Medical Use of Byproduct Material - Recognition of Specialty Boards - Part 35
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
' 35.2	Definitions	**R12-1-102**	B B	**In ' 35.2, the definition >>Radiation Safety Officer== is amended by republishing the introductory text and revising paragraph (1) of the definition, and the definition of >>Preceptor== is revised to read as follows:** * * * * * *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 Radiation Safety Officer. * * * * * *Radiation Safety Officer* means an individual whoC (1) Meets the requirements in '' 35.50(a) or (c)(1) and 35.59; or, before October 24, 2005, '' 35.900(a) and 35.59; or * * * * *			
' 35.50	Training for Radiation Safety	**R12-1-710**	B	**In ' 35.50, paragraph (a), the introductory text of paragraph (b)(1)(I), paragraphs (b)(1)(ii)(G),**			

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	Officer			**and (c) are revised, paragraph (b)(2) is removed and reserved, and paragraphs (d) and (e) are added to read as follows:** * * * * * (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (d) and (e) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1)(i) Hold a bachelor=s or graduate degree from an accredited college or university in physical science or engineering or biological science with a minimum of 20 college credits in physical science; (ii) Have 5 or more years of professional experience in health physics (graduate training may be substituted for no more than 2 years of the required experience) including at least 3 years in applied health physics; and (iii) Pass an examination administered			

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				by diplomates of the specialty board, which evaluates knowledge and competence in radiation physics and instrumentation, radiation protection, mathematics pertaining to the use and measurement of radioactivity, radiation biology, and radiation dosimetry; or (2)(i) Hold a master=s or doctor=s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; (ii) Have 2 years of full-time practical training and/or supervised experience in medical physicsC (A) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in '' 35.290, 35.390, or, before October 24, 2005, '' 35.920, or 35.930; and (iii) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical diagnostic radiological or nuclear			

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				medicine physics and in radiation safety; or (b) * * * (1) * * * (i) 200 hours of classroom and laboratory training in the following areas- (ii) * * * (G) Disposing of byproduct material; or * * * * * (c)(1) Is a medical physicist who has been certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State under ' 35.51(a) and has experience in radiation safety for similar types of use of byproduct material for which the licensee is seeking the approval of the individual as Radiation Safety Officer and who meets the requirements in paragraphs (d) and (e) of this section; or (2) Is an authorized user, authorized medical physicist, or authorized nuclear pharmacist identified on the licensee=s license and has experience with the radiation safety aspects of similar types of use of byproduct material for which the individual has Radiation Safety Officer responsibilities; and, (d) Has obtained written attestation,			

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				signed by a preceptor Radiation Safety Officer, that the individual has satisfactorily completed the requirements in paragraph (e) and in paragraphs (a)(1)(i) and (a)(1)(ii) or (a)(2)(i) and (a)(2)(ii) or (b)(1) or (c)(1) of this section, and has achieved a level of radiation safety knowledge sufficient to function independently as a Radiation Safety Officer for a medical use licensee; and (e) Has training in the radiation safety, regulatory issues, and emergency procedures for the types of use for which a licensee seeks approval. This training requirement may be satisfied by completing training that is supervised by a Radiation Safety Officer, authorized medical physicist, authorized nuclear pharmacist, or authorized user, as appropriate, who is authorized for the type(s) of use for which the licensee is seeking approval.			
' 35.51	Training for an authorized medical physicist.	**R12-1-711**	B	**In ' 35.51, paragraphs (a) and (b) are revised, and paragraph (c) is added to read as follows:** * * * * * (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an			

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				Agreement State and who meets the requirements in paragraphs (b)(2) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Hold a master=s or doctor=s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; (2) Have 2 years of full-time practical training and/or supervised experience in medical physicsC (i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board recognized by the Commission or an Agreement State; or (ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in '' 35.490 or 35.690, or, before October 24, 2005, authorized users			

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				who meet the requirements in '' 35.940 or 35.960; and (3) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in clinical radiation therapy, radiation safety, calibration, quality assurance, and treatment planning for external beam therapy, brachytherapy, and stereotactic radiosurgery; or (b)(1) Holds a master=s or doctor=s degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university; and has completed 1 year of full-time training in medical physics and an additional year of fulltime work experience under the supervision of an individual who meets the requirements for an authorized medical physicist for the type(s) of use for which the individual is seeking authorization. This training and work experience must be conducted in clinical radiation facilities that provide high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services and must include: (i) Performing sealed source leak			

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				tests and inventories; (ii) Performing decay corrections; (iii) Performing full calibration and periodic spot checks of external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and (iv) Conducting radiation surveys around external beam treatment units, stereotactic radiosurgery units, and remote afterloading units as applicable; and (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in ' 35.51, or, before October 24, 2005, ' 35.961, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status;			

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				and (c) Has training for the type(s) of use for which authorization is sought that includes hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system. This training requirement may be satisfied by satisfactorily completing either a training program provided by the vendor or by training supervised by an authorized medical physicist authorized for the type(s) of use for which the individual is seeking authorization.			
' 35.55	Training for an authorized nuclear pharmacist.	**R12-1-712**	B	**In ' 35.55, paragraphs (a), (b)(1)(I) introductory text, and (b)(2) are revised to read as follows:** * * * * * (a) Is certified by a specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (b)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to:			

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				(1) Have graduated from a pharmacy program accredited by the American Council on Pharmaceutical Education (ACPE) or have passed the Foreign Pharmacy Graduate Examination Committee (FPGEC) examination; (2) Hold a current, active license to practice pharmacy; (3) Provide evidence of having acquired at least 4000 hours of training/experience in nuclear pharmacy practice. Academic training may be substituted for no more than 2000 hours of the required training and experience; and (4) Pass an examination in nuclear pharmacy administered by diplomates of the specialty board, that assesses knowledge and competency in procurement, compounding, quality assurance, dispensing, distribution, health and safety, radiation safety, provision of information and consultation, monitoring patient outcomes, research and development; or (b) * * * (1) * * * (i) 200 hours of classroom and laboratory training in the following areasC * * * * * (2) Has obtained written			

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				attestation, signed by a preceptor authorized nuclear pharmacist, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), (a)(2), and (a)(3) or (b)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized nuclear pharmacist.			
' 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist.	**R-12-1-710 through 713**	B	**Section 35.57 is revised to read as follows:** (a)(1) An individual identified as a Radiation Safety Officer, a teletherapy or medical physicist, or a nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State broad scope licensee or master material license permit or by a master material license permittee of broad scope before October 24, 2002, need not comply with the training requirements of '' 35.50, 35.51, or 35.55, respectively. (2) An individual identified as a Radiation Safety Officer, an authorized medical physicist, or an authorized nuclear pharmacist on a Commission or Agreement State license or a permit issued by a Commission or Agreement State			

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				broad scope licensee or master material license permit or by a master material license permittee of broad scope between October 24, 2002 and April 29, 2005 need not comply with the training requirements of '' 35.50, 35.51, or 35.55, respectively. (b)(1) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State broad scope licensee, or a permit issued by a Commission master material license broad scope permittee before October 24, 2002, who perform only those medical uses for which they were authorized on that date need not comply with the training requirements of Subparts D through H of this part. (2) Physicians, dentists, or podiatrists identified as authorized users for the medical use of byproduct material on a license issued by the Commission or Agreement State, a permit issued by a Commission master material licensee, a permit issued by a Commission or Agreement State			

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				broad scope licensee, or a permit issued by a Commission master material license broad scope permittee who perform only those medical uses for which they were authorized between October 24, 2002 and April 29, 2005, need not comply with the training requirements of Subparts D through H of this part.			
' 35.75	Release of individuals containing unsealed byproduct material or implants containing byproduct material	**R12-1-717**	C, paragraphs (a) and (b) D-paragraphs (c) and(d)	In ' 35.75, paragraph (a), footnote 1, remove >>(draft)==.			
' 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	**Exhibit A: Group 100**	H&S	**In ' 35.100, paragraph (b)(2) is revised to read as follows:** (b) (2) A physician who is an authorized user and who meets the requirements specified in '' 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, ' 35.920; or			

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' 35.190	Training for uptake, dilution, and excretion studies.	**R12-1-719**	B	**In ' 35.190, paragraphs (a), the introductory text of (c)(1), (c)(1)(ii)(B) and (c)(2) are revised to read as follows:** (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and (2) Pass an examination, administered by diplomates of the specialty board, that assesses knowledge and competence in radiation safety, radionuclide			

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				handling, and quality control; or * * * * * (c) (1) Has completed 60 hours of training and experience, including a minimum of 8 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies. The training and experience must include: (ii) * * * (B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.190, 35.290, or 35.390, or, before October 24, 2005, '' 35.910, 35.920, or 35.930, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses			

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				authorized under ' 35.100.			
' 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required.	**Exhibit A: Group 200**	H&S	**In ' 35.200, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who meets the requirements specified in '' 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24,2005, ' 35.920; or			
' 35.290	Training for imaging and localization studies.	**R12-1-721**	B	**In ' 35.290, paragraphs (a), (b), the introductory text of (c)(1) and (c)(1)(ii) introductory text, (c)(1)(ii)(B), and (c)(2) are revised to read as follows:** * * * * *(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraph (c)(2) of this section. (The			

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				names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and (2) Pass an examination, administered by diplomates of the specialty board, which assesses knowledge and competence in radiation safety, radionuclide handling, and quality control; or (b) Is an authorized user under ' 35.390 and meets the requirements in ' 35.290(c)(1)(ii)(G), or, before October 24, 2005, ' 35.920, or equivalent Agreement State requirements; or (c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic			

