| State Regulation, 20.3 NMAC | Federal Regulation 10 CFR | Comments |
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| **20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL:** J.(1)<br>(d) The applicant commits to [~~satisfies~~] the following labeling requirements.<br> | *RATS 2018-1 category - B*<br>**§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35**<br>(a)(4) The applicant commits to the following labeling requirements: | **In § 32.72:**<br>**(a) Revise the introductory text of (a)(4);** The applicant commits to the following labeling requirements:<br>Based on RATS 2018-1 letter dated July 16, 2018 |
| **20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL: (J)(2)**<br>(f) Shall provide to the Commission [~~department~~] a copy of<br>(i) each individual's certification by a specialty board whose certification process has been recognized by the Commission [~~department, NRC~~] or agreement state as specified in 10 CFR 35.55(a)[~~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 | *RATS 2018-1 category - B* **§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35**<br>(5) Shall provide to the Commission:<br>(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 | **In § 32.72:**<br>**(b) Revise (b)(5)(i);**<br>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<br>Based on RATS 2018-1 letter dated July 16, 2018 |
| **20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL:**<br>**(f)**<br>ii) the Commission [~~department, NRC~~] or agreement state license, or<br>(iii) Commission [~~the permit issued by a NRC~~] master material licensee permit, or<br>(iv) the permit issued by a licensee or Commission [~~department, NRC or agreement state licensee, or NRC~~] master materials permittee of broad scope, or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or | *none* **§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35**<br>**(5)** (ii) The Commission or Agreement State license, or<br>(iii) Commission master materials licensee permit, or<br>(iv) The permit issued by a licensee or Commission master materials permittee of broad scope or the authorization from a commercial nuclear pharmacy authorized to list its own authorized nuclear pharmacist, or | **RCB Correction**<br>To align with current federal regulation |

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| **20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL:**<br>**(f)**<br>(4) A licensee shall satisfy the labeling requirements in paragraph J(1)(d) of this section [~~Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs~~].<br>(5) Nothing in this section relieves the licensee from complying with applicable FDA, or other federal and state requirements governing radioactive drugs. | RATS 2018-1 category - B<br>**§ 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35**<br>**(c)(2)**<br>(d) A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.<br>(e) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs. | **(c) Redesignate paragraph (d) as paragraph (e); and (d) Add new paragraph (d). to read as follows:**<br>A licensee shall satisfy the labeling requirements in paragraph (a)(4) of this section.<br>Based on RATS 2018-1 letter dated July 16, 2018 |
| **20.3.3.317 TERMS AND CONDITIONS OF LICENSES:**<br>A. Each license issued pursuant to the requirements in this part shall be subject to all the provisions of the act, now or hereafter in effect, and to all rules, regulations and orders of the board or department.<br>(1) No right to the special nuclear material shall be conferred by the license except as defined by the license;<br>(2) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of 20.3.3.317 NMAC;<br>(3) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the department. | *RATS 2018-2 category - C*<br>**§ 70.32 Conditions of licenses.** (a)<br>Each license shall contain and be subject to the following conditions:<br>(2) No right to the special nuclear material shall be conferred by the license except as defined by the license;<br>(3) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act;<br>(8) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the Commission. | **C: 70.32(a)(2), (a)(3), & (a)(8).**<br>(a) Each license shall contain and be subject to the following conditions:<br>(2) No right to the special nuclear material shall be conferred by the license except as defined by the license;<br>(3) Neither the license nor any right under the license shall be assigned or otherwise transferred in violation of the provisions of the Act;<br>(8) The license shall be subject to and the licensee shall observe, all applicable rules, regulations and orders of the Commission.<br>Based on RATS 2018-2 letter dated November 21, 2018 |

