	State section	NRC Section	RATS ID	Category	Subject and Comment
1	20.3.3.317 TERMS AND CONDITIONS OF LICENSES: I. Generators. Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with 20.3.7.706 NMAC of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in 10 CFR 35.204(a) at the time of generator elution, in accordance with 10 CFR 35.3204.	§ 30.34 Terms and conditions of licenses (g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82 generators shall test the generator eluates for molybdenum-99 breakthrough or strontium-82 and strontium-85 contamination, respectively, in accordance with § 35.204 of this chapter. The licensee shall record the results of each test and retain each record for 3 years after the record is made. The licensee shall report the results of any test that exceeds the permissible concentration listed in § 35.204(a) of this chapter at the time of generator elution, in accordance with § 35.3204 of this chapter.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
2	20.3.3.315 radioactive material for medical use under 20.3.7 NMAC.	§ 32.72 Manufacture, preparation, or transfer for commercial distribution of	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions

	J.(1)(d) The applicant [~~satisfies~~] [commits] the following labeling requirements. J.(2)(f)(i) each individual's certification by a specialty board whose certification process has been recognized by the [~~department, NRC~~][Commission] or agreement state as specified in Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(a), with the written attestation signed by a preceptor as required by Subsection C of 20.3.7.714 NMAC, incorporating 10 CFR 35.55(b)(2); or (ii) the [~~department, NRC~~][Commission] or agreement state license, or (iii) the permit issued by a NRC master material licensee, or (iv) the permit issued by a [~~department, NRC~~][Commission] or agreement state licensee, or NRC master materials permittee of broad scope, or	radioactive drugs containing byproduct material for medical use under part 35 (a)(4) The applicant commits to the following labeling requirements: ---------- (b)(5)(i) A copy of each individual's certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in § 35.55(a) of this chapter; or ----------			

	the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or J.(4) [~~Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.~~] [A licensee shall satisfy the labeling requirements in paragraph (d) of this section.] [(5) Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs.]	(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.			
3	20.3.7.7 DEFINITIONS: C. [**"**Associate Radiation Safety Officer (ARSO)" means an individual who— (1) Meets the requirements in §§ 35.50 and 35.59; and (2) Is currently identified as an Associate Radiation Safety	§ 35.2 Definitions. Associate Radiation Safety Officer means an individual who— (1) Meets the requirements in §§ 35.50 and 35.59; and (2) Is currently identified as an Associate Radiation Safety	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions

	Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on— (i) A specific medical use license issued by the Commission or an Agreement State; or (ii) A medical use permit issued by a Commission master material licensee.] [D][~~E.~~] "Authorized medical physicist" means …..(Continue new designation to T) [V. Ophthalmic physicist means an individual who— (1) Meets the requirements in § 35.433(a)(2) and § 35.59; and (2) Is identified as an ophthalmic physicist on a— (i) Specific medical use license issued by the Commission or an Agreement State; (ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;	Officer for the types of use of byproduct material for which the individual has been assigned duties and tasks by the Radiation Safety Officer on— (i) A specific medical use license issued by the Commission or an Agreement State; or (ii) A medical use permit issued by a Commission master material licensee. Ophthalmic physicist means an individual who— (1) Meets the requirements in § 35.433(a)(2) and § 35.59; and (2) Is identified as an ophthalmic physicist on a— (i) Specific medical use license issued by the Commission or an Agreement State; (ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;			

	(iii) Medical use permit issued by a Commission master material licensee; or (iv) Permit issued by a Commission master material licensee broad scope medical use permittee.] [~~U~~][W].“Output” means….. (Continue new designation to end of definitions) [~~AA~~][CC][Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer [or an Associate Radiation Safety Officer].	(iii) Medical use permit issued by a Commission master material licensee; or (iv) Permit issued by a Commission master material licensee broad scope medical use permittee. Preceptor means an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, an authorized medical physicist, an authorized nuclear pharmacist, a Radiation Safety Officer, or an Associate Radiation Safety Officer.			
4	20.3.7.702 A. Radiation Safety Officer. (1) A licensee or licensee’s management shall appoint a radiation safety officer, who	§ 35.24 Authority and responsibilities for the radiation protection program. (b) A licensee's management shall appoint a Radiation Safety Officer who agrees, in	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions