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				radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimumC * * * * * (ii) Work experience, under the supervision of an authorized user, who meets the requirements in '' 35.290, or 35.290(c)(1)(ii)(G) and 35.390, or, before October 24, 2005, ' 35.920, or equivalent Agreement State requirements, involvingC * * * * * (B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.290 or 35.390 and 35.290(c)(1)(ii)(G), or, before October 24, 2005, ' 35.920, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function			

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				independently as an authorized user for the medical uses authorized under '' 35.100 and 35.200.			
' 35.390	Training for use of unsealed byproduct material for which a written directive is required.	**R12-1-723**	B	**In ' 35.390, paragraph (a), the introductory text of paragraphs (b)(1) and (b)(1)(ii) introductory text, paragraphs (b)(1)(ii)(B), (b)(1)(ii)(G)(1), (3) and (4), and (b)(2) are revised, and paragraph (b)(1)(ii)(F) is removed and reserved.** (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(1)(ii)(G) and (b)(2) of this section. (Specialty boards whose certification processes have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To be recognized, a specialty board shall require all candidates for certification to: (1) Successfully complete residency training in a radiation therapy or nuclear medicine training program or a program in a related medical specialty. These residency training programs must include 700 hours of training and experience as described			

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				in paragraphs (b)(1)(i) through (b)(1)(ii)(E) of this section. Eligible training programs must be approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education, the Royal College of Physicians and Surgeons of Canada, or the Committee on Post-Graduate Training of the American Osteopathic Association; and (2) Pass an examination, administered by diplomats of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, quality assurance, and clinical use of unsealed byproduct material for which a written directive is required; or (b)(1) Has completed 700 hours of training and experience, including a minimum of 200 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material requiring a written directive. The training and experience must includeC * * * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in ' 35.390			

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				or, before October 24, 2005, ' 35.930, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in ' 35.390(b) or, before October 24, 2005, ' 35.930(b), must also have experience in administering dosages in the same dosage category or categories (i.e., ' 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involveC * * * * *(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters; * * * * * (G) * * * (1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide IB131, for which a written directive is required; * * * * * (3) Parenteral administration of any beta emitter or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or (4) Parenteral administration of any other radionuclide, for which a written directive is required; and (2) Has obtained written attestation			

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				that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' 35.390 or, before October 24, 2005, ' 35.930, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in ' 35.390(b), or, before October 24, 2005, ' 35.930(b), must have experience in administering dosages in the same dosage category or categories (i.e.,' 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			
' 35.392	Training for the oral administration of sodium iodide IB131 requiring a written directive in quantities less than or	**R12-1-723**	B	**In ' 35.392, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:** (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section and whose certification process has been recognized by the			

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	equal to 1.22 gigabecquerels (33 millicuries).			Commission or an Agreement State and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.); or * * * * * (c) * * * (2) * * * (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under '' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in '' 35.390, 35.392, or 35.394, or, before October 24, 2005, '' 35.930, 35.932, or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets			

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				the requirement in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(1) or (2).			
' 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).	**R12-1-723**	B	**In ' 35.394, paragraphs (a), (c)(2)(ii) and (c)(3) are revised to read as follows:** (a) Is certified by a medical specialty board whose certification process includes all of the requirements in paragraphs (c)(1) and (c)(2) of this section, and whose certification has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (c)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.); or * * * * * (c) * * * (2) * * * (ii) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters; * * * * * (3) Has obtained written attestation that the individual has satisfactorily			

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				completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in '' 35.390 or 35.394, or, before October 24, 2005, '' 35.930 or 35.934, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(2).			
' 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	**R12-1-723**	B	**Section 35.396 is added to read as follows:** Except as provided in ' 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician who-(a) Is an authorized user under ' 35.390 or, before October 24, 2005, ' 35.930 for uses			

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				listed in '' 35.390(b)(1)(ii)(G)(3) or 35.390(b)(1)(ii)(G)(4), or equivalent Agreement State requirements; or (b) Is an authorized user under '' 35.490 or 35.690, or, before October 24, 2005, '' 35.940 or 35.960, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or (c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under '' 35.490 or 35.690, or, before October 24, 2005, '' 35.940 or 35.960; and who meets the requirements in paragraph (d) of this section. (d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must include: (i) Radiation physics and instrumentation; (ii) Radiation protection;			

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				(iii) Mathematics pertaining to the use and measurement of radioactivity; (iv) Chemistry of byproduct material for medical use; and (v) Radiation biology; and (2) Has work experience, under the supervision of an authorized user who meets the requirements in '' 35.390 or 35.396, or, before October 24, 2005, ' 35.930, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in '' 35.390 or 35.930 must have experience in administering dosages as specified in '' 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involveC (i) Ordering, receiving, and unpacking radioactive materials safely, and performing the related radiation surveys; (ii) Performing quality control procedures on instruments used to determine the activity of dosages, and			

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				performing checks for proper operation of survey meters; (iii) Calculating, measuring, and safely preparing patient or human research subject dosages; (iv) Using administrative controls to prevent a medical event involving the use of unsealed byproduct material; (v) Using procedures to contain spilled byproduct material safely, and using proper decontamination procedures; and(vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in '' 35.390, 35.396, or, before October 24, 2005, ' 35.930, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in ' 35.390, or, before October 24, 2005, ' 35.930, must have experience in administering dosages as specified in '' 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).			
' 35.490	Training for use of manual brachytherapy sources.	**R12-1-727**	B	**In ' 35.490, paragraphs (a), (b)(2) and (b)(3) are revised to read as follows:**(a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State, and who meets the requirements in paragraph (b)(3) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Successfully complete a minimum of 3 years of residency training in a			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				radiation oncology program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Post-Graduate Training of the American Osteopathic Association; and (2) Pass an examination, administered by diplomates of the specialty board, that tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of manual brachytherapy; or (b) * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in ' 35.490, or, before October 24, 2005, ' 35.940, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in ' 35.490, or, before October 24, 2005, ' 35.940, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under ' 35.400.			
' 35.491	Training for ophthalmic use of strontium-90.	**R12-1-727**	B	**In ' 35.491, paragraph (b)(3) is revised to read as follows:** (b) * * * (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.490 or 35.491, or, before October 24, 2005, '' 35.940 or 35.941, or equivalent Agreement State requirements, that the individual has			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			
' 35.590	Training for use of sealed sources for diagnosis.	**R12-1-728**	B	**In ' 35.590, paragraphs (a) and (b) are revised and paragraph (c) is added to read as follows:** (a) Is certified by a specialty board whose certification process includes all of the requirements in paragraphs (b) and (c) of this section and whose certification has been recognized by the Commission or an Agreement State. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s Web page.); or (b) Has completed 8 hours of classroom and laboratory training in basic radionuclide handling techniques specifically applicable to the use of the device. The training must includeC (1) Radiation physics and instrumentation; (2) Radiation protection;(3) Mathematics pertaining to the use			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				and measurement of radioactivity; and (4) Radiation biology; and (c) Has completed training in the use of the device for the uses requested.			
' 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	**R12-1-744**	B	**In ' 35.690, paragraphs (a), (b)(2) and (b)(3) are revised, and paragraph (c) is added to read as follows:** (a) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State and who meets the requirements in paragraphs (b)(3) and (c) of this section. (The names of board certifications which have been recognized by the Commission or an Agreement State will be posted on the NRC=s web page.) To have its certification process recognized, a specialty board shall require all candidates for certification to: (1) Successfully complete a minimum of 3 years of residency training in a radiation therapy program approved by the Residency Review Committee of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				Committee on Post-Graduate Training of the American Osteopathic Association; and (2) Pass an examination, administered by diplomates of the specialty board, which tests knowledge and competence in radiation safety, radionuclide handling, treatment planning, quality assurance, and clinical use of stereotactic radiosurgery, remote afterloaders and external beam therapy; or (b) * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in ' 35.690, or, before October 24, 2005, ' 35.960, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				(b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' 35.690, or, before October 24, 2005, ' 35.960, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and (c) Has received training in device operation, safety procedures, and clinical use for the type(s) of use for which authorization is sought. This training requirement may be satisfied by satisfactory completion of a training program provided by the vendor for new users or by receiving training supervised by an authorized user or authorized medical physicist, as appropriate, who is authorized for the type(s) of use for which the			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				individual is seeking authorization.			