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| **20.3.3.317 TERMS AND CONDITIONS OF LICENSES: E. Filing for bankruptcy.**<br>(1) Each general licensee that is required to register by Paragraph (m) of Subsection B of 20.3.3.305 NMAC and each specific licensee shall notify the department and appropriate NRC Regional Administrator in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any chapter of title 11 (bankruptcy) of the United States Code by or against: | RATS 2018-2 category - H&S<br>**§ 70.32 Conditions of licenses.**<br>(a) Each license shall contain and be subject to the following conditions: (9)(i) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: | **H&S: 70.32(a)(9)**<br>§ 70.32 Conditions of licenses.<br>(a) Each license shall contain and be subject to the following conditions:<br>(9)(i) Each licensee shall notify the appropriate NRC Regional Administrator, in writing, immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: Based on RATS 2018-2 letter dated November 21, 2018 |
| **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. | *RATS 2018-1 category - B*<br>**§ 30.34 Terms and conditions of licenses**<br>(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. | **In § 30.34, add a third sentence to paragraph (g) to read as follows:**<br>(g)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. Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.7 DEFINITIONS:**<br>C. "Associate Radiation Safety Officer (ARSO)" means an individual who—<br>(1) Meets the requirements in §§ 35.50 and 35.59; and<br>(2) Is currently identified as an Associate Radiation Safety 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—<br>(a) A specific medical use license issued by the Commission or an Agreement State; or<br>(b) A medical use permit issued by a Commission master material licensee. | *RATS 2018-1 category - B* **§ 35.2 Definitions.**<br>Associate Radiation Safety Officer means an individual who—<br>(1) Meets the requirements in §§ 35.50 and 35.59; and<br>(2) Is currently identified as an Associate Radiation Safety 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—<br>(i) A specific medical use license issued by the Commission or an Agreement State; or<br>(ii) A medical use permit issued by a Commission master material licensee. | **In § 35.2, add, in alphabetical order, the definitions for Associate Radiation Safety Officer...**<br>Based on RATS 2018-1 letter dated July 16, 2018 |
| **20.3.7.7 DEFINITIONS:**<br>V. "Ophthalmic physicist" means an individual who—<br>(1) Meets the requirements in § 35.433(a)(2) and § 35.59; and<br>(2) Is identified as an ophthalmic physicist on a—<br>(a) Specific medical use license issued by the Commission or an Agreement State;<br>(b) Permit issued by a Commission or Agreement State broad scope medical use licensee;<br>(c) Medical use permit issued by a Commission master material licensee; or<br>(d) Permit issued by a Commission master material licensee broad scope medical use permittee. | *RATS 2018-1 category - B* **§ 35.2 Definitions.** *Ophthalmic physicist means an individual who—*<br>*(1) Meets the requirements in §§ 35.433(a)(2) and 35.59; and*<br>*(2) Is identified as an ophthalmic physicist on a—*<br>*(i) Specific medical use license issued by the Commission or an Agreement State;*<br>*(ii) Permit issued by a Commission or Agreement State broad scope medical use licensee;*<br>*(iii) Medical use permit issued by a Commission master material licensee; or*<br>*(iv) Permit issued by a Commission master material licensee broad scope medical use permittee.* | **In § 35.2, add, in alphabetical order, the definitions for.... Ophthalmic physicist….**<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.7 DEFINITIONS:**<br>[~~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, [~~or a~~] R[~~r~~]adiation S[~~s~~]afety O[~~o~~]fficer, or a Associate Radiation Officer. | *RATS 2018-1 category - B*<br>***§ 35.2 Definitions.*** 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. | **In § 35.2, … and revise the definition for Preceptor** … Based on RATS 2018-1 letter dated July 16, 2018 |
| **20.3.7.702GENERAL ADMINISTRATIVE REQUIREMENTS:**<br>A.Radiation safety officer.<br>(1)A licensee or licensee's management shall appoint a radiation safety officer, who 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 | *RATS 2018-1 category - H&S*<br>**§ 35.24 Authority and responsibilities for the 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. A licensee's management may appoint, in writing, one or more..... | **In § 35.24, revise paragraphs (b) to read as follows:** (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.<br>A licensee's management may appoint, in writing, one or more ..... |

