, replace, or test the teletherapy unit shielding or the treatment room shielding; or (2) Until the licensee has received a specific exemption pursuant to Section 20.1301 of this chapter.		
(c) A licensee shall retain a record of the radiation measurements made following installation of a source for the duration of the license. The record must include the date of the measurements, the reason the survey is required, the manufacturer's name, model number and serial number of the teletherapy unit, the source, and the instrument used to measure radiation levels, each dose rate measured around the teletherapy source while in the off position and the average of all measurements, a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points in each area expressed in millirem per hour, the calculated maximum quantity of radiation over a period of one week for each restricted and unrestricted area, and the signature of the Radiation Safety Officer.	(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with Sec. 35.2652.	

CURRENT RULE PROPOSED RULE FINAL RULE

Section 35.643 Modification of teletherapy unit or room before beginning a treatment program.

(a) If the survey required by Section 35.641 indicates that any individual member of the public is likely to receive a dose in excess of the limits specified in Section 20.1301, of this chapter, the licensee shall, before beginning the treatment program:

(1) Either equip the unit with stops or add additional radiation shielding to ensure compliance with Section 20.1301 of this chapter;

(2) Perform the survey required by Section 35.641 again; and

(3) Include in the report required by Section 35.645 the results of the initial survey, a description of the modification made to comply with paragraph (a)(1) of this section, and the results of the second survey.

(b) As an alternative to the requirements set out in paragraph (a) of this section, a licensee may request a license amendment under Section 20.1301(c) of this chapter that authorizes radiation levels in unrestricted areas greater than those permitted by Section 20.1301(a) of this chapter. A licensee may not begin the treatment program until the license amendment has been issued.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.645 Reports of teletherapy surveys, checks, tests, and measurements. A licensee shall mail a copy of the records required in Sections 35.636, 35.641, 35.643, and the output from the teletherapy source expressed as roentgens or rads per hour at one meter from the source and determined during the full calibration required in Section 35.632, to the appropriate Commission Regional Office listed in Section 30.6 of this chapter within thirty days following completion of the action that initiated the record requirement.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.647 Five-year inspection.	Sec. 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.	§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.
(a) A licensee shall have each teletherapy unit fully inspected and serviced during teletherapy source replacement or at intervals not to exceed five years, whichever comes first, to assure proper functioning of the source exposure mechanism.	(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.	(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.
(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.	(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.	(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.
(c) A licensee shall keep a record of the inspection and servicing for the duration of the license. The record must contain the inspector's name, the inspector's license number, the date of inspection, the manufacturer's name and model number and serial number for both the teletherapy unit and source, a list of components inspected, a list of components serviced and the type of service, a list of components replaced, and the signature of the inspector.	(c) A licensee shall keep a record of the inspection and servicing in accordance with Sec. 35.2655.	(c) A licensee shall keep a record of the inspection and servicing in accordance with § 35.2655.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.657 Therapy-related computer systems. The licensee shall: (a) Verify that the computerized operating system and treatment planning system associated with the therapy device are operating appropriately; and (b) Perform acceptance testing on the treatment planning system in accordance with published protocols approved by nationally recognized bodies.	§ 35.657 Therapy-related computer systems. The licensee shall perform acceptance testing on the treatment planning system in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of: (a) The source-specific input parameters required by the dose calculation algorithm; (b) The accuracy of dose, dwell time, and treatment time calculations at representative points; (c) The accuracy of isodose plots and graphic displays; (d) The accuracy of the software used to determine radioactive source positions from radiographic images; and (e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.690 Training for use of therapeutic medical devices.	§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.
	Except as provided in Sec. 35.57, the licensee shall require the authorized user of a sealed source for a use authorized under Sec. 35.600 to be a physician who--	Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who --
	(a) Is certified by a specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been approved by the Commission; or	(a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraph (b) of this section and whose certification has been recognized by the Commission or by an Agreement State; or
	(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical device consisting of both--	(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes --
	(i) 200 hours of didactic training in the following areas–	(i) 200 hours of classroom and laboratory training in the following areas --
	(A) Radiation physics and instrumentation;	(A) Radiation physics and instrumentation;
	(B) Radiation protection;	(B) Radiation protection;
	(C) Mathematics pertaining to the use and measurement of radioactivity; and	(C) Mathematics pertaining to the use and measurement of radioactivity; and
	(D) Radiation biology; and	(D) Radiation biology; and
	(ii) 500 hours of supervised practical experience, under the supervision of an authorized user at a medical institution, involving–	(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements at a medical institution, involving --
		(A) Reviewing full

CURRENT RULE	PROPOSED RULE	FINAL RULE
	(A) Review of the full calibration measurements and periodic spot checks; (B) Preparing treatment plans and calculating treatment doses and times; (C) Using administrative controls to prevent a medical event involving the use of byproduct material; (D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; (E) Checking and using survey meters; and (F) Selecting the proper dose and how it is to be administered; and (2) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association or equivalent program approved by the NRC and an additional two years of clinical experience under the supervision of an authorized user; and (3) Has obtained written certification, signed by a preceptor authorized user, that the required training in paragraphs (b)(1) and (b)(2)	calibration measurements and periodic spot-checks; (B) Preparing treatment plans and calculating treatment doses and times; (C) Using administrative controls to prevent a medical event involving the use of byproduct material; (D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console; (E) Checking and using survey meters; and (F) Selecting the proper dose and how it is to be administered; and (2) Has completed three years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in § 35.690 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written certification, signed by a preceptor authorized user who meets the requirements in § 35.690 or equivalent Agreement State

CURRENT RULE	PROPOSED RULE	FINAL RULE
	of this section has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently function as an authorized user of the therapeutic medical device for which the individual is requesting authorized user status; and	requirements, that the individual has satisfactorily completed the requirements in paragraphs (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of the therapeutic medical unit for which the individual is requesting authorized user status.
	(4) Following completion of the requirements in paragraph (b)(1) and (2) of this section, has demonstrated sufficient knowledge in radiation safety commensurate with the use requested by passing an examination given by an organization or entity approved by the Commission in accordance with appendix A of this part.	
	Subpart I--Reserved	Subpart I -- [Reserved]

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart J--Training and Experience Requirements	Subpart J--Training and Experience Requirements	Subpart J -- [Reserved]
Section 35.900 Radiation Safety Officer. Except as provided in Section 35.901, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in Section 35.32 to be an individual who: (a) Is certified by: (1) American Board of Health Physics in Comprehensive Health Physics; (2) American Board of Radiology; (3) American Board of Nuclear Medicine; (4) American Board of Science in Nuclear Medicine; (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; (6) American Board of Medical Physics in radiation oncology physics; (7) Royal College of Physicians and Surgeons of Canada in nuclear medicine; (8) American Osteopathic Board of Radiology; or (9) American	Sec. 35.900 Radiation Safety Officer. Except as provided in Sec. 35.57, the licensee shall require an individual fulfilling the responsibilities of the Radiation Safety Officer as provided in Sec. 35.24 to be an individual who-- (a) Is certified by the-- (1) American Board of Health Physics in Comprehensive Health Physics; (2) American Board of Radiology; (3) American Board of Nuclear Medicine; (4) American Board of Science in Nuclear Medicine; (5) Board of Pharmaceutical Specialties in Nuclear Pharmacy; (6) American Board of Medical Physics in radiation oncology physics; (7) Royal College of Physicians and Surgeons of Canada in nuclear medicine; (8) American Osteopathic Board of Radiology; or (9) American	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Osteopathic Board of Nuclear Medicine; or (b) Has had classroom and laboratory training and experience as follows: (1) 200 hours of classroom and laboratory training that includes: (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Radiation biology; and (v) Radiopharmaceutical chemistry; and (2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or (c) Be an authorized user identified on the licensee's license.	Osteopathic Board of Nuclear Medicine; or (b) Has had classroom and laboratory training and experience as follows-- (1) 200 hours of classroom and laboratory training that includes-- (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Radiation biology; and (v) Radiopharmaceutical chemistry; and (2) One year of full time experience as a radiation safety technologist at a medical institution under the supervision of the individual identified as the Radiation Safety Officer on a Commission or Agreement State license that authorizes the medical use of byproduct material; or (c) Is an authorized user identified on the licensee's license.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.901 Training for experienced Radiation Safety Officer. An individual identified as a Radiation Safety Officer on a Commission or Agreement State license before October 1, 1986 need not comply with the training requirements of Section 35.900.		