Minor Amendments- Part 20, 30, 32, 35, 40, and 70
(71 FR 15005) RATS ID # 2006-1 Effective date 03/27/06
Date Due For State Adoption 03/27/09

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
20. Appendix B	Standards For Protection Against Radiation AList of Elements@	**Article 4 Appendix B (AZ did not have typo)**	A	In Appendix B to Part 20, >>List of Elements,== the Element >>Thalium,== Atomic Number 69, should be changed to read as >>Thulium.==			
' 32.72	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under part 35.	**R-12-1-311**	B	**In ' 32.72, paragraph (b)(2)(ii) is revised to read as follows:** (b) * * * (2) * * * (ii) This individual meets the requirements specified in 10 CFR 35.55(b) and 35.59 and the licensee has received an approved license amendment identifying this individual			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				as an authorized nuclear pharmacist, or * * * *			
' 32.74	Manufacture and distribution of sources or devices containing byproduct material for medical use.	**R-12-1-311**	B	**In ' 32.74, the introductory text of paragraph (a) is revised to read as follows:** (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in '' 35.400, 35.500, and 35.600 of this chapter will be approved if: * * * * *			
' 35.2	Definitions	**R12-1-102**	B	*Authorized medical physicist* means an individual whoC (1) Meets the requirements in '' 35.51(a) and 35.59; or			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
' 35.2	Definitions	**R12-1-102**	B	*Authorized nuclear pharmacist* means a pharmacist whoC (1) Meets the requirements in '' 35.55(a) and 35.59; or			
' 35.2	Definitions	**R12-1-102**	B	*Authorized user* means a physician, dentist, or podiatrist whoC (1) Meets the requirements in '' 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or			
' 35.2	Definitions	**R12-1-102**	B	*Radiation Safety Officer* means an individual whoC (1) Meets the requirements in '' 35.50(a) or (c)(1) and 35.59; or			
' 35.49	Suppliers for sealed sources or devices for medical use.	Previously completed **R12-1-709**	C	**In ' 35.49, paragraph (b) is revised to read as follows:** (b) Sealed sources or devices noncommercially			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				transferred from a Part 35 licensee or an Agreement State medical use licensee.			
' 35.50	Training for Radiation Safety Officer.	Previously Completed **R12-1-710**	B	**In ' 35.50, paragraph (a)(2)(ii)(B) is revised to read as follows:** (a) * * * (2) * * * (ii) * * * (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in'' 35.290 or 35.390;			
' 35.51	Training for an authorized medical physicist.	**R12-1-711**	B	**In ' 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:** (a) * * * (2) * * *			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				(ii) In clinical radiation facilities providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements for authorized users in '' 35.490 or 35.690; and * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in ' 35.51, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status; and * * * * *			
' 35.59	Recentness of training.	**R12-1-710 (C), 711(C), 712 (C), 719(B), 721(C), 723(D), 727(C), 728(D), and 744(D),**	B	**Section 35.59 is revised to read as follows:** The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the seven years preceding the date of application or the individual must have had related continuing education and experience since the required training			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				and experience was completed.			
' 35.100	Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required.	**Exhibit A Group 100**	H&S	**In ' 35.100, paragraph (b)(2) is revised to read as follows:** b) * * * (2) A physician who is an authorized user and who meets the requirements specified in '' 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or * * * * *			
' 35.190	Training for uptake, dilution, and excretion studies.	**R12-1-719**	B	**In ' 35.190, paragraphs (b), (c)(1)(ii) and (c)(2) are revised to read as follows:** (b) Is an authorized user under '' 35.290, 35.390, or equivalent Agreement State requirements; or (c)(1)* * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in '' 35.190, 35.290,			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				35.390, or equivalent Agreement State requirements, involving c * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ' 35.100.			
' 35.200	Use of unsealed byproduct material for imaging and localization studies for which a written	**Exhibit A Group 200**	H&S	**In ' 35.200, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
	directive is not required.			meets the requirements specified in ' 35.290, or 35.390 and 35.290(c)(1)(ii)(G); or * * * * *			
' 35.290	Training for imaging and localization studies.	**R12-1-721**	B	**In ' 35.290, paragraphs (a)(1), (b), the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (a) * * * (1) Complete 700 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies that includes the topics listed in paragraphs (c)(1)(i) and (c)(1)(ii) of this section; and * * * * * (b) Is an authorized user under ' 35.390 and meets			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				the requirements in 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements; or (c)(1) * * * (ii) Work experience, under the supervision of an authorized user, who meets the requirements in '' 35.290, or 35.290(c)(1)(ii)(G), and 35.390, or equivalent Agreement State requirements, involvingC * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under '' 35.100 and 35.200.			
' 35.300	Use of unsealed byproduct material for which a written directive is required.	**Exhibit A Group 300**	H&S	**In ' 35.300, paragraph (b)(2) is revised to read as follows:** (b) * * * (2) A physician who is an authorized user and who meets the requirements specified in '' 35.290, 35.390, or * * * * *			
' 35.390	Training for use of unsealed byproduct material for which a written directive is required.	**R12-1-723**	B	**In ' 35.390, paragraphs (b)(1)(ii) introductory text, (b)(1)(ii)(G)(*3*), and (b)(2) are revised to read as follows:** (b)(1) * * * (ii) Work experience, under the supervision of			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				an authorized user who meets the requirements in ' 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in ' 35.390(b), must also have experience in administering dosages in the same dosage category or categories (*i.e.*,35.390(b)(1)(ii)(G)) as the individual requesting authorized user status. The work experience must involveC * * * * * (G) * * * (*3*) Parenteral administration of any beta emitter, or a photon-emitting radionuclide with a photon energy less than 150 keV, for which a written directive is required; and/or * * * * * (2) Has obtained written attestation that the			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' 35.390 or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in ' 35.390(b) must have experience in administering dosages in the same dosage category or categories (*i.e.*, ' 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
' 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).	**R12-1-723**	B	**In ' 35.392, paragraph (b), the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under ' 35.390 for uses listed in ' 35.390(b)(1)(ii)(G)(*1*) or (*2*), ' 35.394, or equivalent Agreement State requirements; or (c) * * *(2) Has work experience, under the supervision of an authorized user who meets the requirements in '' 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in ' 35.390(b) must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*1*) or (*2*). The work experience			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				must involveC * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in '' 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirement in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*1*) or (*2*).			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
' 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).	**R12-1-723**	B	**In ' 35.394, paragraph (b), the introductory text of paragraph (c)(2), and paragraph (c)(3) are revised to read as follows:** (b) Is an authorized user under ' 35.390 for uses listed in ' 35.390(b)(1)(ii)(G)(*2*) or equivalent Agreement State requirements; or (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in '' 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*2*). The			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				work experience must involveC * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under ' 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in '' 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in ' 35.390(b), must also have experience in administering dosages as specified in ' 35.390(b)(1)(ii)(G)(*2*).			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
' 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	**R12-1-723**	B	**In ' 35.396, the introductory paragraph, paragraphs (a), (b), (c), the introductory text of paragraphs (d)(1) and (d)(2), paragraph (d)(2)(vi), and paragraph (d)(3) are revised to read as follows:** Except as provided in ' 35.57, the licensee shall require an authorized user for the parenteral administration requiring a written directive, to be a physician whoC (a) Is an authorized user under ' 35.390 for uses listed in '' 35.390(b)(1)(ii)(G)(*3*) or 35.390(b)(1)(ii)(G)(*4*), or equivalent Agreement State requirements; or (b) Is an authorized user			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				under '' 35.490, 35.690, or equivalent Agreement State requirements and who meets the requirements in paragraph (d) of this section; or (c) Is certified by a medical specialty board whose certification process has been recognized by the Commission or an Agreement State under '' 35.490 or 35.690, and who meets the requirements in paragraph (d) of this section. (d)(1) Has successfully completed 80 hours of classroom and laboratory training, applicable to parenteral administrations, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. The training must			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				includeC * * * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in '' 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in ' 35.390 must have experience in administering dosages as specified in '' 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*). The work experience must			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				involveC * * * * * (vi) Administering dosages to patients or human research subjects, that include at least 3 cases involving the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than 150 keV and/or at least 3 cases involving the parenteral administration of any other radionuclide, for which a written directive is required; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in '' 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in ' 35.390, must have experience in administering dosages as specified in '' 35.390(b)(1)(ii)(G)(*3*) and/or 35.390(b)(1)(ii)(G)(*4*).			
' 35.490	Training for use of manual brachytherapy sources.	**R12-1-727**	B	**In ' 35.490, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * *			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in ' 35.490 or equivalent Agreement State requirements at a medical institution, involvingC * * * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in ' 35.490 or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in ' 35.490 or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a)(1), or (b)(1) and (b)(2) of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under ' 35.400.			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
35.491	Training for ophthalmic use of strontium-90.	**R12-1-727**	B	**In ' 35.491, paragraphs (a) and (b)(3) are revised to read as follows:** (a) Is an authorized user under ' 35.490 or equivalent Agreement State requirements; or(b) * * * (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in '' 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraphs (a) and (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	**R12-1-744**	B	**In ' 35.690, the introductory text of paragraph (b)(1)(ii), and paragraphs (b)(2), and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in ' 35.690 or, equivalent Agreement State requirements at a medical institution, involvingC * * * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in ' 35.690 or equivalent Agreement State			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) or (b)(1) and (b)(2), and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was A Comment Generated
				type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in ' 35.690 or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for which the individual is requesting authorized user status; and * * * * *			

