

**PART 35 PRELIMINARY
DRAFT PROPOSED RULE LANGUAGE**

(May 16, 2011)

The Nuclear Regulatory Commission (NRC) is making available preliminary draft rule language for proposed amendments to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 “medical use of byproduct material.” These proposed amendments include lowering the paperwork burden for certain license applications, clarifying certain training and experience (T&E) requirements for authorized users, expanding the ability of licensees to use sealed sources and devices approved in the Sealed Source and Device Registry, expanding and clarifying requirements for parenteral administration of alpha emitters, and other minor changes. The proposed changes are based in part on recommendations from the NRC’s Advisory Committee on Medical Uses of Isotopes.

The NRC is making the preliminary draft rule language available to inform stakeholders of the current status of this proposed rulemaking, and is inviting comments on the language. This preliminary rule language may be subject to significant revisions during the rulemaking process. Public input at this stage will help inform the development of the proposed rule.

Please submit your comments by September 15, 2011. The NRC will review and consider any comments received; however, the NRC will not respond to any comments received at this pre-rulemaking stage. As appropriate, the Statements of Consideration for the proposed rule will briefly discuss any substantive changes made to the preliminary draft rule language as a result of the comments now being solicited. Stakeholders will have a further opportunity to comment on the rule language when it is published as a proposed rule in accordance with the

provisions of the Administrative Procedures Act. The NRC will respond to any such comments in the Statements of Consideration published with the final rule language.

Point of contact for further information is Neelam Bhalla, Office of Federal and State Materials and Environmental Management Programs, telephone (301) 415-6843, e-mail Neelam.Bhalla@nrc.gov.

The following is preliminary draft rule language for proposed changes to 10 CFR Part 35. Redline strikeout format is used to delineate between original rule language in black and the preliminary draft changes. In addition to the preliminary draft amendments listed below, NRC staff is considering several other revisions (e.g. medical event definition, attestation requirements, extending grandfathering to certain certified individuals, assistant/associate RSOs, increased frequency of molybdenum breakthrough testing and reporting) . The proposed rule language for these issues will be developed after NRC staff has conducted two public workshops scheduled for June 20-21, 2011 in New York, NY, and in August 2011, in Houston, Texas. Public input at these workshops will help inform the development of the proposed rule.

§ 35.12 Application for license, amendment, or renewal.

(a) An application must be signed by the applicant's or licensee's management.

(b) An application for a license for medical use of byproduct material as described in §§ 35.100, 35.200, 35.300, 35.400, 35.500, 35.600, and 35.1000 must be made by—

(1) Filing an original ~~and one copy of~~ NRC Form 313, "Application for Material License," that includes the facility diagram, equipment, and training and experience qualifications of the Radiation Safety Officer, authorized user(s), authorized medical physicist(s), and authorized nuclear pharmacist(s); and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(c) A request for a license amendment or renewal must be made by—

(1) Submitting an original ~~and one copy~~ of either—

(i) NRC Form 313, "Application for Material License"; or

(ii) A letter ~~containing all information required by NRC Form 313, requesting the amendment or renewal~~; and

(2) Submitting procedures required by §§ 35.610, 35.642, 35.643, and 35.645, as applicable.

(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include: ~~information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part~~

(1) ~~Any additional aspects of the medical use of the material applicable to radiation safety that are not addressed in, or differ from, Subparts A through C and M of this part;~~

(2) ~~Identification of and commitment to follow the applicable radiation safety program requirements in Subparts D through H of this part that are appropriate for the specific § 35.1000 medical use;~~

(3) ~~Any additional specific information on--~~

(i) Radiation safety precautions and instructions;

(ii) Methodology for measurement of dosages or doses to be administered to patients or human research subjects; and

(iii) Calibration, maintenance, and repair of instruments and equipment necessary for radiation safety; and

~~(2 4) The applicant or licensee shall also provide any~~ Any other information requested by the Commission in its review of the application.

(e) An applicant that satisfies the requirements specified in § 33.13 of this chapter may apply for a Type A specific license of broad scope.

§ 35.13 License amendments.

A licensee shall apply for and must receive a license amendment--

(a) – (g) No change

~~(h) Before it receives a sealed source from a different manufacturer or of a different model number than authorized by its license unless the sealed source is used for manual brachytherapy, is listed in the Sealed Source and Device Registry, and is in a quantity and for an isotope authorized by the license.~~

§ 35.14 Notifications.

(a) No change

(b) A licensee shall notify the Commission no later than 30 days after:

(1) An authorized user, an authorized nuclear pharmacist, a Radiation Safety Officer, or an authorized medical physicist permanently discontinues performance of duties under the license or has a name change;

(2) The licensee permits ~~an authorized user or~~ an individual qualified to be a Radiation Safety Officer under §§ 35.50 and 35.59 to function as a temporary Radiation Safety Officer and to perform the functions of a Radiation Safety Officer in accordance with § 35.24(c).