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| **Continued**<br>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 radiation protection program. | **Continued**<br>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 radiation protection program. | **Continued**<br>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 SafetyOfficer. 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 radiation protection program. Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS: G. Written directive.**<br>(3)(f) For permanent implant brachytherapy:<br>(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and<br>(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 [~~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).~~] | *RATS 2018-1 category - H & S*<br>**§ 35.40 Written directives.**<br>(6) For permanent implant brachytherapy:<br>(i) Before implantation: The treatment site, the radionuclide, and the total source strength; and<br>(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 | **(b) revise paragraph (b)(6) to read as follows**<br>(6) For permanent implant brachytherapy:<br>(i) Before implantation: the treatment site, the radionuclide, and the total source strength; and<br>(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<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS: G. Written directive.**<br>(3)(g) for all other brachytherapy, including low, medium and pulsed dose rate remote afterloaders: before implantation: the 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. | *RATS 2018-1 category - H & S*<br>**§ 35.40 Written directives.**<br>*(7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:*<br>*(i) Before implantation: The treatment site, radionuclide, and dose; and*<br>*(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.* | **(b) revise paragraph (b)(6) to read as follows** (7) For all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders:<br>(i) Before implantation: the treatment site, radionuclide, and dose; and<br>(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.<br>(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 stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS:**<br>**G. Written directive.** (4)<br>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. | *RATS 2018-1 category - H & S*<br>**§ 35.40 Written directives.** *(c)(1)*<br>*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.* | **Redesignate paragraph (c)(1) as paragraph (c)(2)**<br>**to read as follows:**<br>(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 stereotactic radiosurgery dose, the teletherapy dose, or the next fractional dose. |

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| **Continued** 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. | **Continued** (2) 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. | **Continued**<br>(2) 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.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.702 GENERAL ADMINISTRATIVE REQUIREMENTS:**<br>H. Procedures for administrations requiring a written directive. (2)(e) Determining if a medical event, as defined in 20.3.7.716 NMAC and 10 CFR 35.3045, has occurred; and<br>(f) Determining, for permanent implant brachytherapy, within 60 calendar days from the date 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. | *RATS 2018-1 category - H & S*<br>**§ 35.41 Procedures for administrations requiring a written directive.** (5) Determining if a medical event, as defined in § 35.3045, has occurred; and<br>(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date 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. | add new paragraphs (b)(5) and (b)(6) to read as follows:<br>(5) Determining if a medical event, as defined in § 35.3045, has occurred; and<br>(6) Determining, for permanent implant brachytherapy, within 60 calendar days from the date 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.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.706 PERMISSIBLE MOLYBDENUM-99, STRONTIUM-82 AND STRONTIUM-85 CONCENTRATIONS:**<br>B. Measurement.<br>(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.<br>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 subsection D of 20.3.7.716 NMAC and 10 CFR 35.3204. | *RATS 2018-1 category - H&S*<br>**§ 35.204 Permissible molybdenum-99, strontium-82, and strontium-85 concentrations.**<br>(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.<br>(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. | In § 35.204, revise paragraph (b) and add new paragraph (e) to read as follows:<br>(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.<br><br>(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.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.708 USE OF UNSEALED RADIOACTIVE MATERIAL FOR WHICH A WRITTEN DIRECTIVE IS REQUIRED:**<br>A licensee may use any unsealed byproduct [~~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~~]: | *RATS 2018-1 category - B* **§ 35.300 Use of unsealed byproduct material for which a written directive is required.**<br>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— | revise the introductory text to read as follows: 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—<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.710 MANUAL BRACHYTHERAPY:**<br>A. Use of sources for manual brachytherapy. The regulations of the NRC set forth in 10 CFR 35.400 are hereby incorporated by reference. [~~A licensee shall use only brachytherapy sources for therapeutic medical uses:~~<br>~~(1) as approved in the sealed source and device registry; or~~<br>~~(2) in research in accordance with an active investigational device exemption application accepted by the FDA provided the requirements of Paragraph (1) of Section I of 20.3.7.702 NMAC are met.~~] | *RATS 2018-1 category - B* **§**<br>**35.400 Use of sources for manual brachytherapy.**<br>A licensee must use only brachytherapy sources:<br>(a) Approved in the Sealed Source and Device Registry for manual brachytherapy medical use. The manual brachytherapy sources may be used for manual brachytherapy 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; or<br>(b) In research to deliver therapeutic doses for medical use 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. | In § 35.400 revise paragraphs (a) and (b) to read as follows:<br>A licensee must use only brachytherapy sources:<br>(a) Approved in the Sealed Source and Device Registry..... are met.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.710 MANUAL BRACHYTHERAPY:**<br>G. Decay of strontium-90 sources for ophthalmic treatments. 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.~~<br>~~(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.~~] | *RATS 2018-1 category - B* **§ 35.433 Strontium-90 sources for ophthalmic treatments.**<br>(a) Licensees who use strontium-90 for ophthalmic treatments must ensure that certain activities as specified in paragraph (b) of this section are performed by either:<br>(1) An authorized medical physicist; or<br>(2) An individual who:<br>(i) is identified as an ophthalmic physicist on a specific medical use license issued by the Commission or an Agreement State; permit issued by a Commission or Agreement State broad scope medical use licensee; medical use permit issued by a Commission master material licensee; or permit issued by a Commission master material licensee broad scope medical use permittee; and<br>(ii) holds a master's or doctor's degree in physics, medical physics, other physical sciences, engineering, or applied mathematics from an accredited college or university; and (iii) has successfully completed 1 year of full-time training in medical physics and an additional year of full-time work experience under the supervision of a medical physicist; and<br>(iv) Has documented training in: | In § 35.433, revise paragraph (a), add new paragraphs (b), (b)(1) and (2), and redesignate paragraph (c) to read as follows: (a) Licensees who use strontium-90 for ophthalmic treatments must ensure that ..... Based on RATS 2018-1 letter dated July 16, 2018 |