Medical Use of Byproduct Material - Minor Corrections and Clarifications 10 CFR Parts 32 and 35
(72 FR 45147, 54207) RATS ID # 2007-1 Effective date 10/29/07
Date Due for State Adoption 10/29/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 32.72 (b)(5)	Manufacture, preparation, or transfer for commercial distribution of radioactive drugs containing byproduct material for medical use under Part 35.	**R12-1-311 (G)**	B	**In Sec. 32.72, paragraph (b)(5) is revised to read as follows:** (b) * * * (5) Shall provide to the Commission a copy of each individual's: (i)(A) Certification by a specialty board whose certification process has been recognized by the Commission or an Agreement State as specified in Sec. 35.55(a) of this chapter with the written attestation signed by a preceptor as required by Sec. 35.55(b)(2) of this chapter; or (B) The Commission or Agreement State license; or (C) The permit issued by a licensee of broad scope; and (ii) State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				nuclear pharmacist.			
' 32.74(a)	Manufacture and distribution of sources or devices containing byproduct material for medical use	**R12-1-311 (I)**	B	**In Sec. 32.74, the introductory text of paragraph (a) is revised to read as follows:** (a) An application for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed under part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in Sec. Sec. 35.400, 35.500, 35.600, and 35.1000 of this chapter will be approved if: * * * * *			
' 35.75(a)	Release of individuals containing unsealed byproduct material or implants containing byproduct material	**R12-1-717 (A)**	C	**In Sec. 35.75, the text of paragraph (a) is republished and footnote 1 is revised to read as follows:** a) A licensee may authorize the release from its control of any individual who has been administered unsealed byproduct material or			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem).\1\ * * * * * \1\ The current revision of NUREG-1556, Vol. 9, ``Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Licenses'' describes methods for calculating doses to other individuals and contains tables of activities not likely to cause doses exceeding 5 mSv (0.5 rem).			
'35.92	Decay-in-storage is an: “H&S” for States authorizing this activity and “D” for States that do not authorize this activity	**R12-1-438 (C)**	H&S	**In Sec. 35.92, the introductory text of paragraph (a) is revised to read as follows:** (a) A licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				decay-in-storage before disposal without regard to its radioactivity if it-- * * * * *			
'35.190	Training for uptake, dilution, and excretion studies	**R12-1-719 (A)**	B	**In Sec. 35.190, paragraph (a)(1) is revised to read as follows:** (a) * * * (1) Complete 60 hours of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for uptake, dilution, and excretion studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(F) of this section; and * * * * *			
'35.290	Training for imaging and localization studies	**R12-1-721 (A)**	B	**10. In Sec. 35.290, paragraph (a)(1) is revised to read as follows:** (a) * * * (1) Complete 700 hours			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				of training and experience in basic radionuclide handling techniques and radiation safety applicable to the medical use of unsealed byproduct material for imaging and localization studies as described in paragraphs (c)(1)(i) through (c)(1)(ii)(G) of this section; and * * * * *			

Exemptions From Licensing, General Licenses, and Distribution of Byproduct Material: Licensing and Reporting Requirements 10 CFR Parts 30, 31, 32, and 150
(72 FR 58473) RATS ID # 2007-2 Effective date 12/17/07
Date Due for State Adoption 12/17/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§30.14	Exempt Concentrations	**R12-1-303 (A)**	B	**In Sec. 30.14, paragraphs (c) and (d) are revised to read as follows:** (c) A manufacturer, processor, or producer of a product or material is exempt from the requirements for a license set forth in section 81 of the Act			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				and from the regulations in this part and parts 31 through 36 and 39 of this chapter to the extent that this person transfers byproduct material contained in a product or material in concentrations not in excess of those specified in §30.70 and introduced into the product or material by a licensee holding a specific license issued by the Commission expressly authorizing such introduction. This exemption does not apply to the transfer of byproduct material contained in any food, beverage, cosmetic, drug, or other commodity or product designed for ingestion or inhalation by, or application to, a human being. (d) No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under this section or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11 of this			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				chapter.			
§30.15	Certain items containing byproduct material	**R12-1-303 (B)**	B	**In Sec. 30.15, paragraphs (a)(2), (a)(4), (a)(6), and (a)(10) are removed and reserved, paragraphs (a)(3) and (a)(5) are revised, and paragraph (a)(7) is added to read as follows:** (a)*** (2) [Reserved] (3) Balances of precision containing not more than 1 millicurie of tritium per balance or not more than 0.5 millicurie of tritium per balance part manufactured before December 17, 2007. (4) [Reserved] (5) Marine compasses containing not more than 750 millicuries of tritium gas and other marine navigational instruments containing not more than 250 millicuries of tritium gas manufactured before December 17, 2007. (6) [Reserved]			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				(7) Ionization chamber smoke detectors containing not more than 1 microcurie (μCi) of americium-241 per detector in the form of a foil and designed to protect life and property from fires.*** (10) [Reserved]			
§30.16	Resins containing scandium-46 and designed for sand consolidation in oil wells	**R12-1-303(B)**	B	[Removed]			
§30.18	Exempt quantities	**R12-1-303(C)**	B	**In Sec. 30.18 paragraph (a) is revised and paragraph (e) is added to read as follows:** (a) Except as provided in paragraphs (c) through (e) of this section, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in part 30 through 34, 36 and 39 of this chapter to the extent that such person receives, posses, uses, transfers, owns, or acquires byproduct material in individual quantities, each of which does			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				not exceed the applicable quantity set forth in §30.71, Schedule B. (e) No person may, for purposes of producing an increased radiation level, combine quantities of byproduct material covered by this exemption so that the aggregate quantity exceeds the limits set forth in § 30.71, Schedule B, except for byproduct material combined within a device placed in use before May 3, 1999, or as otherwise permitted by the regulations in this part.			
§31.5	Certain detecting, measuring, gauging, or controlling devices and certain devices for producing light or an ionized	**R12-1-306 (B)**	B	**In Sec. 31.5, paragraph (c)(8)(ii) introductory text and paragraph (c)(8)(iii) are revised to read as follows:** (c)*** (8)*** (ii) Shall within 30 days after the transfer of a device to a specific licensee or export,			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	atmosphere			furnish a report to the Director of the Office of Federal and State Materials and Environmental Management Programs by an appropriate method listed in §30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/ GLTS. The report must contain- *** (iii) Shall obtain written NRC approval before transferring the device to any other specific licensee not specifically identified in paragraph (c)(8)(I) of this section; however a holder of a specific license may transfer a device for possession and use under its own specific license without prior approval, if, the holder: (A) Verifies that the specific license authorizes the possession and use, or applies for and obtains an amendment to the license authorizing the possession and use; (B) Removes, alters, covers, or clearly and unambiguously augments the existing label (otherwise required by (c)(1) of this section) so that the device			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				is labeled in compliance with §20.1904 of this chapter; however the manufacturer, model number, and serial number must be retained; (C) Obtains manufacturer's or initial transferor's information concerning maintenance that would be applicable under the specific license (such as leak testing procedures); and (D) Reports the transfer under paragraph (c)(8)(ii) of this section.			
§32.13	Same: Prohibition of introduction	**R12-1-303 (A)(4)**	C	**Sec. 32.13 is revised to read as follows:** No person may introduce byproduct material into a product or material knowing or having reason to believe that it will be transferred to persons exempt under §30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under §32.11.			
§32.17	Resins containing scandium-46 and designed	**R12-1-303 previously removed)**	B	**[Removed]**			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	for sand-consolidation in oil wells: requirements for license to manufacture, or initially transfer for sale or distribution.						
§150.20	Recognition of Agreement State licenses.	**R12-1-320**	C	**In Sec. 150.20 paragraph (b) introductory text, and paragraph (b)(3) are revised to read as follows:** (b) Not withstanding any provision to the contrary in any specific license issued by an Agreement State to a person engaging in activities in a non-Agreement State, or in offshore waters under the general license provided in this section, the general licenses provided in this section are subject to all provisions of the Act, now or hereafter in effect, and to all applicable rules, regulations, and orders of the Commission including provisions of §§30.7(a) through (f), 30.9, 30.10, 30.34, 30.41, and 30.51 through			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				30.63 of this chapter; §§40.7(a) through (f), 40.9, 40.10, 40.41, 40.51, 40.61 through 40.63, 40.71, and 40.81 of this chapter; §§70.7(a) through (f), 70.9 70.10, 70.32, 7042, 70.52, 70.55, 70.56, 70.60 through 70.62 of this chapter; §§74.11, 74.15, and 74.19 of this chapter; and to the provisions of 10 CFR parts 19, 20 and 71 and subparts C through H of part 34, §§39.15 and 39.31 through39.77 of this chapter. In addition, any person engaging in activities in non-Agreement States, in areas of exclusive Federal jurisdiction within Agreement States, or in offshore waters under the general licenses provided in this section: *** (3) Shall not, in any non-Agreement State, in an area of exclusive Federal jurisdiction within an Agreement State, or in offshore waters, transfer or dispose of radioactive material possessed or used under the general licenses provided in this section, except by transfer			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				to a person who is specifically licensed by the Commission to receive this material.			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Date Due for State Adoption 11/30/10

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
'20.1003	Definition: Accelerator-produced radioactive material	**R12-1-102**	H&S	**In § 20.1003, the definition of *Accelerator-produced radioactive material,* is added to read as follows:** *Accelerator-produced radioactive material* means any material made radioactive by a particle accelerator.			
'20.1003	Definition: Byproduc	**R12-1-102**	[H&S]***	**In § 20.1003, the definition of *Byproduct material* is revised to**			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	t Material		**(***please note 10 CFR 20.1003 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)**	**read as follows:** *Byproduct material* means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material; (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ‘‘byproduct material’’ within this definition; (3)(i) Any discrete source of			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (4) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any			