	agrees, in writing, to be responsible for implementing a 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. [A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for	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. A licensee's management may appoint, in writing, one or more Associate Radiation Safety Officers to support the Radiation Safety Officer. The Radiation Safety Officer, with written agreement of the licensee's management, must assign the specific duties and tasks to each Associate Radiation Safety Officer. These duties and tasks are restricted to the types of use for which the Associate Radiation Safety Officer is listed on a license. The Radiation Safety Officer may delegate duties and tasks to the Associate Radiation Safety Officer but shall not delegate the authority or responsibilities for implementing the			

	implementing the radiation protection program.]	radiation protection program.			
5	20.3.7.702 G. Written Directive (3)(e) for high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions and total dose; or (f) [~~for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders, before implantation: treatment site, the radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose).~~][For permanent implant brachytherapy: (i) Before implantation: The treatment site, the radionuclide, and the total source strength; and	§ 35.40 Written Directive (b) (5) For high dose-rate remote afterloading brachytherapy: the radionuclide, treatment site, dose per fraction, number of fractions, and total dose; (b)(6) For permanent implant brachytherapy: (i) Before implantation: The treatment site, the radionuclide, and the total source strength; and	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions

	(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or (g) for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders, before implantation: treatment site, the radionuclide and dose; and after implantation but before completion of the procedure: the radionuclide, treatment site, number of sources, total source strength and exposure time (or the total dose); and date.]	(ii) After implantation but before the patient leaves the post-treatment recovery area: The treatment site, the number of sources implanted, the total source strength implanted, and the date; or (7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders: (i) Before implantation: The treatment site, radionuclide, and dose; and (ii) After implantation but before completion of the procedure: The radionuclide; treatment site; number of sources; total source strength and exposure time (or the total dose); and date.			
5	20.3.7.702 G. Written Directive (2) 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][~~radioactive~~] material, the brachytherapy	§ 35.40 Written Directive (c) (1) 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	2018-1		Sent to NRC for review and comment prior to implementation of the revisions

	dose, the gamma stereotactic radiosurgery dose, the teletherapy dose or the next fractional dose. 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, provided that the oral revision is documented as soon as possible in writing in the patient's record. A revised written directive documenting the oral revision must be prepared, dated and signed by the authorized user within 48 hours of the oral revision.	stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose.			
6	20.3.7.702 H. Procedures for Administrations Requiring a Written Directive. (2)… [(e) Determining if a medical event, as defined in § 35.3045, has occurred; and (f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date	§ 35.41 Procedures for administrations requiring a written directive. (b) (5) Determining if a medical event, as defined in § 35.3045, has occurred; and (6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date	2018-1		Sent to NRC for review and comment prior to implementation of the revisions

	the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.]	the implant was performed, the total source strength administered outside of the treatment site compared to the total source strength documented in the post-implantation portion of the written directive, unless a written justification of patient unavailability is documented.			
7	20.3.7.714 TRAINING REQUIREMENTS: A. Radiation Safety Officer [and Associate Radiation Safety Officer]. The regulations of the NRC set forth in 10 CFR 35.50 are hereby incorporated by reference.	§ 35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
8	20.3.7.714 TRAINING REQUIREMENTS: B. Training for an Authorized Medical Physicist. The regulations of the NRC set forth in 10 CFR 35.51 are hereby incorporated by reference.	§ 35.51 Training for an authorized medical physicist.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
9	20.3.7.714 TRAINING REQUIREMENTS: C. Training for an Authorized Nuclear Pharmacist. The regulations of the NRC set	§ 35.55 Training for an authorized nuclear pharmacist.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions

	forth in 10 CFR 35.55 are hereby incorporated by reference.				
10	20.3.7.714 TRAINING REQUIREMENTS: D. Training for Experienced Radiation Safety Officer, Teletherapy or Medical Physicist, Authorized Medical Physicist, Authorized User, Nuclear Pharmacist and Authorized Nuclear Pharmacist. The regulations of the NRC set forth in 10 CFR 35.57 are hereby incorporated by reference.	§ 35.57 Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
11	20.3.7.714 TRAINING REQUIREMENTS: F. Training for Uptake, Dilution, and Excretion Studies. (For use of unsealed radioactive material under 20.3.7.704 NMAC) The regulations of the NRC set forth in 10 CFR 35.190 are hereby incorporated by reference.	§ 35.190 Training for uptake, dilution, and excretion studies.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
12	20.3.7.706 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82 AND STRONTIUM-85 CONCENTRATIONS: B. Measurement.	§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions