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| **Continued** | **Continued** (A) The creation, modification, and completion of written directives;<br>(B) Procedures for administrations requiring a written directive; and<br>(C) Performing the calibration measurements of brachytherapy sources as detailed in § 35.432.<br>(b) The individuals who are identified in paragraph (a) of this section must:<br>(1) 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; and<br>(2) Assist the licensee in developing, implementing, and maintaining written procedures to provide high confidence that the administration is in accordance with the written directive. These procedures must include the frequencies that the individual meeting the requirements in paragraph (a) of this section will observe treatments, review the treatment methodology, calculate treatment time for the prescribed dose, and review records to verify that the administrations were in accordance with the written directives.<br>(c) Licensees must retain a record of the activity of each strontium-90 source in accordance with § 35.2433. | **Continued** |

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| **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 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.<br>(5[4]) A licensee shall provide operational and safety instruction, initially and at least annually, to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties, in:<br>(a) the procedures identified in Subparagraph (d) of Paragraph (1) of this subsection; and<br>(b) the operating procedures for the unit. | *RATS 2018-1 category - H&S* **§ 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.<br><br>(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as appropriate to the individual's assigned duties. The instructions shall include instruction in—<br>(i) The procedures identified in paragraph (a)(4) of this section; and<br>(ii) The operating procedures for the unit. | **In § 35.610, add new paragraph (d)(1) and revise paragraphs (d) and (g) to read as follows:**<br><br>*********<br>(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.<br>(2) A licensee shall provide operational and safety instructions initially and at least annually to all individuals who operate the unit at the facility, as |

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| **Continued**<br>(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. | **Continued** | **Continued**<br>appropriate to the individual's assigned duties. The instructions shall include instruction in— (i) The procedures identified in paragraph (a)(4) of this section; and (ii) The operating procedures for the unit.<br>*<br>(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.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.711 PHOTON EMITTING REMOTE AFTERLOADER UNITS, TELETHERAPY UNITS AND GAMMA STEREOTACTIC RADIOSURGERY UNITS:** 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. | *RATS 2018-1 category - H&S* **§ 35.655 Full-inspection servicing for teletherapy and gamma stereotactic radiosurgery units.** (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. | **In § 35.655, revise the section heading and paragraph (a) to read as follows:** (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. Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.712 SEALED SOURCES FOR DIAGNOSIS:**<br>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.<br>B. A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the 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. | *RATS 2018-1 category - C*<br>**§ 35.500 Use of sealed sources and medical devices for diagnosis.**<br>(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.<br><br>(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the 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. | **In § 35.500 revise paragraph (a), and add new paragraphs (b) and (c) to read as follows:**<br>(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.<br>(b) A licensee must only use medical devices containing sealed sources for diagnostic medical uses if both the sealed sources and medical devices are approved in the Sealed Source and Device Registry for diagnostic medical uses. |