Requirements for Expanded Definition of Byproduct Material 10 CFR Parts 20, 30, 31, 32, 33, 35, 50, 61, 62, 72, 110, 150, 170, and 171
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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity. * * * *			
' 20.1003	Definition : Discrete Source	**R12-1-102**	H&S	**In § 20.1003, the definition of *Discrete source* is added to read as follows:** *Discrete source* means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
'20.1003	Definition: Particle Accelerator	**R12-1-102 (previously adopted)**	H&S	**In § 20.1003, the definition of *Particle accelerator* is added to read as follows:** *Particle accelerator* means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, ''accelerator'' is an equivalent term.			
'20.1003	Definition: Waste	**R12-1-102 (Previously adopted)**	B	**In § 20.1003, the definition of *Waste* is added to read as follows:** *Waste* means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of Byproduct material set forth in this section.			
'20.2001 (a)(4)	General requirements	**R12-1-434**	C	**In § 20.2001, paragraph (a)(4) is revised to read as follows:** a) * * * (4) As authorized under §§20.2002, 20.2003, 20.2004, 20.2005, or 20.2008.			
'20.2006 (e)	Transfer for disposal and	**R12-1-439**	B	**In § 20.2006, paragraph (e) is added to read as follows:** (e) Any licensee shipping			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	manifests			byproduct material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in § 20.1003 intended for ultimate disposal at a land disposal facility licensed under part 61 of this chapter must document the information required on the NRC's Uniform Low- Level Radioactive Waste Manifest and transfer this recorded manifest information to the intended consignee in accordance with appendix G to this part.			
' 20.2008	Disposal of 11e.(3) and 11e.(4) byproduct material	**R12-1-438.01**	B	**Section 20.2008 is added to read as follows:** (a) Licensed material as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in §20.1003 may be disposed of in accordance with part 61 of this chapter, even though it is not defined as low level radioactive			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				waste. Therefore, any licensed byproduct material being disposed of at a facility, or transferred for ultimate disposal at a facility licensed under part 61 of this chapter, must meet the requirements of §20.2006. (b) A licensee may dispose of byproduct material, as defined in paragraphs (3) and (4) of the definition of *Byproduct material* set forth in §20.1003, at a disposal facility authorized to dispose of such material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005.			
Part 20 Appendix B	Annual Limits on Intake (ALIs)	**Appendix B**	A	**In Appendix B to part 20, the List of Elements table is amended by adding Nitrogen and Oxygen in alphabetical**			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
	and Derived Air Concentrations (DACs) of Radionuclides for Occupational Exposure; Effluent Concentrations; Concentrations for Release to Sewerage			**order, and page 1 of Tables 1, 2, and 3 following the List of Elements is revised to read as follows:** See tables at the end of the document.			
' 30.3(a)	Activities requiring license	**R12-1-304**	C	**Section 30.3(a) is revised to read as follows:** (a) Except as provided in			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				paragraphs (b)(2), (b)(3), (c)(2), and (c)(3) of this section and for persons exempt as provided in this part and part 150 of this chapter, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license issued in accordance with the regulations in this chapter.			
' 30.4	Definition: Accelerator produced radioactive material	**R-12-1-102 (previously adopted)**	H&S	**In § 30.4, the definition of *Accelerator-produced radioactive material,* is added to read as follows:** *Accelerator-produced radioactive material* means any material made radioactive by a particle accelerator.			
' 30.4	Definition: Byproduct material	**R-12-1-102**	[H&S]*** **(***please note 10 CFR**	**In § 30.4, the definition of *Byproduct material* is revised, to read as follows:**			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
			30.4 Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)	*Byproduct material* means— (1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material; (2)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (3) Any discrete source of naturally occurring radioactive			

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				material, other than source material, that— (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to the public health and safety or the common defense and security; and (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.			
' 30.4	Definition: Consortium	**R12-1-102**	C	**In § 30.4, the definition of *Consortium,* is added to read as follows:**			

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				Consortium means an association of medical use licensees and a PET radionuclide production facility in the same geographical area that jointly own or share in the operation and maintenance cost of the PET radionuclide production facility that produces PET radionuclides for use in producing radioactive drugs within the consortium for noncommercial distributions among its associated members for medical use. The PET radionuclide production facility within the consortium must be located at an educational institution or a Federal facility or a medical facility.			
' 30.4	Definition : Discrete Source	**R12-1-102**	H&S	**In § 30.4, the definition of *Discrete source*, is added to read as follows:** *Discrete source* means a radionuclide that has been			

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				processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.			
' 30.4	Definition : Particle accelerat or	**R-12-1-102**	H&S	**In § 30.4, the definition of *Particle accelerator* is added to read as follows:** *Particle accelerator* means any machine capable of accelerating electrons, protons, deuterons, or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 megaelectron volt. For purposes of this definition, accelerator is an equivalent term.			
' 30.15 (a)(1)(viii)	Certain items containin	**R12-1-303 (B)(1)(a)(viii)**	B	**In § 30.15, paragraph (a)(1)(viii) is added to read as follows:**			

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	g byproduct material			(a) * * * (1) * * * (viii) 0.037 megabecquerel (1 microcurie) of radium-226 per timepiece in intact timepieces manufactured prior to November 30, 2007.			
' 30.18 (b)	Exempt quantities	**R12-1-303(C)(6)**	B	**In § 30.18, paragraph (b) is revised to read as follows:** (b) Any person, who possesses byproduct material received or acquired before September 25, 1971, under the general license then provided in § 31.4 of this chapter or similar general license of a State, is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 30 through 34, 36 and 39 of this chapter to the extent that this person possesses, uses, transfers, or owns byproduct			

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				material.			
' 30.20(a)	Gas and aerosol detectors containing byproduct material	**R12-1-303 (B)(3)**	B	**In § 30.20, paragraph (a) is revised to read as follows:** (a) Except for persons who manufacture, process, produce, or initially transfer for sale or distribution gas and aerosol detectors containing byproduct material, any person is exempt from the requirements for a license set forth in section 81 of the Act and from the regulations in parts 19, 20, and 30 through 36, and 39 of this chapter to the extent that the person receives, possesses, uses, transfers, owns, or acquires byproduct material in gas and aerosol detectors designed to protect life or property from fires and airborne hazards, and manufactured, processed, produced, or initially transferred in accordance with a specific license issued under §			

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				32.26 of this chapter, which license authorizes the initial transfer of the product for use under this section. This exemption also covers gas and aerosol detectors manufactured or distributed before November 30, 2007 in accordance with a specific license issued by a State under comparable provisions to § 32.26 of this chapter authorizing distribution to persons exempt from regulatory requirements.			
' 30.32(g)	Application for specific licenses	**R12-1-308**	C	**In § 30.32, paragraphs (g)(1) and (g)(2) are revised and paragraphs (g)(3) are added to read as follows:** (g) * * * (1) Identify the source or device by manufacturer and model number as registered with the Commission under § 32.210 of this chapter, with an Agreement State, or for a			

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				source or a device containing radium-226 or accelerator-produced radioactive material with a State under provisions comparable to § 32.210 of this chapter; or (2) Contain the information identified in § 32.210(c) of this chapter; or (3) For sources or devices containing naturally occurring or accelerator produced radioactive material manufactured prior to November 30, 2007 that are not registered with the Commission under § 32.210 of this chapter or with an Agreement State, and for which the applicant is unable to provide all categories of information specified in §32.210(c) of this chapter, the applicant must provide: (i) All available information			

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				identified in § 32.210(c) of this chapter concerning the source, and, if applicable, the device; and (ii) Sufficient additional information to demonstrate that there is reasonable assurance that the radiation safety properties of the source or device are adequate to protect health and minimize danger to life and property. Such information must include a description of the source or device, a description of radiation safety features, the intended use and associated operating experience, and the results of a recent leak test.			
' 30.32(j)	Application for specific licenses	**R12-1-311 (G)**	B	**In § 30.32, paragraph (j) is added to read as follows:** (j) An application from a medical facility, educational institution, or Federal facility to produce			

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				Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to licensees in its consortium authorized for medical use under part 35 of this chapter or equivalent Agreement State requirements shall include: (1) A request for authorization for the production of PET radionuclides or evidence of an existing license issued under part 30 of this chapter or Agreement State requirements for a PET radionuclide production facility within its consortium from which it receives PET radionuclides. (2) Evidence that the applicant is qualified to produce radioactive drugs for medical use by meeting one of the criteria in § 32.72(a)(2) of this chapter. (3) Identification of individual(s)			

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				authorized to prepare the PET radioactive drugs if the applicant is a pharmacy, and documentation that each individual meets the requirements of an authorized nuclear pharmacist as specified in § 32.72(b)(2) of this chapter. (4) Information identified in § 32.72 (a)(3) of this chapter on the PET drugs to be noncommercially transferred to members of its consortium.			
' 30.34 (g)	Terms and conditions of licenses	**R12-1-313 R12-1-720**	H&S*** **(***please note 10 CFR 30.34(g) Terms and Conditions of Licenses was changed from**	**In § 30.34, paragraph (g) is revised to read as follows:** (g) Each licensee preparing technetium-99m radiopharmaceuticals from molybdenum-99/technetium-99m generators or rubidium-82 from strontium-82/rubidium-82			

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			a Compatibility Category D to a Compatibility Category H&S)	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.			
' 30.34(j)	Terms and conditions of licenses	**R12-1-311(G)**	B	**In § 30.34, paragraph (j) is added to read as follows:** (j)(1) Authorization under § 30.32(j) to produce Positron Emission Tomography (PET) radioactive drugs for noncommercial transfer to medical use licensees in its consortium does not relieve the licensee from complying with applicable FDA, other Federal, and State requirements governing radioactive drugs.			