(3) The licensee's mailing address changes;

(4) The licensee's name changes, but the name change does not constitute a transfer of control of the license as described in § 30.34(b) of this chapter; ~~or~~

(5) The licensee has added to or changed the areas of use identified in the application or on the license where byproduct material is used in accordance with either § 35.100 or § 35.200 if the change does not include addition or relocation of either an area where PET radionuclides are produced or a PET radioactive drug delivery line from the PET radionuclide/PET radioactive drug production area; ~~or~~

(6) The licensee obtains a sealed source for use in manual brachytherapy from a different manufacturer or with a different model number than authorized by its license. The notification must include the manufacturer and model number of the sealed source, the isotope, and the quantity per sealed source.

(c) No change

§ 35.50 Training for Radiation Safety Officer.

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

(a) – (b) No change

(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 ~~a Commission or Agreement State the licensee's~~ license, ~~a Commission master~~

material permit or a permit issued by a Commission or Agreement State Broad scope medical use licensee 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 ; or ~~and~~,

(3) Has experience with the radiation safety aspects of the types of use of byproduct material for which the individual is seeking approval both as the Radiation Safety Officer and the authorized user on the same new Commission or Agreement State license; and,

(d) Except for those individuals identified in paragraphs (c)(2) and (c)(3) of this section, ~~h~~Has obtained written attestation, 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) ~~or (e)(2)~~ 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) No change

§ 35.51 Training for an authorized medical physicist.

Except as provided in § 35.57, the licensee shall require the authorized medical physicist to be an individual who—

(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 (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 physics—

(i) Under the supervision of a medical physicist who is certified in medical physics by a specialty board ~~recognized~~ whose certification process has been recognized under this section 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 in § 35.57, 35.490, or 35.690; 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) – (c) No change

§ 35.65 Authorization for calibration, transmission, and reference sources.

(a) Byproduct material authorized by this provision shall not be:

(1) Used for medical use as defined in § 35.2; or

(2) Combined to create an activity greater than the nominal activity of any single source; i.e., bundled or aggregated.

(b) Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use.

(1 a) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations.

(2 b) Sealed sources, not exceeding 1.11 GBq (30 mCi) each, redistributed by a licensee authorized to redistribute the sealed sources manufactured and distributed by a person licensed under § 32.74 of this chapter or equivalent Agreement State regulations, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions.

(3 e) Any byproduct material with a half-life not longer than 120 days in individual amounts not to exceed 0.56 GBq (15 mCi).

(4 d) Any byproduct material with a half-life longer than 120 days in individual amounts not to exceed the smaller of 7.4 MBq (200 [micro]Ci) or 1000 times the quantities in Appendix B of Part 30 of this chapter.

(5 e) Technetium-99m in amounts as needed.

§ 35.290 Training for imaging and localization studies.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.200 to be a physician who—

(a) – (b) No change

(c)(1) Has completed 700 hours of training and experience, including a minimum of 80 hours of classroom and laboratory training, in basic radionuclide handling techniques applicable to the medical use of unsealed byproduct material for imaging and localization studies. The training and experience must include, at a minimum—

(i) Classroom and laboratory training in the following areas—

- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity;
- (D) Chemistry of byproduct material for medical use;
- (E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.290, or 35.390 and 35.290(c)(1)(ii)(G), or equivalent Agreement State requirements. **An authorized nuclear pharmacist who meets the requirements in §§ 35.55 or 35.57 may provide the supervised work experience for paragraph (c)(1)(ii)(G) of this section. Work experience must involve involving—**

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

(B) Performing quality control procedures on instruments used to determine the activity of dosages and performing checks for proper operation of survey meters;

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

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

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

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

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

(2) Has obtained written 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.

Except as provided in § 35.57, the licensee shall require an authorized user of unsealed byproduct material for the uses authorized under § 35.300 to be a physician who—

(a) Is certified by a medical specialty board whose certification process 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 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 diplomates 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 include—

(i) Classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

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

(E) Radiation biology; and

(ii) Work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 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 individual requesting authorized user status. The work experience must involve—

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

(B) Performing quality control procedures on instruments used to determine the activity of dosages, and performing checks for proper operation of survey meters;

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

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

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

(F) [Reserved]

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

(1) Oral administration of less than or equal to 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131, for which a written directive is required;

(2) Oral administration of greater than 1.22 gigabecquerels (33 millicuries) of sodium iodide I-131²;

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

(3) Parenteral administration of any ~~radionuclide that is primarily used for its beta radiation characteristics beta-emitter, or a photon-emitting radionuclide with a~~ for its photon energy of less than 150 keV, for which a written directive is required;

(4) Parenteral administration of any radionuclide that is primarily used for its photon energy of 150 keV or more, for which a written directive is required;

(5) Parenteral administration of any radionuclide that is primarily used for its alpha radiation characteristics, for which a written directive is required; and/or

(6 4) Parenteral administration of any other radionuclide for which a written directive is required; and

(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.