	(1) A licensee preparing technetium-99m radiopharmaceutical from molybdenum-99/technetium-99m generators shall measure the molybdenum-99 concentration [~~of the first eluate after the receipt of the generator to demonstrate compliance with Subsection A of this section~~][in each eluate from a generator to demonstrate compliance with Subsection A of this section of this section]. D. Reporting. [The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with 10 CFR 35.3204.]	(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 from a generator to demonstrate compliance with paragraph (a) of this section. (e) The licensee shall report any measurement that exceeds the limits in paragraph (a) of this section at the time of generator elution, in accordance with § 35.3204.			
13	20.3.7.714 TRAINING REQUIREMENTS: G. Training for Imaging and Localization Studies. (For use of unsealed radioactive material under 20.3.7.705 NMAC) The regulations of	§ 35.290 Training for imaging and localization studies.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions

	the NRC set forth in 10 CFR 35.290 are hereby incorporated by reference.				
14	20.3.7.708 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED: A licensee may use any unsealed radioactive material [identified in 10 CFR 35.390(b)(1)(ii)(G)] prepared for medical use and for which a written directive is required that is [~~either~~]:	§ 35.300 Use of unsealed byproduct material for which a written directive is required. A licensee may use any unsealed byproduct material identified in § 35.390(b)(1)(ii)(G) prepared for medical use and for which a written directive is required that is—	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
15	20.3.7.714 TRAINING REQUIREMENTS: H. Training for Use of Unsealed Radioactive Material for Which a Written Directive is Required. (For use of unsealed radioactive material under 20.3.7.708 NMAC) The regulations of the NRC set forth in 10 CFR 35.390 are hereby incorporated by reference.	§ 35.390 Training for use of unsealed byproduct material for which a written directive is required.	2018-1		Sent to NRC for review and comment prior to implementation of the revisions
16	20.3.7.714 TRAINING REQUIREMENTS: I. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Less than or Equal to 33 millicuries (1.22	§ 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).	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions

	gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.392 are hereby incorporated by reference.				
17	20.3.7.714 TRAINING REQUIREMENTS: J. Training for the Oral Administration of Sodium Iodide I-131 Requiring a Written Directive in Quantities Greater than 33 millicuries (1.22 gigabecquerels). The regulations of the NRC set forth in 10 CFR 35.394 are hereby incorporated by reference.	§ 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).	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
18	20.3.7.714 TRAINING REQUIREMENTS: K. Training for the Parenteral Administration of Unsealed Byproduct Material Requiring a Written Directive. The regulations of the NRC set forth in 10 CFR 35.396 are hereby incorporated by reference.	§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.	2018-1		Sent to NRC for review and comment prior to implementation of the revisions
19	20.3.7.710 MANUAL BRACHYTHERAPY: G. Decay of Strontium-90 Sources for Ophthalmic Treatments.	§ 35.433 Strontium-90 sources for ophthalmic treatments.	2018-1		Sent to NRC for review and comment prior to implementation of the revisions

	The regulations of the NRC set forth in 10 CFR 35.433 are hereby incorporated by reference. [~~(1) 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 Subsection F of 20.3.7.710 NMAC.~~ ~~(2) A licensee shall retain a record of the activity of each strontium-90 source in accordance with Subsection S of 20.3.7.715 NMAC.~~]				
20	20.3.7.714 TRAINING REQUIREMENTS: L. Training for Use of Manual Brachytherapy Sources. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.490 are hereby incorporated by reference.	§ 35.490 Training for use of manual brachytherapy sources.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions
21	20.3.7.714 TRAINING REQUIREMENTS:	§ 35.491 Training for ophthalmic use of strontium-90.	2018-1	B	Sent to NRC for review and comment prior to implementation of the revisions