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				(2) Each licensee authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall: (i) Satisfy the labeling requirements in § 32.72(a)(4) of this chapter for each PET radioactive drug transport radiation shield and each syringe, vial, or other container used to hold a PET radioactive drug intended for noncommercial distribution to members of its consortium. (ii) Possess and use instrumentation to measure the radioactivity of the PET radioactive drugs intended for noncommercial distribution to members of its consortium and meet the procedural, radioactivity measurement, instrument test,			

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				instrument check, and instrument adjustment requirements in § 32.72(c) of this chapter. (3) A licensee that is a pharmacy authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical use licensees in its consortium shall require that any individual that prepares PET radioactive drugs shall be: (i) an authorized nuclear pharmacist that meets the requirements in § 32.72(b)(2) of this chapter, or (ii) an individual under the supervision of an authorized nuclear pharmacist as specified in § 35.27 of this chapter. (4) A pharmacy, authorized under § 30.32(j) to produce PET radioactive drugs for noncommercial transfer to medical			

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				use licensees in its consortium that allows an individual to work as an authorized nuclear pharmacist, shall meet the requirements of § 32.72(b)(5) of this chapter.			
'30.71	Schedule B	**Exhibit B**	B	**Section 30.71 is amended by adding Cesium 129 (Cs 129), Cobalt 57 (Co 57), Gallium 67 (Ga 67), Germanium 68 (Ge 68), Gold 195 (Au 195), Indium 111 (In 111), Iodine 123 (I 123), Iron 52n (Fe 52), Potassium 43 (K 43), Rubidium 81 (Rb 81), Sodium 22 (Na 22), Yttrium 87 (Y 87), and Yttrium 88 (Y 88) in alphabetical order by element as follows:** See table at end of document.			
'30.72	Schedule C –	**Exhibit D**	H&S	**Section 30.72 is amended by adding radium-226 in**			

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	Quantities of radioactive material requiring consideration of the need for an emergency plan for responding to a release			**alphabetical order to read as follows:** See table at end of document.			
' 31.5 (b)(1) & (c)(13)	Certain detecting, measuring, gauging, or controlling devices	**R12-1-306 (B)**	B	**In § 31.5, paragraphs (b)(1)(i), (b)(1)(ii), and (c)(13)(i) are revised and paragraph (b)(1)(iii) is added to read as follows:** (b)(1) * * * (i) A specific license issued under § 32.51 of this chapter; or (ii) An equivalent specific license			

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	and/or an ionizing atmosphere			issued by an Agreement State; or (iii) An equivalent specific license issued by a State with provisions comparable to § 32.51 of this chapter. * * * * * (c) * * * (13)(i) Shall register, in accordance with paragraphs (c)(13)(ii) and (iii) of this section, devices containing at least 370 megabecquerels (10 millicuries) of cesium-137, 3.7 megabecquerels (0.1 millicurie) of strontium-90, 37 megabecquerels (1 millicurie) of cobalt-60, 3.7 megabecquerels (0.1 millicurie) of radium-226, or 37 megabecquerels (1 millicurie) of americium-241 or any other transuranic (i.e., element with atomic number greater than uranium (92)), based on the activity indicated on the label. Each address for a location of use, as described under			

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				paragraph (c)(13)(iii)(D) of this section, represents a separate general licensee and requires a separate registration and fee.			
' 31.12	General license for certain items and self-luminous products containin g radium-226	**R12-1-306 (H)(I)(J)**	C	**Sections 31.12, 31.13, and 31.14 are redesignated as § 31.21, § 31.22, and § 31.23, respectively, §§31.13 through 31.20 are reserved, and a new § 31.12 is added to read as follows:** (a) A general license is hereby issued to any person to acquire, receive, possess, use, or transfer, in accordance with the provisions of paragraphs (b), (c), and (d) of this section, radium-226 contained in the following products manufactured prior to November 30, 2007. (1) Antiquities originally intended for use by the general public. For the purposes of this paragraph, antiquities mean products			

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				originally intended for use by the general public and distributed in the late 19th and early 20th centuries, such as radium emanator jars, revigators, radium water jars, radon generators, refrigerator cards, radium bath salts, and healing pads. (2) Intact timepieces containing greater than 0.037 megabecquerel (1 microcurie), nonintact timepieces, and timepiece hands and dials no longer installed in timepieces. (3) Luminous items installed in air, marine, or land vehicles. (4) All other luminous products, provided that no more than 100 items are used or stored at the same location at any one time. (5) Small radium sources containing no more than 0.037 megabecquerel (1 microcurie) of radium-226. For the purposes of this paragraph, ‘‘small radium			

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				sources'' means discrete survey instrument check sources, sources contained in radiation measuring instruments, sources used in educational demonstrations (such as cloud chambers and spinthariscopes), electron tubes, lightning rods, ionization sources, static eliminators, or as designated by the NRC. (b) Persons who acquire, receive, possess, use, or transfer byproduct material under the general license issued in paragraph (a) of this section are exempt from the provisions of 10 CFR parts 19, 20, and 21, and § 30.50 and 30.51 of this chapter, to the extent that the receipt, possession, use, or transfer of byproduct material is within the terms of the general license; provided, however, that this			

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				exemption shall not be deemed to apply to any such person specifically licensed under this chapter. (c) Any person who acquires, receives, possesses, uses, or transfers byproduct material in accordance with the general license in paragraph (a) of this section: (1) Shall notify the NRC should there be any indication of possible damage to the product so that it appears it could result in a loss of the radioactive material. A report containing a brief description of the event, and the remedial action taken, must be furnished to the Director of the Office of Federal and State Materials and Environmental Management Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001			

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				within 30 days. (2) Shall not abandon products containing radium-226. The product, and any radioactive material from the product, may only be disposed of according to § 20.2008 of this chapter or by transfer to a person authorized by a specific license to receive the radium- 226 in the product or as otherwise approved by the NRC. (3) Shall not export products containing radium-226 except in accordance with part 110 of this chapter. (4) Shall dispose of products containing radium-226 at a disposal facility authorized to dispose of radioactive material in accordance with any Federal or State solid or hazardous waste law, including the Solid Waste Disposal Act, as authorized under the Energy Policy Act of 2005, by transfer to a person authorized to			

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				receive radium-226 by a specific license issued under part 30 of this chapter, or equivalent regulations of an Agreement State, or as otherwise approved by the NRC. (5) Shall respond to written requests from the NRC to provide information relating to the general license within 30 calendar days of the date of the request, or other time specified in the request. If the general licensee cannot provide the requested information within the allotted time, it shall, within that same time period, request a longer period to supply the information by providing the Director of the Office of Federal and State Materials and Environmental Management Programs, by an appropriate method listed in § 30.6(a) of this chapter, a written justification for the request.			

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				(d) The general license in paragraph (a) of this section does not authorize the manufacture, assembly, disassembly, repair, or import of products containing radium-226, except that timepieces may be disassembled and repaired.			
' 32.57	Calibration or reference sources containing americium-241 or radium-226: Requirements for license to manufacture or	**R12-1-311(C)**	B	**In § 32.57, the heading and the introductory text are revised to read as follows:** An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241 or radium-226, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if: (a) The applicant satisfies the			

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	initially transfer			general requirements of § 30.33 of this chapter; (b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including: (1) Chemical and physical form and maximum quantity of americium 241 or radium-226 in the source; (2) Details of construction and design; (3) Details of the method of incorporation and binding of the americium-241 or radium-226 in the source; (4) Procedures for and results of prototype testing of sources,			

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				which are designed to contain more than 0.005 microcurie of americium-241 or radium-226, to demonstrate that the americium-241 or radium-226 contained in each source will not be released or be removed from the source under normal conditions of use; (5) Details of quality control procedures to be followed in manufacture of the source; (6) Description of labeling to be affixed to the source or the storage container for the source; (7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source. (c) Each source will contain no more than 5 microcuries of			

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				americium-241 or radium-226. (d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241 or radium-226, that: (1) The method of incorporation and binding of the americium-241 or radium-226 in the source is such that the americium-241 will not be released or be removed from the source under normal conditions of use and handling of the source; and (2) The source has been subjected to and has satisfactorily passed the prototype tests prescribed by § 32.102, Schedule C, of this part.			
' 32.58	Same:	**R12-1-311(C)**	B	**Section 32.58 is revised to read**			

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	labeling of devices			**as follows:** Each person licensed under § 32.57 shall affix to each source, or storage container for the source, a label which shall contain sufficient information relative to safe use and storage of the source and shall include the following statement or a substantially similar statement which contains the information called for in the following statement: The receipt, possession, use, and transfer of this source, Model , Serial No., are subject to a general license and the regulations of the United States Nuclear Regulatory Commission or of a State with which the Commission has entered into an agreement for the exercise of regulatory authority. Do not remove this label. CAUTION-			

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				RADIOACTIVE MATERIAL–THIS SOURCE CONTAINS AMERICIUM-241 (or RADIUM-226). DO NOT TOUCH RADIOACTIVE PORTION OF THIS SOURCE _____ (Name of manufacturer or initial transferor)			
' 32.59	Same: Leak testing of each source	**R12-1-311(C)**	B	**Section 32.59 is revised to read as follows:** Each person licensed under § 32.57 shall perform a dry wipe test upon each source containing more than 3.7 kilobecquerels (0.1 microcurie) of americium-241 or radium-226 before transferring the source to a general licensee under § 31.8 of this chapter. This test shall be performed by wiping the entire radioactive surface of the source with a filter paper with the application of moderate finger			

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				pressure. The radioactivity on the paper shall be measured by using radiation detection instrumentation capable of detecting 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226. If this test discloses more than 0.185 kilobecquerel (0.005 microcurie) of radioactive material, the source shall be deemed to be leaking or losing americium-241 or radium-226 and shall not be transferred to a general licensee under § 31.8 of this chapter or equivalent regulations of an Agreement State.			
'32.71 (b)(8) & (c)(1)	Manufacture and distribution of byproduct material for certain in	**R12-1-306(F)**	B	**In § 32.71, paragraph (b)(8) is added, and paragraph (c)(1) is revised to read as follows:** (b) * * * (8) Cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries) each.			