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.910 Training for uptake, dilution, and excretion studies. Except as provided in Sections 35.970 and 35.971, the licensee shall require the authorized user of a radiopharmaceutical in Section 35.100(a) to be a physician who: (a) Is certified in: (1) Nuclear medicine by the American Board of Nuclear Medicine; (2) Diagnostic radiology by the American Board of Radiology; or (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows: (1) 40 hours of classroom and laboratory training that	Sec. 35.910 Training for uptake, dilution, and excretion studies. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a radiopharmaceutical in Sec. 35.100(a) to be a physician who-- (a) Is certified in-- (1) Nuclear medicine by the American Board of Nuclear Medicine; (2) Diagnostic radiology by the American Board of Radiology; (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, and supervised clinical experience as follows-- (1) 40 hours of classroom and laboratory training that	

CURRENT RULE	PROPOSED RULE	FINAL RULE
includes: (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Radiation biology; and (v) Radiopharmaceutical chemistry; and (2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes: (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications; (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages; (iii) Administering dosages to patients or human research subjects and using syringe radiation shields; (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and (v) Patient or	includes-- (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Radiation biology; and (v) Radiopharmaceutical chemistry; and (2) 20 hours of supervised clinical experience under the supervision of an authorized user and that includes-- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications; (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages; (iii) Administering dosages to patients or human research subjects and using syringe radiation shields; (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and (v) Patient or	

CURRENT RULE	PROPOSED RULE	FINAL RULE
human research subject followup; or	human research subject follow up; or	
(c) Has successfully completed a six-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.	(c) Has successfully completed a 6-month training program in nuclear medicine as part of a training program that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.920 Traininq for imaging and localization studies. Except as provided in Section 35.970 or 35.971, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in Section 35.200(a) to be a physician who: (a) Is certified in: (1) Nuclear medicine by the American Board of Nuclear Medicine; (2) Diagnostic radiology by the American Board of Radiology; (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work experience, and	Sec. 35.920 Training for imaging and localization studies. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a radiopharmaceutical, generator, or reagent kit in Sec. 35.200(a) to be a physician who-- (a) Is certified in-- (1) Nuclear medicine by the American Board of Nuclear Medicine; (2) Diagnostic radiology by the American Board of Radiology; (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or (5) American Osteopathic Board of Nuclear Medicine in nuclear medicine; or (b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of prepared radiopharmaceuticals, generators, and reagent kits, supervised work	

CURRENT RULE	PROPOSED RULE	FINAL RULE
supervised clinical experience as follows: (1) 200 hours of classroom and laboratory training that includes: (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Radiopharmaceutical chemistry; and (v) Radiation biology; and (2) 500 hours of supervised work experience under the supervision of an authorized user that includes: (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters; (iii) Calculating and safely preparing patient or human research subject dosages; (iv) Using administrative controls to prevent the	experience, and supervised clinical experience as follows-- (1) 200 hours of classroom and laboratory training that includes-- (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Radiopharmaceutical chemistry; and (v) Radiation biology; and (2) 500 hours of supervised work experience under the supervision of an authorized user that includes-- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (ii) Calibrating dose calibrators and diagnostic instruments and performing checks for proper operation of survey meters; (iii) Calculating and safely preparing patient or human research subject dosages; (iv) Using administrative controls to prevent the medical	

CURRENT RULE	PROPOSED RULE	FINAL RULE
misadministration of byproduct material; (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and (vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and	event of byproduct material; (v) Using procedures to contain spilled byproduct material safely and using proper decontamination procedures; and (vi) Eluting technetium-99m from generator systems, measuring and testing the eluate for molybdenum-99 and alumina contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals; and	
(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes: (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications; (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages; (iii) Administering dosages to patients or human research subjects and using syringe radiation	(3) 500 hours of supervised clinical experience under the supervision of an authorized user that includes-- (i) Examining patients or human research subjects and reviewing their case histories to determine their suitability for radioisotope diagnosis, limitations, or contraindications; (ii) Selecting the suitable radiopharmaceuticals and calculating and measuring the dosages; (iii) Administering dosages to patients or human research subjects and using syringe radiation	

CURRENT RULE	PROPOSED RULE	FINAL RULE
shields; (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and (v) Patient or human research subject followup; or (c) Has successfully completed a six-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.	shields; (iv) Collaborating with the authorized user in the interpretation of radioisotope test results; and (v) Patient or human research subject follow up; or (c) Has successfully completed a 6-month training program in nuclear medicine that has been approved by the Accreditation Council for Graduate Medical Education and that included classroom and laboratory training, work experience, and supervised clinical experience in all the topics identified in paragraph (b) of this section.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.930 Training for therapeutic use of unsealed byproduct material.	Sec. 35.930 Training for therapeutic use of unsealed byproduct material.	
Except as provided in Section 35.970, the licensee shall require the authorized user of radiopharmaceuticals in Section 35.300 to be a physician who:	Except as provided in Sec. 35.57, the licensee shall require the authorized user of radiopharmaceuticals in Sec. 35.300 to be a physician who--	
(a) Is certified by:	(a) Is certified by--	
(1) The American Board of Nuclear Medicine;	(1) The American Board of Nuclear Medicine;	
(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;	(2) The American Board of Radiology in radiology, therapeutic radiology, or radiation oncology;	
(3) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or	(3) The Royal College of Physicians and Surgeons of Canada in nuclear medicine; or	
(4) The American Osteopathic Board of Radiology after 1984; or	(4) The American Osteopathic Board of Radiology after 1984; or	
(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows:	(b) Has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of therapeutic radiopharmaceuticals, and supervised clinical experience as follows--	
(1) 80 hours of classroom and laboratory training that includes:	(1) 80 hours of classroom and laboratory training that includes--	
(i) Radiation physics and instrumentation;	(i) Radiation physics and instrumentation;	
(ii) Radiation	(ii) Radiation	

CURRENT RULE	PROPOSED RULE	FINAL RULE
protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; and (2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes: (i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and (ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.	protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; and (2) Supervised clinical experience under the supervision of an authorized user at a medical institution that includes-- (i) Use of iodine-131 for diagnosis of thyroid function and the treatment of hyperthyroidism or cardiac dysfunction in 10 individuals; and (ii) Use of iodine-131 for treatment of thyroid carcinoma in 3 individuals.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.932 Training for treatment of hyperthyroidism. Except as provided in Section 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows: (a) 80 hours of classroom and laboratory training that includes: (1) Radiation physics and instrumentation; (2) Radiation protection, (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; and (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.	Sec. 35.932 Training for treatment of hyperthyroidism. Except as provided in Sec. 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of hyperthyroidism to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating hyperthyroidism, and supervised clinical experience as follows-- (a) 80 hours of classroom and laboratory training that includes-- (1) Radiation physics and instrumentation; (2) Radiation protection, (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; and (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for diagnosis of thyroid function, and the treatment of hyperthyroidism in 10 individuals.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.934 Training for treatment of thyroid carcinoma. Except as provided in Section 35.970, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows: (a) 80 hours of classroom and laboratory training that includes: (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; and (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.	Sec. 35.934 Training for treatment of thyroid carcinoma. Except as provided in Sec. 35.57, the licensee shall require the authorized user of only iodine-131 for the treatment of thyroid carcinoma to be a physician with special experience in thyroid disease who has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of iodine-131 for treating thyroid carcinoma, and supervised clinical experience as follows-- (a) 80 hours of classroom and laboratory training that includes-- (1) Radiation physics and instrumentation; (2) Radiation protection; (3) Mathematics pertaining to the use and measurement of radioactivity; and (4) Radiation biology; and (b) Supervised clinical experience under the supervision of an authorized user that includes the use of iodine-131 for the treatment of thyroid carcinoma in 3 individuals.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.940 Training for use of brachytherapy sources. Except as provided in Section 35.970, the licensee shall require the authorized user of a brachytherapy source listed in Section 35.400 for therapy to be a physician who: (a) Is certified in: (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; (2) Radiation oncology by the American Osteopathic Board of Radiology; (3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or (b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical experience as follows:	Sec. 35.940 Training for use of brachytherapy sources. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a brachytherapy source listed in Sec. 35.400 for therapy to be a physician who-- (a) Is certified in-- (1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; (2) Radiation oncology by the American Osteopathic Board of Radiology; (3) Radiology, with specialization in radiotherapy, as a British ``Fellow of the Faculty of Radiology'' or ``Fellow of the Royal College of Radiology''; or (4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or (b) Is in the active practice of therapeutic radiology, has had classroom and laboratory training in radioisotope handling techniques applicable to the therapeutic use of brachytherapy sources, supervised work experience, and supervised clinical	