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| **Continued** C.<br>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. | **Continued** (c)<br>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. | **Continued**<br>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.<br>(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.<br>Based on RATS 2018-1 letter dated July 16, 2018 |
| **20.3.7.714 TRAINING REQUIREMENTS:**<br>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. | *RATS 2018-1 category - B* **§**<br>**35.50 Training for Radiation Safety Officer and Associate Radiation Safety Officer.** | Revise § 35.50 to read as follows: incorporated by reference<br>Based on RATS 2018-1 letter dated July 16, 2018 |

**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 byproduct [~~radioactive~~] material or radiation from byproduct [~~radioactive~~] material, except permanent implant brachytherapy, results in:

(a) a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue or 50 rems (0.5 sievert) shallow dose equivalent to the skin; and:

(i) the total dose delivered differs from the prescribed dose by twenty percent or more;

(ii) the total dosage delivered differs from the prescribed dosage by twenty 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 fifty percent or more;

(b) a dose that exceeds 5 rems (50 millisieverts) effective dose equivalent, 50 rems (0.5 sievert) to an organ or tissue, or 50 rems (0.5 sievert) shallow dose equivalent to the skin from any of the following:

*RATS 2018-1 category - C*

**Subpart M—Reports**

**§ 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—

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage 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

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more.

(ii) A dose that 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—

**In § 35.3045, revise paragraph (a) to read as follows:**

(a) A licensee shall report any event as a medical event, exceptfor 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—

(i) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage 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

(A) The total dose delivered differs from the prescribed dose by 20 percent or more;

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| **Continued**<br>(i) an administration of a wrong radioactive drug containing byproduct[~~radioactive~~] material;<br>(ii) an administration of a radioactive drug containing radioactive material by the wrong route of administration;<br>(iii) an administration of a dose or dosage to the wrong individual or human research subject;<br>(iv) an administration of a dose or dosage delivered by the wrong mode of treatment; or<br>(v) a leaking sealed source; and | **Continued**<br>A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;<br>(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration;<br>(C) An administration of a dose or dosage to the wrong individual or human research subject;<br>(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or<br>(E) A leaking sealed source. | **Continued**<br>(B) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or<br>(C) The fractionated dose delivered differs from the prescribed dose for a single fraction, by 50 percent or more20 percent of the total source strength documented in the post-implantation portion of the written directive; or |
| (c) a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rems (0.5 sievert) to an organ or tissue and fifty percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).<br>(d) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in— | (iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:<br>(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and<br>(B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration.<br>(2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in— | **Continued** (ii)<br>A dose that 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—<br>(A) An administration of a wrong radioactive drug containing byproduct material or the wrong radionuclide for a brachytherapy procedure;<br>(B) An administration of a radioactive drug containing byproduct material by the wrong route of administration; |

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| **Continued**<br>(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;<br>(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<br>(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 exceeds 0.5 Sv (50 rem) to an organ or tissue. | **Continued** (i)<br>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;<br>(ii) The total source strength administered outside of thetreatment site exceeding 20 percent of the total source strength documented in the post-implantation portion of the written directive; or<br>(iii) An administration that includes any of the following:<br>(A) The wrong radionuclide;<br>(B) The wrong individual or human research subject;<br>(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<br>(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue. | **Continued**<br>(C) An administration of a dose or dosage to the wrong individual or human research subject;<br>(D) An administration of a dose or dosage delivered by the wrong mode of treatment; or<br>(E) A leaking sealed source.<br>(iii) A dose to the skin or an organ or tissue other than the treatment site that exceeds by:<br>(A) 0.5 Sv (50 rem) or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration; and |