§ 35.396 Training for the parenteral administration of unsealed byproduct material requiring a written directive.

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 for uses listed in § 35.390(b)(1)(ii)(G)(3), ~~or~~ 35.390(b)(1)(ii)(G)(4), 35.390(b)(1)(ii)(G)(5), or 35.390(b)(1)(ii)(G)(6), or equivalent Agreement State requirements; or

(b) Is an authorized user 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 ~~listed in § 35.390(b)(1)(ii)(G), 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;
- (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 §§ 35.57, 35.390, 35.396, or equivalent Agreement State requirements, in the parenteral ~~administrations listed in § 35.390(b)(1)(ii)(G) 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 ~~in the same category or categories as the individual requesting authorized user status.~~ The work experience must involve—

(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 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 in each category of involving the parenteral administrations as specified in § 35.390(b)(1)(ii)(G), 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 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 have experience in administering dosages in the same category or categories as the individual requesting authorized user status.

§ 35.400 Use of sources for manual brachytherapy.

A licensee shall use only brachytherapy sources for therapeutic medical uses:

- (a) ~~As A~~ approved in the Sealed Source and Device Registry for medical brachytherapy.

The manual brachytherapy sources shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

- (b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.490 Training for use of manual brachytherapy sources.

Except as provided in § 35.57, the licensee shall require an authorized user of a manual brachytherapy source for the uses authorized under § 35.400 to be a physician who—

- (a) No change

(b)(1) Has completed a structured educational program in basic radionuclide handling techniques applicable to the use of manual brachytherapy sources that includes—

- (i) 200 hours of classroom and laboratory training in the following areas—

- (A) Radiation physics and instrumentation;
- (B) Radiation protection;
- (C) Mathematics pertaining to the use and measurement of radioactivity; and
- (D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.490, or equivalent Agreement State requirements at a medical institution, clinic, or private practice involving—

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

- (B) Checking survey meters for proper operation;
- (C) Preparing, implanting, and removing brachytherapy sources;
- (D) Maintaining running inventories of material on hand;
- (E) Using administrative controls to prevent a medical event involving the use of byproduct material;
- (F) Using emergency procedures to control byproduct material; and
- (2) – (3) No change

35.500 Use of sealed sources and medical devices for diagnosis.

(a) A licensee shall use only sealed sources for diagnostic medical use:

(1) ~~as A~~ approved in the Sealed Source and Device Registry for ~~uses in~~ diagnostic medicine. ~~The sealed sources shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or~~

(2) ~~In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met; and~~

(b) A licensee shall use only diagnostic medical devices containing sealed sources:

(1) ~~Approved in the Sealed Source and Device Registry for diagnostic medicine. The diagnostic medical devices shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or~~

(2) ~~In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.~~

§ 35.600 Use of a sealed source in a remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit.

(a) A licensee shall use sealed sources in photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units for therapeutic medical uses:

(1a) ~~As A~~ approved in the Sealed Source and Device Registry for use in the medical remote afterloader unit, teletherapy unit, or gamma stereotactic radiosurgery unit. The sealed sources shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2b) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met; and

(b) A licensee shall use photon emitting remote afterloader units, teletherapy units, or gamma stereotactic radiosurgery units:

(1) Approved in the Sealed Source and Device Registry for therapeutic medical uses. These devices shall be used in accordance with radiation safety conditions and limitations described in the Sealed Source and Device Registry; or

(2) In research in accordance with an active Investigational Device Exemption (IDE) application accepted by the FDA provided the requirements of § 35.49(a) are met.

§ 35.690 Training for use of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

Except as provided in § 35.57, the licensee shall require an authorized user of a sealed source for a use authorized under § 35.600 to be a physician who—

(a) No change

(b)(1) Has completed a structured educational program in basic radionuclide techniques applicable to the use of a sealed source in a therapeutic medical unit that includes—

(i) 200 hours of classroom and laboratory training in the following areas—

(A) Radiation physics and instrumentation;

(B) Radiation protection;

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

(D) Radiation biology; and

(ii) 500 hours of work experience, under the supervision of an authorized user who meets the requirements in §§ 35.57, 35.690, or equivalent Agreement State requirements at a medical institution, **clinic, or private practice** involving—

(A) Reviewing full calibration measurements and periodic spot-checks;

(B) Preparing treatment plans and calculating treatment doses and times;

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

(D) Implementing emergency procedures to be followed in the event of the abnormal operation of the medical unit or console;

(E) Checking and using survey meters; and

(F) Selecting the proper dose and how it is to be administered; and

(2) – (3) No change