CURRENT RULE	PROPOSED RULE	FINAL RULE
(1) 200 hours of classroom and laboratory training that includes: (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes: (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (ii) Checking survey meters for proper operation; (iii) Preparing, implanting, and removing sealed sources; (iv) Maintaining running inventories of material on hand; (v) Using administrative controls to prevent the misadministration of byproduct material; and (vi) Using emergency procedures to control byproduct material; and	experience as follows-- (1) 200 hours of classroom and laboratory training that includes-- (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes-- (i) Ordering, receiving, and unpacking radioactive materials safely and performing the related radiation surveys; (ii) Checking survey meters for proper operation; (iii) Preparing, implanting, and removing sealed sources; (iv) Maintaining running inventories of material on hand; (v) Using administrative controls to prevent a medical event involving byproduct material; and (vi) Using emergency procedures to control byproduct material; and	

CURRENT RULE	PROPOSED RULE	FINAL RULE
(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes:	(3) Three years of supervised clinical experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association, and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes–	
(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;	(i) Examining individuals and reviewing their case histories to determine their suitability for brachytherapy treatment, and any limitations or contraindications;	
(ii) Selecting the proper brachytherapy sources and dose and method of administration;	(ii) Selecting the proper brachytherapy sources and dose and method of administration;	
(iii) Calculating the dose; and	(iii) Calculating the dose; and	
(iv) Post-administration followup and review of case histories in collaboration with the authorized user.	(iv) Post-administration follow up and review of case histories in collaboration with the authorized user.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.941 Training for ophthalmic use of strontium-90.	Sec. 35.941 Training for ophthalmic use of strontium-90.	
Except as provided in Section 35.970, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows:	Except as provided in Sec. 35.57, the licensee shall require the authorized user of only strontium-90 for ophthalmic radiotherapy to be a physician who is in the active practice of therapeutic radiology or ophthalmology, and has had classroom and laboratory training in basic radioisotope handling techniques applicable to the use of strontium-90 for ophthalmic radiotherapy, and a period of supervised clinical training in ophthalmic radiotherapy as follows--	
(a) 24 hours of classroom and laboratory training that includes:	(a) 24 hours of classroom and laboratory training that includes--	
(1) Radiation physics and instrumentation;	(1) Radiation physics and instrumentation;	
(2) Radiation protection;	(2) Radiation protection;	
(3) Mathematics pertaining to the use and measurement of radioactivity; and	(3) Mathematics pertaining to the use and measurement of radioactivity; and	
(4) Radiation biology;	(4) Radiation biology;	
(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a	(b) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a	

CURRENT RULE	PROPOSED RULE	FINAL RULE
medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes: (1) Examination of each individual to be treated; (2) Calculation of the dose to be administered; (3) Administration of the dose; and (4) Followup and review of each individual's case history.	medical institution that includes the use of strontium-90 for the ophthalmic treatment of five individuals that includes-- (1) Examination of each individual to be treated; (2) Calculation of the dose to be administered; (3) Administration of the dose; and (4) Follow up and review of each individual's case history.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.950 Training for use of sealed sources for diagnosis. Except as provided in Section 35.970, the licensee shall require the authorized user of a sealed source in a device listed in Section 35.500 to be a physician, dentist, or podiatrist who: (a) Is certified in: (1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; (2) Nuclear medicine by the American Board of Nuclear Medicine; (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or (b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes: (1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and	Sec. 35.950 Training for use of sealed sources for diagnosis. Except as provided in Sec. 35.57, the licensee shall require the authorized user of a sealed source in a device listed in Sec. 35.500 to be a physician, dentist, or podiatrist who-- (a) Is certified in-- (1) Radiology, diagnostic radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology; (2) Nuclear medicine by the American Board of Nuclear Medicine; (3) Diagnostic radiology or radiology by the American Osteopathic Board of Radiology; or (4) Nuclear medicine by the Royal College of Physicians and Surgeons of Canada; or (b) Has had 8 hours of classroom and laboratory training in basic radioisotope handling techniques specifically applicable to the use of the device that includes-- (1) Radiation physics, mathematics pertaining to the use and measurement of radioactivity, and instrumentation; (2) Radiation	

CURRENT RULE	PROPOSED RULE	FINAL RULE
instrumentation; (2) Radiation biology; (3) Radiation protection; and (4) Training in the use of the device for the uses requested.	biology; (3) Radiation protection; and (4) Training in the use of the device for the uses requested.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.960 Training for teletherapy.	Sec. 35.960 Training for use of therapeutic medical devices.	
Except as provided in Section 35.970, the licensee shall require the authorized user of a sealed source listed in Section 35.600 in a teletherapy unit to be a physician who:	Except as provided in Sec. 35.57, the licensee shall require the authorized user of a sealed source listed in Sec. 35.600 to be a physician who--	
(a) Is certified in:	(a) Is certified in--	
(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;	(1) Radiology, therapeutic radiology, or radiation oncology by the American Board of Radiology;	
(2) Radiation oncology by the American Osteopathic Board of Radiology;	(2) Radiation oncology by the American Osteopathic Board of Radiology;	
(3) Radiology, with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology"; or	(3) Radiology, with specialization in radiotherapy, as a British `Fellow of the Faculty of Radiology'' or ``Fellow of the Royal College of Radiology''; or	
(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or	(4) Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons; or	
(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a teletherapy unit, supervised work experience, and	(b) Is in the active practice of therapeutic radiology, and has had classroom and laboratory training in basic radioisotope techniques applicable to the use of a sealed source in a therapeutic medical device, supervised work experience, and	

CURRENT RULE	PROPOSED RULE	FINAL RULE
supervised clinical experience as follows: (1) 200 hours of classroom and laboratory training that includes: (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes: (i) Review of the full calibration measurements and periodic spot checks; (ii) Preparing treatment plans and calculating treatment times; (iii) Using administrative controls to prevent misadministrations; (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and (v) Checking and using survey meters; and (3) Three years of supervised clinical	supervised clinical experience as follows-- (1) 200 hours of classroom and laboratory training that includes-- (i) Radiation physics and instrumentation; (ii) Radiation protection; (iii) Mathematics pertaining to the use and measurement of radioactivity; and (iv) Radiation biology; (2) 500 hours of supervised work experience under the supervision of an authorized user at a medical institution that includes-- (i) Review of the full calibration measurements and periodic spot-checks; (ii) Preparing treatment plans and calculating treatment times; (iii) Using administrative controls to prevent medical events; (iv) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical device or console; and (v) Checking and using survey meters; and (3) Three years of supervised clinical	