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| **Continued** | **Continued** | **Continued** (B) 50 percent or more the expected dose to that site from the procedure if the administration had been given in accordance with the written directive prepared or revised before administration. (2) For permanent implant brachytherapy, the administration of byproduct material or radiation from byproduct material (excluding sources that were implanted in the correct site but migrated outside the treatment site) that results in—<br>(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; |
| **Continued** | **Continued** | **Continued**<br>(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<br>(iii) An administration that includes any of the following:<br>(A) The wrong radionuclide;<br>(B) The wrong individual or human research subject; |

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| **Continued** | **Continued** | **Continued**<br>(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<br>(D) A leaking sealed source resulting in a dose that exceeds 0.5 Sv (50 rem) to an organ or tissue.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

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| **20.3.7.716 REPORTS:** D. Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations:<br>(1) The licensee shall notify by telephone the department and NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the department and NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken. | *RATS 2018-1 category - C* **§ 35.3204 Report and notification for an eluate exceeding permissible molybdenum-99, strontium-82, and strontium-85 concentrations.** (a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken. | **Add a new § 35.3204 to subpart M to read as follows:**<br>(a) The licensee shall notify by telephone the NRC Operations Center and the distributor of the generator within 7 calendar days after discovery that an eluate exceeded the permissible concentration listed in § 35.204(a) at the time of generator elution. The telephone report to the NRC must include the manufacturer, model number, and serial number (or lot number) of the generator; the results of the measurement; the date of the measurement; whether dosages were administered to patients or human research subjects, when the distributor was notified, and the action taken. |

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| **Continued** (2) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the department and appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (1) of this section. | **Continued** (b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section. | Continued<br>(b) By an appropriate method listed in § 30.6(a) of this chapter, the licensee shall submit a written report to the appropriate NRC Regional Office listed in § 30.6 of this chapter within 30 calendar days after discovery of an eluate exceeding the permissible concentration at the time of generator elution. The written report must include the action taken by the licensee; the patient dose assessment; the methodology used to make this dose assessment if the eluate was administered to patients or human research subjects; |
| **Continued** | **Continued** | **Continued** and the probable cause and an assessment of failure in the licensee's equipment, procedures or training that contributed to the excessive readings if an error occurred in the licensee's breakthrough determination; and the information in the telephone report as required by paragraph (a) of this section.<br>Based on RATS 2018-1 letter dated July 16, 2018 |

| RCB Corrections and Amendments | | |
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| **20.3.3.307 FILING APPLICATION FOR SPECIFIC LICENSES:**<br>E. An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows:<br>(4) The license required report of events or notification in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 71, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469. | *none* | **RCB Correction to allign with NRC regulations.** |

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| **20.3.3.315 SPECIAL REQUIREMENTS FOR A SPECIFIC LICENSE TO MANUFACTURE, ASSEMBLE, REPAIR OR DISTRIBUTE COMMODITIES, PRODUCTS OR DEVICES WHICH CONTAIN RADIOACTIVE MATERIAL:** J. Manufacture, preparation or transfer for commercial distribution of radioactive drugs containing byproduct [~~radioactive~~] material for medical use under 20.3.7 NMAC. | *None* PART 32—SPECIFIC DOMESTIC LICENSES TO MANUFACTURE OR TRANSFER CERTAIN ITEMS CONTAINING BYPRODUCT MATERIAL § 32.72 Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35 | **RCB Correction to align with current federal regulation** |
| **20.3.5.10 SPECIFIC LICENSE FOR INDUSTRIAL RADIOGRAPHY:** E. An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows: (4)for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81 the licensee shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information. | *none* | **RCB Correction to allign with NRC regulations.** |

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| **20.3.7.7006 GENERAL REGULATORY REQUIREMENTS:** E. Application for license, amendment or renewal. (3)An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows: (d) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address when applicable: New Mexico environment department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information. | *none* | **RCB Correction to allign with NRC regulations.** |
| **20.3.12.9 SPECIFIC LICENSES FOR WELL LOGGING:** B. An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows: (4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), and 10 CFR 37.81, the licensee shall use the following address when applicable: New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information. | *none* | **RCB Correction to allign with NRC regulations.** |