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	vitro clinical or laboratory testing under general license			(c) * * * (1) Identifying the radioactive contents as to chemical form and radionuclide, and indicating that the amount of radioactivity does not exceed 0.37 megabecquerel (10 microcuries) of iodine-131, iodine-125, selenium-75, or carbon-14; 1.85 megabecquerels (50 microcuries) of hydrogen-3 (tritium); or 0.74 megabecquerel (20 microcuries) of iron-59; or Mock Iodine-125 in units not exceeding 1.85 kilobecquerels (0.05 microcurie) of iodine-129 and 0.185 kilobecquerel (0.005 microcurie) of americium-241 each; or cobalt-57 in units not exceeding 0.37 megabecquerel (10 microcuries); and			
'32.72 (a)(2)(i), (iii), (iv),	Manufacture, preparati	**R12-1-311(G)**	B	**In § 32.72, paragraphs (a)(2)(i), (a)(2)(iii), (a)(2)(iv), (b)(2)(ii), (b)(4), and (b)(5) are revised,**			

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(v), & (b)	on, or transfer for commercial distribution of radioactive drugs, containing byproduct material for certain in vitro clinical or laboratory testing under general license			**and a new paragraph (a)(2)(v) is added to read as follows:** (a) * * * (2) * * * (i) Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacture, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a); * * * * * (iii) Licensed as a pharmacy by a State Board of Pharmacy; (iv) Operating as a nuclear pharmacy within a Federal medical institution; or (v) A Positron Emission Tomography (PET) drug production facility registered with a State agency. * * * * *			

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				(b) * * * (2) * * * (ii) This individual meets the requirements specified in § 35.55(b) and 35.59 of this chapter, and the licensee has received an approved license amendment identifying this individual as an authorized nuclear pharmacist; or * * * * * (4) May designate a pharmacist (as defined in § 35.2 of this chapter) as an authorized nuclear pharmacist if: (i) The individual was a nuclear pharmacist preparing only radioactive drugs containing accelerator-produced radioactive material, and (ii) The individual practiced at a pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other pharmacies before August 8, 2009, or an			

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				earlier date as noticed by the NRC. (5) Shall provide to the Commission: (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 with the written attestation signed by a preceptor as required by § 35.55(b)(2) of this chapter; or (ii) The Commission or Agreement State license, or (iii) Commission master materials licensee permit, or (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			

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				(v) Documentation that only accelerator-produced radioactive materials were used in the practice of nuclear pharmacy at a Government agency or Federally recognized Indian Tribe before November 30, 2007 or at all other locations of use before August 8, 2009, or an earlier date as noticed by the NRC; and (vi) A copy of the State pharmacy licensure or registration, no later than 30 days after the date that the licensee allows, under paragraphs (b)(2)(i) and (b)(2)(iii) of this section, the individual to work as an authorized nuclear pharmacist.			
' 32.102	Schedule -C prototype tests for calibratio n or	**R12-1-304(D)**	B	**In § 32.102, the heading and the introductory paragraph are revised to read as follows:** An applicant for a license under § 32.57 shall, for any type of			

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	reference sources containing americium-241			source which is designed to contain more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, conduct prototype tests, in the order listed, on each of five prototypes of the source, which contains more than 0.185 kilobecquerel (0.005 microcurie) of americium-241 or radium-226, as follows:			
'35.2	Definition: Positron Emission Tomography (PET) radionuclide production facility	**R12-1-102**	H&S	**In § 35.2, new definition for *Positron Emission Tomography (PET) radionuclide production facility* is added to read as follows:** *Positron Emission Tomography (PET) radionuclide production facility* is defined as a facility operating a cyclotron or accelerator for the purpose of producing PET radionuclides.			

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'35.11(a)	License required	**Primarily adopted by R12-1-701 Fed and Indian license issues do not apply to AZ**	C	**In § 35.11, paragraph (a) is revised to read as follows:** (a) A person may manufacture, produce, acquire, receive, possess, prepare, use, or transfer byproduct material for medical use only in accordance with a specific license issued by the Commission or an Agreement State, or as allowed in paragraph (b) or (c) of this section.			
'35.63 (b)(2)(ii), (b)(2)(iii), & (c)(3)	Determination of dosages of unsealed byproduct material for medical use	**R12-1-713 (B)**	H&S	**In § 35.63, paragraphs (b)(2)(ii) and (c)(3) are revised, and paragraph (b)(2)(iii) is added to read as follows:** (b) * * * (2) * * * (ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an			

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				Investigational New Drug (IND) protocol accepted by FDA; or (iii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements. (c) * * * (3) Combination of volumetric *measurements and mathematical calculations,* based on the measurement made by: (i) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (ii) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements.			
' 35.100 (a) & (b)	Use of unsealed byproduct material	**Exhibit A**	H&S	**In § 35.100, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:**			

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	for uptake, dilution, and excretion studies for which a written directive is not required			(a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or (b) Excluding production of PET radionuclides, prepared by:			
' 35.200 (a) & (b)	Use of unsealed byproduct material for imaging and localization studies for which	**Exhibit A**	H&S	**In § 35.200, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:** (a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug			

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	a written directive is not required.			producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or (b) Excluding production of PET radionuclides, prepared by:			
'35.204 (a)	Permissible molybdenum-99 concentrations	**R12-1-720 (A)**	H&S	**In § 35.204, the heading and paragraph (a) are revised to read as follows:** (a) A licensee may not administer to humans a radiopharmaceutical that contains: (1) More than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m); or (2) More than 0.02 kilobecquerel of strontium-82 per megabecquerel of rubidium-82 chloride injection (0.02 microcurie of strontium-82 per millicurie of			

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				rubidium-82 chloride); or more than 0.2 kilobecquerel of strontium-85 per megabecquerel of rubidium-82 chloride injection (0.2 microcurie of strontium-85 per millicurie of rubidium-82).			
' 35.300 (a) & (b)	Use of unsealed byproduct material for which a written directive is required	**Exhibit A**	H&S	**In § 35.300, paragraph (a) and the introductory text of paragraph (b) are revised to read as follows:** (a) Obtained from: (1) A manufacturer or preparer licensed under § 32.72 of this chapter or equivalent Agreement State requirements; or (2) A PET radioactive drug producer licensed under § 30.32(j) of this chapter or equivalent Agreement State requirements; or (b) Excluding production of PET radionuclides, prepared by:			

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Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 61.2	Definition: Waste	**R12-1-102**	B	**In § 61.2, the definition for *Waste* is revised to read as follows:** *Waste* means those low-level radioactive wastes containing source, special nuclear, or byproduct material that are acceptable for disposal in a land disposal facility. For the purposes of this definition, low-level radioactive waste means radioactive waste not classified as high-level radioactive waste, transuranic waste, spent nuclear fuel, or byproduct material as defined in paragraphs (2), (3), and (4) of the definition of *Byproduct material* set forth in § 20.1003 of this chapter.			
' 150.3	Definition: Byproduct material	**R12-1-102**	H&S******* **(***please note 10 CFR 150.3**	**In § 150.3, the definition of *Byproduct material* is revised to read as follows:** *Byproduct material* means—			

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			Definition of Byproduct Material was changed from a Compatibility Category A to a Compatibility Category H&S)	(1) Any radioactive material (except special nuclear material) yielded in, or made radioactive by, exposure to the radiation incident to the process of producing or using special nuclear material; (2) The tailings or wastes produced by the extraction or concentration of uranium or thorium from ore processed primarily for its source material content, including discrete surface wastes resulting from uranium solution extraction processes. Underground ore bodies depleted by these solution extraction operations do not constitute ‘‘byproduct material’’ within this definition; (3)(i) Any discrete source of radium-226 that is produced, extracted, or converted after extraction, before, on, or after			

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				August 8, 2005, for use for a commercial, medical, or research activity; or (ii) Any material that— (A) Has been made radioactive by use of a particle accelerator; and (B) Is produced, extracted, or converted after extraction, before, on, or after August 8, 2005, for use for a commercial, medical, or research activity; and (4) Any discrete source of naturally occurring radioactive material, other than source material, that— (i) The Commission, in consultation with the Administrator of the Environmental Protection Agency, the Secretary of Energy, the Secretary of Homeland Security, and the head of any other appropriate Federal agency, determines would pose a threat similar to the threat posed by a discrete source of radium-226 to			

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				the public health and safety or the common defense and security; and (ii) Before, on, or after August 8, 2005, is extracted or converted after extraction for use in a commercial, medical, or research activity.			
' 150.3	Definition : Discrete source	**R12-1-102**	H&S	**In § 150.3, the definition of *Discrete source* is added to read as follows:** *Discrete source* means a radionuclide that has been processed so that its concentration within a material has been purposely increased for use for commercial, medical, or research activities.			