CURRENT RULE	PROPOSED RULE	FINAL RULE
experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes: (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy treatment, and any limitations or contraindications; (ii) Selecting the proper dose and how it is to be administered; (iii) Calculating the teletherapy doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects' reaction to radiation; and	experience that includes one year in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional two years of clinical experience in therapeutic radiology under the supervision of an authorized user at a medical institution that includes-- (i) Examining individuals and reviewing their case histories to determine their suitability for teletherapy, remote afterloader, or gamma stereotactic radiosurgery treatment, and any limitations or contraindications; (ii) Selecting the proper dose and how it is to be administered; (iii) Calculating the doses and collaborating with the authorized user in the review of patients' or human research subjects' progress and consideration of the need to modify originally prescribed doses as warranted by patients' or human research subjects'	

CURRENT RULE	PROPOSED RULE	FINAL RULE
(iv) Post-administration followup and review of case histories.	reaction to radiation; and (iv) Post-administration follow up and review of case histories.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Section 35.961 Training for teletherapy physicist. The licensee shall require the teletherapy physicist to be an individual who: (a) Is certified by the American Board of Radiology in: (1) Therapeutic radiological physics; (2) Roentgen ray and gamma ray physics; (3) X-ray and radium physics; or (4) Radiological physics; or (b) Is certified by the American Board of Medical Physics in radiation oncology physics; or (c) Holds a master's or doctor's degree in physics, biophysics, radiological physics, or health physics, and has completed one year of full time training in therapeutic radiological physics and an additional year of full time work experience under the supervision of a teletherapy physicist at a medical institution that includes the tasks listed in Sections 35.59, 35.632, 35.634, and 35.641 of this part.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Section 35.970 Training for experienced authorized users. Physicians, dentists, or podiatrists identified as authorized users for the medical, dental, or podiatric use of byproduct material on a Commission or Agreement State license issued before April 1, 1987 who perform only those methods of use for which they were authorized on that date need not comply with the training requirements of subpart J. Section 35.971 Physician training in a three month program. A physician who, before July 1, 1984, began a three month nuclear medicine training program approved by the Accreditation Council for Graduate Medical Education and has successfully completed the program need not comply with the requirements of Sections 35.910 or 35.920.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Section 35.972 Recentness of training. The training and experience specified in this subpart must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.	

Section 35.980 Training for an authorized nuclear pharmacist.

The licensee shall require the authorized nuclear pharmacist to be a pharmacist who:

(a) Has current board certification as a nuclear pharmacist by the Board of Pharmaceutical Specialties, or

(b)(1) Has completed 700 hours in a structured educational program consisting of both:

(i) Didactic training in the following areas:

(A) Radiation physics and instrumentation;

(B) Radiation protection;

(C) Mathematics pertaining to the use and measurement of radioactivity;

(D) Chemistry of byproduct material for medical use; and

(E) Radiation biology; and

(ii) Supervised experience in a nuclear pharmacy involving the following:

(A) Shipping, receiving, and performing related radiation surveys;

(B) Using and performing checks for proper operation of dose calibrators, survey meters, and, if appropriate, instruments used to measure alpha- or beta-emitting radionuclides;

(C) Calculating, assaying, and safely preparing dosages for patients or human research subjects;

(D) Using administrative controls to

avoid mistakes in the administration of byproduct material;

(E) Using procedures to prevent or minimize contamination and using proper decontamination procedures; and

(2) Has obtained written certification, signed by a preceptor authorized nuclear pharmacist, that the above training has been satisfactorily completed and that the individual has achieved a level of competency sufficient to independently operate a nuclear pharmacy.

Section 35.981 Training for experienced nuclear pharmacists.

A licensee may apply for and must receive a license amendment identifying an experienced nuclear pharmacist as an authorized nuclear pharmacist before it allows this individual to work as an authorized nuclear pharmacist. A pharmacist who has completed a structured educational program as specified in Section 35.980(b)(1) before December 2, 1994, and who is working in a nuclear pharmacy would qualify as an experienced nuclear pharmacist. An experienced nuclear pharmacist need not comply with the requirements on preceptor statement (Section 35.980(b)(2)) and recentness of training (Section 35.972) to qualify as an authorized nuclear pharmacist.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE PROPOSED RULE FINAL RULE