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| **20.3.15.1502 SPECIFIC LICENSES FOR IRRADIATORS:**<br>B. An application for a specific license of category 1 and category 2 quantities of radioactive material shall comply with 10 CFR 37. The licensee shall comply with 10 CFR 37 except as follows: (4) for any reporting or notification requirements that the licensee must follow in 10 CFR 37.45, 10 CFR 37.57, 10 CFR 37.77(a) through (d), 10 CFR 37.81, the licensee shall use, when applicable, New Mexico Environment Department/RCB, P.O. Box 5469, Santa Fe, NM 87502-5469 address information. | *none* | **RCB Correction to allign with NRC regulations.** |
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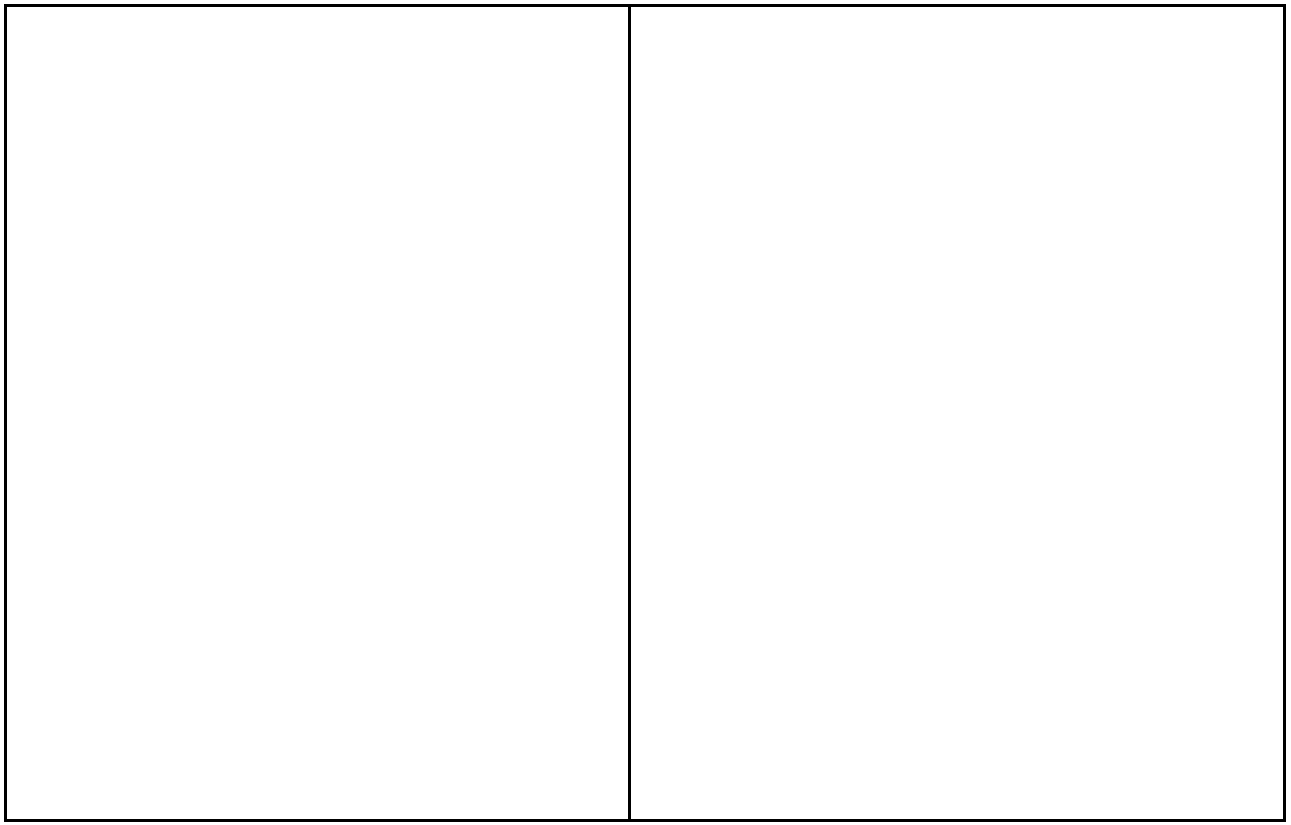

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