	M. Training for Ophthalmic Use of Strontium-90. (For use of radioactive material under 20.3.7.710 NMAC) The regulations of the NRC set forth in 10 CFR 35.491 are hereby incorporated by reference.				
22	20.3.7.712 SEALED SOURCES FOR DIAGNOSIS: A. 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~~.] [if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the	§ 35.500 Use of sealed sources and medical devices for diagnosis. (a) A licensee must use only sealed sources that are not in medical devices for diagnostic medical uses if the sealed sources are approved in the Sealed Source and Device Registry for diagnostic medicine. The sealed sources may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. (b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the	2018-1		Sent to NRC for review and comment prior to implementation of the revisions

	sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. C. Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of 10 CFR 35.49(a) are met.] [D.][~~B~~] Survey Instrument. A licensee authorized to use radioactive material as a sealed source for diagnostic purposes shall have available for use a portable radiation survey meter capable of detecting dose rates ranging from 0.1 millirem (1	sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. The diagnostic medical devices may be used for diagnostic medical uses that are not explicitly listed in the Sealed Source and Device Registry but must be used in accordance with the radiation safety conditions and limitations described in the Sealed Source and Device Registry. (c) Sealed sources and devices for diagnostic medical uses may be used in research in accordance with an active Investigational Device Exemption (IDE) application accepted by the U.S. Food and Drug Administration provided the requirements of § 35.49(a) are met.			

	millisievert) per hour to 1000 millirems (10 millisieverts) per hour. The instrument shall be operable and calibrated in accordance with section Subsection C of 20.3.7.703 NMAC.				
23	20.3.7.714 TRAINING REQUIREMENTS: N. Training for Use of Sealed Sources for Diagnosis: (For use of radioactive material under 20.3.7.712 NMAC) The regulations of the NRC set forth in 10 CFR 35.590 are hereby incorporated by reference.	§ 35.590 Training for use of sealed sources and medical devices for diagnosis.			
24	20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS: D(4) [Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor	§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units. (d)(1) Prior to the first use for patient treatment of a new unit or an existing unit with a manufacturer upgrade that affects the operation and safety of the unit, a licensee shall ensure that vendor operational and safety training is provided to all individuals who will operate the unit. The vendor			

	operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training.] **[(4)][(5)]** 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: (Continue re-designation) **[(8)][(~~7~~)]**A licensee shall retain a copy of the procedures required by Subparagraph (d) of Paragraph (1) and Subparagraph (b) of Paragraph (5[4]) of this subsection in accordance with Subsection U of 20.3.7.715 NMAC.	operational and safety training must be provided by the device manufacturer or by an individual certified by the device manufacturer to provide the operational and safety training. (g) A licensee shall retain a copy of the procedures required by paragraphs (a)(4) and (d)(2)(ii) of this section in accordance with § 35.2610.			
25	20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS:	§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.	2018-1	H&S	Sent to NRC for review and comment prior to implementation of the revisions

	O. Five-Year Inspection for Teletherapy and Gamma Stereotactic Radiosurgery Units. (1) 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 and other safety components. The interval between each full inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.	(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during each source replacement to assure proper functioning of the source exposure mechanism and other safety components. The interval between each full-inspection servicing shall not exceed 5 years for each teletherapy unit and shall not exceed 7 years for each gamma stereotactic radiosurgery unit.			
26	20.3.7.714 TRAINING REQUIREMENTS: O. Training for Use of Remote Afterloader Units, Teletherapy Units and Gamma Stereotactic Radiosurgery Units (For use of radioactive material under	§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	2018-1	B	

	20.3.7.711 NMAC). The regulations of the NRC set forth in 10 CFR 35.690 are hereby incorporated by reference.				
27	20.3.7.716 REPORTS: A. Report and Notification of a Medical Event. (1) A licensee shall report any event, except for an event that results from patient intervention, in which the administration of radioactive material or radiation from byproduct [~~radioactive~~] material , except permanent implant brachytherapy, results in: (b)(i) an administration of a wrong radioactive drug containing byproduct [~~radioactive~~] material; [(d) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material	§ 35.3045 Report and notification of a medical event. (a) A licensee shall report any event as a medical event, except for an event that results from patient intervention, in which— (1) The administration of byproduct material or radiation from byproduct material, except permanent implant brachytherapy, results in— (A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure; (2) For permanent implant brachytherapy, the administration of byproduct	2018-1		

	(excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in— (i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive; (ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or (iii) An administration that includes any of the following: the wrong radionuclide; the wrong individual or human research subject; sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or a leaking sealed source resulting in a dose that	material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in— (i) The total source strength administered differing by 20 percent or more from the total source strength documented in the post-implantation portion of the written directive; (ii) The total source strength administered outside of the treatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or (iii) An administration that includes any of the following: (A) The wrong radionuclide; (B) The wrong individual or human research subject; (C) Sealed source(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive; or			

	exceeds 0.5 Sv (50 rem) to an organ or tissue.]	(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.			