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Subpart K--Other Medical Uses of Byproduct Material or Radiation From Byproduct Material	Subpart K--Other Medical Uses of Byproduct Material or Radiation from Byproduct Material
	Sec. 35.1000 Other medical uses of byproduct material or radiation from byproduct material.	§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.
	A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if--	A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if --
	(a) The applicant or licensee has submitted the information required by Sec. 35.12(d); and	(a) The applicant or licensee has submitted the information required by § 35.12(b) through (d); and
	(b) The applicant or licensee has received written approval from the Commission in a license and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.	(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Subpart L--Records	Subpart L--Records
	Sec. 35.2024 Records of authority and responsibilities for radiation protection programs.	§ 35.2024 Records of authority and responsibilities for radiation protection programs.
	(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with Sec. 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.	(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with § 35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.
	(b) The licensee shall retain a current copy of the authorities, duties and responsibilities of the radiation safety officer, as required by Sec. 35.24(d), and a signed copy of the radiation safety officer's willingness to be responsible for implementing the radiation safety program, as required by Sec. 35.24(b). The records must include the signature of the radiation safety officer and licensee management.	(b) The licensee shall retain a current copy of the authority, duties, and responsibilities of the Radiation Safety Officer as required by § 35.24(e), and a signed copy of the Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by § 35.24(b). The records must include the signature of the Radiation Safety Officer and licensee management.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2026 Records of radiation protection program safety changes. A licensee shall retain a record of each radiation protection program change made in accordance with Sec. 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the radiation safety officer and the licensee management that reviewed and approved the change.	§ 35.2026 Records of radiation protection program changes. A licensee shall retain a record of each radiation protection program change made in accordance with § 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2040 Records of written directives. A licensee shall retain a copy of each written directive as required by Sec. 35.40 for 3 years.	§ 35.2040 Records of written directives. A licensee shall retain a copy of each written directive as required by § 35.40 for 3 years.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2045 Records of medical events. A licensee shall retain a record of medical events reported pursuant to Sec. 35.3045 for 3 years. The record must contain the licensee's name, names of all the individuals involved, the affected or potentially affected individual's social security number or other identification number if one has been assigned, a brief description of the medical event, why it occurred, the effect on the individual, and the actions taken to prevent recurrence.	§ 35.2045 Records of medical events. (a) A licensee shall retain a record of medical events reported in accordance with § 35.3045 for 3 years. (b) The record must include-- (1) The licensee’s name; (2) Names of all the individuals involved; (3) The affected or potentially affected individual’s social security number or other identification number if one has been assigned; (4) A brief description of the medical event and why it occurred; (5) The effect, if any, on the individual; and (6) The actions, if any, taken or planned to prevent recurrence.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2060 Records of instrument calibrations. A licensee shall maintain a record of instrument calibrations required by Secs. 35.60 and 35.62 for 3 years. The records must include-- (a) For constancy, the model and serial number of the instrument, the identity of the radionuclide contained in the check source, the date of the check, and the activity measured, and the name of the individual who performed the check; (b) For accuracy, the model and serial number of the instrument, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, and the results of the test, and the name of the individual who performed the test; (c) For linearity, the model and serial number of the instrument, the calculated activities, the measured activities, and the date of the test, and the name of the individual who performed the test; and (d) For geometric dependence, the model and serial number of the instrument, the configuration of the source measured, the activity measured for each volume measured, and the date of the test, and the name of the individual who performed the test.	§ 35.2047 Record of a dose to an embryo/fetus or a nursing child. (a) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child reported in accordance with § 35.3047 for 3 years. (b) The record must include-- (1) The licensee's name; (2) Names of all the individuals involved; (3) The affected or potentially affected individual's social security number or other identification number if one has been assigned; (4) A brief description of the event and why it occurred; (5) The effect, if any, on the embryo/fetus or nursing child; and (6) The actions, if any, taken or planned to prevent recurrence.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2061 Records of radiation survey instrument calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by Sec. 35.61 for 3 years. The record must include-- (a) A description of the calibration procedure; and (b) The date of the calibration, a description of the source used and the certified exposure rates from the source, and the rates indicated by the instrument being calibrated, the correction factors deduced from the calibration data, and the name of the individual who performed the calibration.	§ 35.2060 Records of calibrations of instruments to measure the activity of unsealed byproduct materials. A licensee shall maintain a record of instrument calibrations required by § 35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2063 Records of dosages of unsealed byproduct material for medical use. (a) A licensee shall maintain a record of dosage determinations required by Sec. 35.63 for 3 years. (b) To satisfy this requirement, the record must contain the-- (1) Radionuclide, generic name, trade name, or abbreviation of the radiopharmaceutical, and its lot number; (2) Patient's or human research subject's name, or identification number if one has been assigned; (3) Prescribed dosage and activity of the dosage at the time of determination, or a notation that the total activity is less than 1.1 MBq (30 <greek-m>Ci); (4) Date and time of the dosage determination; and (5) Name of the individual who determined the dosage.	
	Sec. 35.2067 Records of possession of sealed sources and brachytherapy sources. (a) A licensee shall retain records of leak tests required by Sec. 35.67(b) for 3 years. The records must contain the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the measured activity of each test sample, a description of the	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	method used to measure each test sample, the date of the test, and the name of the individual who performed the test. (b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by Sec. 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.	§ 35.2061 Records of radiation survey instrument calibrations. A licensee shall maintain a record of radiation survey instrument calibrations required by § 35.61 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2070 Records of surveys for ambient radiation exposure rate. A licensee shall retain a record of each survey required by Sec. 35.70 for 3 years. The record must include the date of the survey, a plan of each area surveyed, the trigger level established for each area, the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in disintegrations per minute per 100 square centimeters, the instrument used to make the survey or analyze the samples, and the name of the individual who performed the survey.	§ 35.2063 Records of dosages of unsealed byproduct material for medical use. (a) A licensee shall maintain a record of dosage determinations required by § 35.63 for 3 years. (b) The record must contain-- (1) The radiopharmaceutical; (2) The patient's or human research subject's name, or identification number if one has been assigned; (3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 µCi); (4) The date and time of the dosage determination; and (5) The name of the individual who determined the dosage.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2075 Records of the release of individuals containing radiopharmaceuticals or implants. (a) A licensee shall retain records of the release of individuals containing pharmaceuticals or implants in accordance with Sec. 35.75 for 3 years after the date of release (b) A licensee shall retain a record in accordance with paragraph (a) of this section that describes the basis for authorizing the release of individuals if the total effective dose equivalent is calculated by-- (1) Using the retained activity rather than the activity administered; (2) Using an occupancy factor less than 0.25 at 1 meter; (3) Using the biological or effective half-life; or (4) Considering the shielding by tissue. (c) A licensee shall retain a record that the instructions required by Sec. 35.75(b) were provided to a breast-feeding woman if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).	§ 35.2067 Records of possession of sealed sources and brachytherapy sources. (a) A licensee shall retain records of leak tests required by § 35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested, the identity of each source radionuclide and its estimated activity, the results of the test, the date of the test, and the name of the individual who performed the test. (b) A licensee shall retain records of the semi-annual physical inventory of sealed sources and brachytherapy sources required by § 35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2080 Records of administrative and technical requirements that apply to the provision of mobile services. (a) A licensee shall retain a copy of the letter(s) that permits the use of byproduct material at a client's address of use, in accordance with Sec. 35.80(a)(1). This letter must clearly delineate the authority and responsibility of each entity and must be retained for 3 years after the last provision of service. (b) A licensee shall retain the record of each survey required by Sec. 35.80(a)(4) for 3 years. The record must include the date of the survey, a plan of each area that was surveyed, the measured dose rate at several points in each area of use expressed in millirem per hour, the instrument used to make the survey, and the name of the individual who performed the survey.	§ 35.2070 Records of surveys for ambient radiation exposure rate. A licensee shall retain a record of each survey required by § 35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2092 Records of waste disposal. A licensee shall maintain records of the disposal of licensed materials made in accordance with Sec. 35.92 for 3 years. The record must include the date of the disposal, the radionuclides disposed, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.	§ 35.2075 Records of the release of individuals containing unsealed byproduct material or implants containing byproduct material. (a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with § 35.75, if the total effective dose equivalent is calculated by -- (1) Using the retained activity rather than the activity administered; (2) Using an occupancy factor less than 0.25 at 1 meter; (3) Using the biological or effective half-life; or (4) Considering the shielding by tissue. (b) A licensee shall retain a record that the instructions required by § 35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem). (c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2204 Records of molybdenum-99 concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by Sec. 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as microcuries of molybdenum per millicurie of technetium, the time and date of the measurement, and the name of the individual who made the measurement.	§ 35.2080 Records of administrative and technical requirements that apply to the provision of mobile medical services. (a) A licensee shall retain a copy of the letter(s) that permits the use of byproduct material at a client's address, as required by § 35.80(a)(1). This letter must clearly delineate the authority and responsibility of the licensee and the client and must be retained for 3 years after the last provision of service. (b) A licensee shall retain the record of each survey required by § 35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2310 Records of instruction and training. A licensee shall maintain a record of instructions and training required by Secs. 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction or training, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.	§ 35.2092 Records of decay-in-storage. A licensee shall maintain records of the disposal of licensed materials, as required by § 35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background dose rate, the dose rate measured at the surface of each waste container, and the name of the individual who performed the disposal.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2404 Records of radiation surveys of patients and human research subjects. A licensee shall maintain a record of the radiation surveys of patients and human research subjects required by Secs. 35.404 and 35.604 for 3 years. Each record must include the date, location, and results of the survey, an identifier for the patient or the human research subject, the survey instrument used, and the name of the individual who made the survey.	§ 35.2204 Records of molybdenum-99 concentrations. A licensee shall maintain a record of the molybdenum-99 concentration tests required by § 35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2406 Records of brachytherapy source inventory. (a) A licensee shall maintain a record of brachytherapy source accountability required by Sec. 35.406 for 3 years. (b) For temporary implants, the record must include-- (1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and (2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them from storage. (c) For permanent implants, the record must include-- (1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage; (2) The number and activity of sources returned to storage, the date they were returned to storage, and the name of the individual who returned them to storage; and (3) The number and activity of sources permanently implanted in the patient or human research subject.	§ 35.2310 Records of safety instruction. A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.2404 Records of surveys after source implant and removal. A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2432 Records of full calibrations on brachytherapy sources. A licensee shall maintain a record of the full calibrations on brachytherapy sources required by Sec. 35.432 for 3 years after the last use of the source. The record must include the date of the calibration; the manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source; the source output; source positioning accuracy within applicators; and the name of the individual or the source manufacturer who performed the calibration.	§ 35.2406 Records of brachytherapy source accountability. (a) A licensee shall maintain a record of brachytherapy source accountability required by § 35.406 for 3 years. (b) For temporary implants, the record must include -- (1) The number and activity of sources removed from storage, the time and date they were removed from storage, the name of the individual who removed them from storage, and the location of use; and (2) The number and activity of sources returned to storage, the time and date they were returned to storage, and the name of the individual who returned them to storage. (c) For permanent implants, the record must include -- (1) The number and activity of sources removed from storage, the date they were removed from storage, and the name of the individual who removed them from storage; (2) The number and activity of sources not implanted, the date they were returned to storage, and the name of the individual who returned them to storage; and (3) The number and activity of sources permanently implanted in the patient or human research subject.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2605 Records of installation, maintenance, and repair. A licensee shall retain a record of the installation, maintenance, and repair of therapeutic medical devices as required by Sec. 35.605 for 3 years. For each installation, maintenance, and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.	§ 35.2432 Records of calibration measurements of brachytherapy sealed sources. (a) A licensee shall maintain a record of the calibrations of brachytherapy sources required by § 35.432 for 3 years after the last use of the source. (b) The record must include-- (1) The date of the calibration; (2) The manufacturer's name, model number, and serial number for the source and the instruments used to calibrate the source; (3) The source output or activity; (4) The source positioning accuracy within the applicators; and (5) The signature of the authorized medical physicist.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2630 Records of dosimetry equipment. (a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with Sec. 35.630 for the duration of the license. (b) For each calibration, intercomparison, or comparison, the record must include-- (1) The date; (2) The model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of Sec. 35.630; (3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and (4) The name(s) of the individual(s) who performed the calibration, intercomparison, or comparison. Sec. 35.2632 Records of teletherapy full calibrations. (a) A licensee shall maintain a record of the teletherapy full calibrations required by Sec. 35.632 for 3 years.	§ 35.2605 Records of installation, maintenance, adjustment, and repair. A licensee shall retain a record of the installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units as required by § 35.605 for 3 years. For each installation, maintenance, adjustment and repair, the record must include the date, description of the service, and name(s) of the individual(s) who performed the work.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	(b) The record must include-- (1) The date of the calibration; (2) The manufacturer's name, model number, and serial number for the teletherapy unit, source, and instruments used to calibrate the teletherapy unit; (3) Tables that describe the output of the unit over the range of field sizes and for the range of distances used in radiation therapy; (4) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; (5) An assessment of timer accuracy and linearity; (6) The calculated on-off error; (7) The estimated accuracy of each distance measuring and localization device; and (8) The signature of the authorized medical physicist who performed the full calibration.	§ 35.2630 Records of dosimetry equipment. (a) A licensee shall retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with § 35.630 for the duration of the license. (b) For each calibration, intercomparison, or comparison, the record must include -- (1) The date; (2) The manufacturer's name, model numbers and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of § 35.630; (3) The correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and (4) The names of the individuals who performed the calibration, intercomparison, or comparison. § 35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations. (a) A licensee shall maintain a record of the teletherapy unit, remote afterloader unit, and gamma stereotactic radiosurgery unit full calibrations required by §§ 35.632, 35.633, and 35.635 for 3 years. (b) The record must