Occupational Dose Records, Labeling Containers, and the Total Effective Dose Equivalent Parts – 19 and 20
(72 FR 68043) RATS ID # 2008-1 Effective date 02/15/08
Date Due for State Adoption 02/15/11

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
' 19.13	Notification and reports to individuals	**R12-1-1004 and R12-1-446**	C	**In § 19.13, paragraphs (b) and (d) are revised to read as follows:** (b) Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of 10 CFR 20.2106. The licensee shall provide an annual report to each individual monitored under 10 CFR 20.1502 of the dose received in that monitoring year if: (1) The individual's occupational dose exceeds 1 mSv (100 mrem) TEDE or 1 mSv (100 mrem) to any individual organ or tissue; or (2) The individual requests his or her annual dose report. * * * * * (d) When a licensee is required by			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				§§ 20.2202, 20.2203 or 20.2204 of this chapter to report to the Commission any exposure of an individual to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to the Commission. This report must be transmitted no later than the transmittal to the Commission.			
' 20.1003	Definition: Total Effective Dose Equivalent (TEDE)	**R12-1-102**	A	**In § 20.1003, the definition of *Total Effective Dose Equivalent (TEDE)* is revised to read as follows:** *Total Effective Dose Equivalent* (TEDE) means the sum of the effective dose equivalent (for external exposures) and the committed effective dose equivalent (for internal exposures).			
' 20.1201	Occupational Dose Limits for	**R12-1-408**	A	**In § 20.1201, paragraph (c) is revised to read as follows:**			

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	Adults			(c) When the external exposure is determined by measurement with an external personal monitoring device, the deep-dose equivalent must be used in place of the effective dose equivalent, unless the effective dose equivalent is determined by a dosimetry method approved by the NRC. The assigned deep-dose equivalent must be for the part of the body receiving the highest exposure. The assigned shallow-dose equivalent must be the dose averaged over the contiguous 10 square centimeters of skin receiving the highest exposure. The deep-dose equivalent, lens dose equivalent, and shallow-dose equivalent may be assessed from surveys or other radiation measurements for the purpose of demonstrating compliance with the occupational dose limits, if the individual monitoring device was not in the region of highest potential exposure, or the results of individual monitoring are			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				unavailable.			
'20.2205	Reports to Individuals of Exceeding Dose Limits	**R12-1-446**	C	**Section 20.2205 is revised to read as follows:** When a licensee is required by §§ 20.2203 or 20.2204 to report to the Commission any exposure of an identified occupationally exposed individual, or an identified member of the public, to radiation or radioactive material, the licensee shall also provide the individual a report on his or her exposure data included in the report to Commission. This report must be transmitted no later than the transmittal to the Commission.			

Medical Use of Byproduct Material—Authorized User Clarification, Part 35
(74 FR 33901) RATS ID # 2009-1 Effective date 09/28/09
Date Due for State Adoption 09/28/12

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
§ 35.50	Training for Radiation Safety Officer	**Previously adopted as** **R12-1-710(A)(1)(b)(ii)(2)**	B	**In § 35.50, paragraph (a)(2)(ii)(B) is** **revised to read as follows:** * * * * * (a) * * * (2) * * * (ii) * * * (B) In clinical nuclear medicine facilities providing diagnostic and/or therapeutic services under the direction of physicians who meet the requirements for authorized users in §§ 35.57, 35.290, or 35.390;			
§ 35.51	Training for an authorized medical physicist.	**R12-1-711**	B	**In § 35.51, paragraphs (a)(2)(ii) and (b)(2) are revised to read as follows:** (a) * * * (2) * * * (ii) In clinical radiation facilities			

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				providing high-energy, external beam therapy (photons and electrons with energies greater than or equal to 1 million electron volts) and brachytherapy services under the direction of physicians who meet the requirements in § 35.57, 35.490, or 35.690; and * * * * * (b) * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c) and (a)(1) and (a)(2), or (b)(1) and (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting authorized medical physicist status. The written attestation must be signed by a preceptor authorized medical physicist who meets the requirements in §§ 35.51, 35.57, or equivalent Agreement State requirements for an authorized medical physicist for each type of therapeutic medical unit for which the individual is requesting			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				authorized medical physicist status; and * * * * *			
§ 35.57	Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized medical physicist, authorized user, nuclear pharmacist, and authorized nuclear pharmacist**.**	**R12-1-710, R12-1-711, R12-1-712 R12-1-719**	B	**In § 35.57, a new paragraph (c) is added to read as follows:** (c) Individuals who need not comply with training requirements as described in this section may serve as preceptors for, and supervisors of, applicants seeking authorization on NRC licenses for the same uses for which these individuals are authorized.			
§ 35.190	Training for uptake, dilution, and excretion studies.	**R12-1-719**	B	**In § 35.190, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (c)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, 35.390, or equivalent Agreement State			

Change to NRC Section	Title	State Section	Compatibility Category	Summary of Change to CFR	Difference Yes/No	Significant Yes/No	If Difference, Why or Why Not Was a Comment Generated
				requirements, involving— * * * * * (2) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.190, 35.290, or 35.390, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.100.			
§ 35.290	Training for imaging and localization studies.	**R12-1-721**	B	**In § 35.290, the introductory text of paragraph (c)(1)(ii) and paragraph (c)(2) are revised to read as follows:** (c)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, involving— * * * * * (2) Has obtained written			

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				attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1) or (c)(1) of this section and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under §§ 35.100 and 35.200.			
§ 35.390	Training for use of unsealed byproduct material for which a written directive is required.	**R12-1-723**	B	**In § 35.390, the introductory text of paragraph (b)(1)(ii) and paragraph (b)(2) are revised to read as follows:** (b)(1) * * * (ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the			

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				individual requesting authorized user status. The work experience must involve— * * * * * (2) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (a)(1) and (b)(1)(ii)(G) or (b)(1) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, or equivalent Agreement State requirements. The preceptor authorized user, who meets the requirements in § 35.390(b) must have experience in administering dosages in the same dosage category or categories (i.e., § 35.390(b)(1)(ii)(G)) as the individual requesting authorized user status.			
§ 35.392	Training for the oral administration of sodium iodide I-131	**R12-1-723**	B	**In § 35.392, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:**			

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	requiring a written directive in quantities less than or equal to 1.22 gigabecquerels (33 millicuries).			(c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A supervising authorized user who meets the requirements in § 35.390(b) must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2). The work experience must involve— * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.392, 35.394, or equivalent Agreement State requirements. A			

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				preceptor authorized user, who meets the requirement in § 35.390(b), must also have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(1) or 35.390(b)(1)(ii)(G)(2).			
§ 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).	**R12-1-723**	B	**In § 35.394, the introductory text of paragraph (c)(2) and paragraph (c)(3) are revised to read as follows:** (c) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A supervising authorized user, who meets the requirements in § 35.390(b), must also have experience in administering dosages as specified in § 35.390(b)(1)(ii)(G)(2). The work experience must involve— * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraphs (c)(1) and (c)(2) of this section, and has achieved a level of competency			

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				sufficient to function independently as an authorized user for medical uses authorized under § 35.300. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.394, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390(b), must also have experience in administering osages as specified in § 35.390(b)(1)(ii)(G)(2).			
§ 35.396	Training for the parenteral administration of unsealed byproduct material requiring a written directive.	**R12-1-723**	B	**In § 35.396, the introductory text of paragraph (d)(2) and paragraph (d)(3) are revised to read as follows:** (d) * * * (2) Has work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral administration, for which a written directive is required, of any beta emitter, or any photon-emitting radionuclide with a photon energy less than			

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				150 keV, and/or parenteral administration of any other radionuclide for which a written directive is required. A supervising authorized user who meets the requirements in § 35.390 must have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4). The work experience must involve— * * * * * (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (b) or (c) of this section, and has achieved a level of competency sufficient to function independently as an authorized user for the parenteral administration of unsealed byproduct material requiring a written directive. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements. A preceptor authorized user, who meets the requirements in § 35.390, must			

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				have experience in administering dosages as specified in §§ 35.390(b)(1)(ii)(G)(3) and/or 35.390(b)(1)(ii)(G)(4).			
§ 35.490	Training for use of manual brachytherapy sources.	**R12-1-727**	B	**In § 35.490, the introductory text of paragraph (b)(1)(ii) and paragraphs (b)(2) and (b)(3) are revised to read as follows**: (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation oncology, under an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of			

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				Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (a)(1), or paragraphs (b)(1) and (b)(2), of this section and has achieved a level of competency sufficient to function independently as an authorized user of manual brachytherapy sources for the medical uses authorized under § 35.400.			
§ 35.491	Training for ophthalmic use of strontium-90.	**R12-1-727**	B	**In § 35.491, paragraph (b)(3) is revised to read as follows:** (b) * * * (3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in			

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				§§ 35.57, 35.490, 35.491, or equivalent Agreement State requirements, that the individual has satisfactorily completed the requirements in paragraph (b) of this section and has achieved a level of competency sufficient to function independently as an authorized user of strontium-90 for ophthalmic use.			
§ 35.690	Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.	**R12-1-744**	B	**In § 35.690, the introductory text of paragraph (b)(1)(ii) and paragraphs (b)(2) and (b)(3) are revised to read as follows:** (b)(1) * * * (ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements at a medical institution, involving— * * * * * (2) Has completed 3 years of supervised clinical experience in radiation therapy, under an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements, as part of a formal training program approved by the Residency Review Committee for			

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				Radiation Oncology of the Accreditation Council for Graduate Medical Education or the Royal College of Physicians and Surgeons of Canada or the Committee on Postdoctoral Training of the American Osteopathic Association. This experience may be obtained concurrently with the supervised work experience required by paragraph (b)(1)(ii) of this section; and (3) Has obtained written attestation that the individual has satisfactorily completed the requirements in paragraph (a)(1) or paragraphs (b)(1) and (b)(2), and paragraph (c), of this section, and has achieved a level of competency sufficient to function independently as an authorized user of each type of therapeutic medical unit for which the individual is requesting authorized user status. The written attestation must be signed by a preceptor authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements for an authorized user for each type of therapeutic medical unit for			

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				which the individual is requesting authorized user status; and			