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2633 Records of remote afterloader full calibrations. (a) A licensee shall maintain a record of the remote afterloader full calibrations required by Sec. 35.633 for 3 years. (b) The record must include-- (1) The date of the calibration; (2) The manufacturer's name, model number, and serial number for the remote afterloader, source, and instruments used to calibrate the unit; the source output; (3) An assessment of timer accuracy and linearity, source positioning accuracy, source guide tube and connector lengths, and source retraction functionality; and (4) The signature of the authorized medical physicist who performed the full calibration.	include -- (1) The date of the calibration; (2) The manufacturer's name, model number, and serial number of the teletherapy, remote afterloader, and gamma stereotactic radiosurgery unit(s), the source, and the instruments used to calibrate the unit(s); (3) The results and an assessment of the full calibrations; (4) The results of the autoradiograph required for low dose-rate remote afterloader units; and (5) The signature of the authorized medical physicist who performed the full calibration.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2635 Records of gamma stereotactic radiosurgery unit full calibrations. (a) A licensee shall maintain a record of the gamma stereotactic radiosurgery full calibrations required by Sec. 35.635 for 3 years. (b) The record must include-- (1) The date of the calibration; (2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit, source, and instruments used to calibrate the unit; (3) The unit output; (4) An assessment of the relative helmet factors, isocenter coincidence, timer accuracy and linearity, on-off error, and trunnion centricity; and (5) The signature of the authorized medical physicist who performed the full calibration.	
	Sec. 35.2642 Records of periodic spot-checks for teletherapy units. (a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by Sec. 35.642 for 3 years. (b) The record must include -- (1) The date of the spot-check; (2) The manufacturer's name, model number, and serial number for the	

teletherapy unit, source and instrument used to measure the output of the teletherapy unit;

(3) An assessment of timer linearity and constancy;

(4) The calculated on-off error;

(5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;

(6) The determined accuracy of each distance measuring and localization device;

(7) The difference between the anticipated output and the measured output;

(8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and

(9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2643 Records of periodic spot-checks for remote afterloaders. (a) A licensee shall retain a record of each spot-check for remote afterloaders required by Secs. 35.643 and 35.644 for 3 years. (b) The record must include-- (1) The date of the spot-check; (2) The manufacturer's name, model number, and serial number for the remote afterloader, source, and instrument used to measure the output of the remote afterloader; (3) The difference between the anticipated output and the measured output; (4) Notations indicating the operability of each entrance door electrical interlock, source retraction mechanism, radiation monitors, source exposure indicator lights, viewing and intercom systems if applicable, applicators and connectors, and source positioning accuracy; and (5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.	§ 35.2642 Records of periodic spot-checks for teletherapy units. (a) A licensee shall retain a record of each periodic spot-check for teletherapy units required by § 35.642 for 3 years. (b) The record must include -- (1) The date of the spot-check; (2) The manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit; (3) An assessment of timer linearity and constancy; (4) The calculated on-off error; (5) A determination of the coincidence of the radiation field and the field indicated by the light beam localizing device; (6) The determined accuracy of each distance measuring and localization device; (7) The difference between the anticipated output and the measured output; (8) Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and (9) The name of the individual who performed the periodic spot-check and the signature of the authorized

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units. (a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by Sec. 35.645 for 3 years. (b) The record must include-- (1) The date of the spot-check; (2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; (3) The measured source output and source output against computer calculations; (4) Notations indicating the operability of radiation monitors, helmet microswitchs, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination systems, hydraulic cutoff switch and stereotactic frames and	medical physicist who reviewed the record of the spot-check.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	localizing devices (trunnions); and (5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.	§ 35.2643 Records of periodic spot-checks for remote afterloader units. (a) A licensee shall retain a record of each spot-check for remote afterloader units required by § 35.643 for 3 years. (b) The record must include, as applicable -- (1) The date of the spot-check; (2) The manufacturer's name, model number, and serial number for the remote afterloader unit and source; (3) An assessment of timer accuracy; (4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom systems, and clock and decayed source activity in the unit’s computer; and (5) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2647 Records of additional technical requirements for mobile remote afterloaders. (a) A licensee shall retain a record of each check for mobile remote afterloaders required by Sec. 35.647 for 3 years. (b) The record must include-- (1) The date of the check; (2) The manufacturer's name, model number, and serial number of the remote afterloader; (3) Notations accounting for all sources before the licensee departs from a facility; (4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators and connectors, and source positioning accuracy; and (5) The signature of the individual who performed the check.	§ 35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units. (a) A licensee shall retain a record of each spot-check for gamma stereotactic radiosurgery units required by § 35.645 for 3 years. (b) The record must include -- (1) The date of the spot-check; (2) The manufacturer's name, model number, and serial number for the gamma stereotactic radiosurgery unit and the instrument used to measure the output of the unit; (3) An assessment of timer linearity and accuracy; (4) The calculated on-off error; (5) A determination of trunnion centricity;

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2652 Records of surveys of therapeutic treatment units. (a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with Sec. 35.652 for the duration of use of the unit. (b) The record must include-- (1) The date of the measurements; (2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; (3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and (4) The signature of the individual who performed the test.	

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic surgery units. (a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by Sec. 35.655 for the duration of use of the unit. (b) The record must contain-- (1) The inspector's radioactive materials license number; (2) The date of inspection; (3) The manufacturer's name and model number and serial number of both the treatment unit and source; (4) A list of components inspected and serviced, and the type of service; and (5) The signature of the inspector.	§ 35.2647 Records of additional technical requirements for mobile remote afterloader units. (a) A licensee shall retain a record of each check for mobile remote afterloader units required by § 35.647 for 3 years. (b) The record must include -- (1) The date of the check; (2) The manufacturer's name, model number, and serial number of the remote afterloader unit; (3) Notations accounting for all sources before the licensee departs from a facility; (4) Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and (5) The signature of the individual who performed the check.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.2652 Records of surveys of therapeutic treatment units. (a) A licensee shall maintain a record of radiation surveys of treatment units made in accordance with § 35.652 for the duration of use of the unit. (b) The record must include -- (1) The date of the measurements; (2) The manufacturer's name, model number and serial number of the treatment unit, source, and instrument used to measure radiation levels; (3) Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and (4) The signature of the individual who performed the test.

CURRENT RULE	PROPOSED RULE	FINAL RULE
		§ 35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units. (a) A licensee shall maintain a record of the 5-year inspections for teletherapy and gamma stereotactic radiosurgery units required by § 35.655 for the duration of use of the unit. (b) The record must contain -- (1) The inspector's radioactive materials license number; (2) The date of inspection; (3) The manufacturer's name and model number and serial number of both the treatment unit and source; (4) A list of components inspected and serviced, and the type of service; and (5) The signature of the inspector.

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(6) The difference between the anticipated output and the measured output; (7) An assessment of source output against computer calculations; (8) Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, and stereotactic frames and localizing devices (trunnions); and (9) The name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check.		
§ 35.2433 Records of decay of strontium-90 sources for ophthalmic treatments. (a) A licensee shall maintain a record of the activity of a strontium-90 source required by § 35.433 for the life of the source. (b) The record must include-- (1) The initial activity of the source and date; and (2) For each decay calculation, the date and the source activity as determined under § 35.432.		

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE PROPOSED RULE FINAL RULE

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Subpart M--Reports	Subpart M--Reports
	Sec. 35.3045 Reports of medical events.	§ 35.3045 Report and notification of a medical event.
	(a) A licensee shall report any administration, except for administrations resulting from a direct intervention of a patient or human research subject that could not have been reasonably prevented by the licensee, that results in either--	(a) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in --
	(1) A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and	(1) A dose that differs from the prescribed dose by more than 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and
	(i) The total dose or dosage delivered differs from the prescribed dose or dosage by 20 percent or more; or	(i) The total dose delivered differs from the prescribed dose by 20 percent or more;
	(ii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.	(ii) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or
		(iii) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.
	(2) A dose that exceeds 0.05 Sv (5 rem) effective dose	(2) A dose that

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	equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following– (i) An administration of a wrong pharmaceutical; (ii) An administration of a radiopharmaceutical by the wrong route of administration; (iii) An administration of a dose or dosage to the wrong individual or human research subject; (iv) An administration of a dose or dosage delivered by the wrong treatment mode; or (v) A leaking sealed source. (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 20 percent the dose expected from the administration defined in the written directive.	exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following – (i) An administration of a wrong radioactive drug containing byproduct material; (ii) An administration of a radioactive drug containing byproduct material by the wrong route of administration; (iii) An administration of a dose or dosage to the wrong individual or human research subject; (iv) An administration of a dose or dosage delivered by the wrong mode of treatment; or (v) A leaking sealed source. (3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants,

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		seeds that were implanted in the correct site but migrated outside the treatment site). (b) A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in an unintended permanent functional damage to an organ or a physiological system, as determined by a physician.
	(b) The licensee shall notify by telephone the NRC Operations Center (301-951-0550) no later than the next calendar day after discovery of the medical event.	(c) The licensee shall notify by telephone the NRC Operations Center[1] no later than the next calendar day after discovery of the medical event.
	(c) The licensee shall submit a written report to the appropriate NRC Regional Office listed in Sec. 30.6 of this chapter within 15 days after discovery of the medical event.	(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 15 days after discovery of the medical event.
	(1) The written report must include--	(1) The written report must include --
	(i) The licensee's name;	(i) The licensee's name;
	(ii) The name of the prescribing physician;	(ii) The name of the prescribing physician;
	(iii) A brief description of the event;	(iii) A brief description of the
	(iv) Why the event occurred;	
	(v) The effect on the individual(s) who received the administration;	
	(vi) What improvements are needed to prevent recurrence;	
	(vii) Actions taken to prevent recurrence;	

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		event;
	(viii) Whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and	(iv) Why the event occurred;
		(v) The effect, if any, on the individual(s) who received the administration;
	(ix) If there was notification, what information was provided.	(vi) What actions, if any, have been taken or are planned to prevent recurrence;
	(2) The report must not contain the individual's name or any other information that could lead to identification of the individual.	(vii) Whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and
	(d) The licensee shall notify the referring physician and also notify the individual affected by the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not	(viii) If there was notification, what information was provided.
		(2) The report may not contain the individual's name or any other information that could lead to identification of the individual.
		(e) The licensee shall notify the referring physician and also notify the individual affected by the medical event no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he or she will inform the individual or that,

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	delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this section, the notification of the individual receiving the medical event may be made instead to that individual's responsible relative or guardian, when appropriate. (e) If the individual was notified pursuant to paragraph (d) of this section, the licensee shall also furnish, within 15 days after discovery of the medical event, a written report to the individual by sending either-- (1) A copy of the report that was submitted to the NRC; or (2) A brief description of both the event and the consequences as they may affect the individual. (f) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or	based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the affected individual cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the medical event, because of any delay in notification. To meet the requirements of this section, the notification of the individual receiving the medical event may be made instead to that individual's responsible relative or guardian. (f) If the individual was notified under paragraph (e) of this section, the licensee shall also furnish a written report to the individual within 15 days after discovery of the medical event. A licensee may send either -- (1) A copy of the report that was

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	to that individual's responsible relatives or guardians.	submitted to the NRC; or (2) A brief description of both the event and the consequences as they may affect the individual. (g) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals affected by the medical event, or to that individual's responsible relatives or guardians. (h) A licensee shall retain a record of a medical event in accordance with § 35.2045.

CURRENT RULE	PROPOSED RULE	FINAL RULE
	Sec. 35.3047 Report of a dose to an embryo/fetus or a nursing child.	§ 35.3047 Report and notification of a dose to an embryo/fetus or a nursing child.
	(a) A licensee shall report any dose to an embryo/fetus that is greater than 5 mSv (500 mrem) absorbed dose that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.	(a) A licensee shall report any dose to an embryo/fetus that is greater than 50 mSv (5 rem) dose equivalent that is a result of an administration of byproduct material or radiation from byproduct material to a pregnant individual unless the dose to the embryo/fetus was specifically approved, in advance, by the authorized user.
	(b) A licensee shall report any dose to a nursing child that is greater than 5 mSv (500 mrem) total effective dose equivalent that is a result of an administration of byproduct material to a breast feeding individual.	(b) A licensee shall report any dose to a nursing child that is a result of an administration of byproduct material to a breast-feeding individual that -- (1) Is greater than 50 mSv (5 rem) total effective dose equivalent; or (2) Has resulted in unintended permanent functional damage to an organ or a physiological system of the child, as determined by a physician.
	(c) The licensee shall notify by telephone the NRC Operations Center within 5 days after discovery of a dose to the embryo/fetus or nursing child that	(c) The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day after discovery of a dose to the embryo/fetus or

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	requires a report in paragraphs (a) or (b) in this section.	nursing child that requires a report in paragraphs (a) or (b) in this section.
	(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in Sec. 30.6 no later than 15 days after discovery of a dose to the embryo/fetus or nursing child hat requires a report in paragraphs (a) or (b) in this section.	(d) The licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter no later than 15 days after discovery of a dose to the embryo/fetus or nursing child that requires a report in paragraphs (a) or (b) in this section.
	(1) The written report must include--	(1) The written report must include --
	(i) The licensee's name;	(i) The licensee's name;
	(ii) The name of the prescribing physician;	(ii) The name of the prescribing physician;
	(iii) A brief description of the event;	(iii) A brief description of the event;
	(iv) Why the event occurred;	(iv) Why the event occurred;
	(v) The effect on the embryo/fetus or the nursing child;	(v) The effect, if any, on the embryo/fetus or the nursing child; and
	(vi) What improvements are needed to prevent recurrence; and	(vi) What actions, if any, have been taken or are planned to prevent recurrence;
	(vii) Actions taken to prevent recurrence.	
	(2) The report must not contain the individual's or child's name or any other information that could lead to identification of the individual or child.	(2) The report must not contain the individual's or child’s name or any other information that could lead to identification of the individual or child.
	(e) The licensee shall notify the referring physician and also notify the	(e) The licensee shall notify the referring physician

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	pregnant individual or mother, hereafter referred to as the mother, within 5 days of discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgment, telling the mother would be harmful;	and also notify the pregnant individual or mother, both hereafter referred to as the mother, no later than 24 hours after discovery of an event that would require reporting under paragraph (a) or (b) of this section, unless the referring physician personally informs the licensee either that he or she will inform the mother or that, based on medical judgement, telling the mother would be harmful.
	(f) To meet the requirements of this section, the notification of the mother may be made instead to the mother's or child's responsible relative or guardian, when appropriate.	(f) To meet the requirements of this section, the notification may be made to the mother's or child's responsible relative or guardian instead of the mother, when appropriate.
	(g) The licensee is not required to notify the mother without first consulting the referring physician. If the referring physician or mother cannot be reached within 5 days, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event, because of any delay in notification.	(g) The licensee is not required to notify the mother without first consulting with the referring physician. If the referring physician or mother cannot be reached within 24 hours, the licensee shall make the appropriate notifications as soon as possible thereafter. The licensee may not delay any appropriate medical care for the embryo/fetus or for the nursing child, including any necessary remedial care as a result of the event,

CURRENT RULE	PROPOSED RULE	FINAL RULE
	(h) If notification was made pursuant to paragraphs (e) and (f) of this section, the licensee shall also furnish, within 15 days after discovery of the event, a written report to the mother or responsible relative or guardian, by sending either-- (1) A copy of the report that was submitted to the NRC; or (2) A brief description of both the event and the consequences as they may affect the embryo/fetus or nursing child.	because of any delay in notification. (h) If notification was made under paragraphs (e) and (f) of this section, the licensee shall also furnish a written report to the mother or responsible relative or guardian within 15 days after discovery of the event. A licensee may send either -- (1) A copy of the report that was submitted to the NRC; or (2) A brief description of both the event and the consequences as they may affect the embryo/fetus or nursing child. (i) A licensee shall retain a record of a dose to an embryo/fetus or a nursing child in accordance with § 35.2047.

Sec. 35.3067 Reports of leaking sources.	§ 35.3067 Report of a leaking source.
A licensee shall file a report within 5 days if a leakage test required by Sec. 35.67 reveals the presence of 185 Bq (0.005 <greek-m>Ci) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in Sec. 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the measured activity of each test sample expressed in microcuries; a description of the method used to measure each test sample; the date of the test; and the action taken.	A licensee shall file a report within 5 days if a leak test required by § 35.67 reveals the presence of 185 Bq (0.005 µCi) or more of removable contamination. The report must be filed with the appropriate NRC Regional Office listed in § 30.6 of this chapter, with a copy to the Director, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. The written report must include the model number and serial number if assigned, of the leaking source; the radionuclide and its estimated activity; the results of the test; the date of the test; and the action taken.

1. The commercial telephone number of the NRC Operations Center is (301) 951-0550.

10 CFR PART 35, MEDICAL USE OF BYPRODUCT MATERIAL-RULEMAKING MATRIX

CURRENT RULE	PROPOSED RULE	FINAL RULE
Subpart K--Enforcement	Subpart N--Enforcement	Subpart N--Enforcement
Section 35.990 Violations.	Sec. 35.4001 Violations.	§ 35.4001 Violations.
(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of-- (1) The Atomic Energy Act of 1954, as amended; (2) Title II of the Energy Reorganization Act of 1974, as amended; or (3) A regulation or order issued pursuant to those Acts.	(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of-- (1) The Atomic Energy Act of 1954, as amended; (2) Title II of the Energy Reorganization Act of 1974, as amended; or (3) A regulation or order issued pursuant to those Acts.	(a) The Commission may obtain an injunction or other court order to prevent a violation of the provisions of -- (1) The Atomic Energy Act of 1954, as amended; (2) Title II of the Energy Reorganization Act of 1974, as amended; or (3) A regulation or order issued under those Acts.
(b) The Commission may obtain a court order for the payment of a civil penalty imposed under section 234 of the Atomic Energy Act: (1) For violations of-- (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended; (ii) Section 206 of the Energy Reorganization Act; (iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section; (iv) Any term, condition, or limitation	(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act: (1) For violations of-- (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended; (ii) Section 206 of the Energy Reorganization Act; (iii) Any rule, regulation, or order issued pursuant to the sections specified in paragraph (b)(1)(i) of this section; (iv) Any term, condition, or limitation	(b) The Commission may obtain a court order for the payment of a civil penalty imposed under Section 234 of the Atomic Energy Act: (1) For violations of -- (i) Sections 53, 57, 62, 63, 81, 82, 101, 103, 104, 107, or 109 of the Atomic Energy Act of 1954, as amended; (ii) Section 206 of the Energy Reorganization Act; (iii) Any rule, regulation, or order issued under the sections specified in paragraph (b)(1)(i) of this section; (iv) Any term, condition, or limitation

CURRENT RULE	PROPOSED RULE	FINAL RULE
of any license issued under the sections specified in paragraph (b)(1)(i) of this section. (2) For any violation for which a license may be revoked under section 186 of the Atomic Energy Act of 1954, as amended.	of any license issued under the sections specified in paragraph (b)(1)(i) of this section. (2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.	of any license issued under the sections specified in paragraph (b)(1)(i) of this section. (2) For any violation for which a license may be revoked under Section 186 of the Atomic Energy Act of 1954, as amended.

CURRENT RULE	PROPOSED RULE	FINAL RULE
Section 35.991 Criminal penalties. (a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of section 223, all the regulations in part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section. (b) The regulations in part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of section 223 are as follows: Sections 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.57, 35.100, 35.600, 35.901, 35.970, 35.971, 35.990, 35.991, and 35.999. Section 35.999 Resolution of conflicting requirements during transition period. If the rules in this part conflict with the licensee's radiation safety program as identified	Sec. 35.4002 Criminal penalties. (a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section. (b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: Secs. 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.600, 35.4001, and 35.4002.	§ 35.4002 Criminal penalties. (a) Section 223 of the Atomic Energy Act of 1954, as amended, provides for criminal sanctions for willful violation of, attempted violation of, or conspiracy to violate, any regulation issued under sections 161b, 161i, or 161o of the Act. For purposes of Section 223, all the regulations in 10 CFR part 35 are issued under one or more of sections 161b, 161i, or 161o, except for the sections listed in paragraph (b) of this section. (b) The regulations in 10 CFR part 35 that are not issued under subsections 161b, 161i, or 161o for the purposes of Section 223 are as follows: §§ 35.1, 35.2, 35.7, 35.8, 35.12, 35.15, 35.18, 35.19, 35.65, 35.100, 35.200, 35.300, 35.600, 35.4001, and 35.4002 .

in its license, and if that license was approved by the Commission before April 1, 1987 and has not been renewed since April 1, 1987, then the requirements in the license will apply. However, if that licensee exercises its privilege to make minor changes in its radiation safety procedures that are not potentially important to safety under Section 35.31 of this chapter, the portion changed must comply with the requirements of this part. At the time of license renewal and thereafter, these amendments to this part shall apply.