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.

(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.

(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 license, a permit issued by a Commission or Agreement State broad scope license, 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 license, a permit issued by a Commission or Agreement State broad scope license, 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.

(3) Physicians, dentists, or podiatrists who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses performed 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, need not comply with the training requirements of subparts D through H of this part when performing the same medical uses. A physician, dentist, or podiatrist, who used only accelerator-produced radioactive materials, discrete sources of radium-226, or both, for medical uses at the locations and time period identified in this paragraph, qualifies as an authorized user for those materials and uses performed before these dates, for purposes of this chapter.
§ 35.59 Recentness of training.

The training and experience specified in Subparts B, D, E, F, G, and H of this part must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed.

[71 FR 15008, Mar. 27, 2006]

Subpart C—General Technical Requirements

§ 35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material.

(a) For direct measurements performed in accordance with §35.63, a licensee shall possess and use instrumentation to measure the activity of unsealed byproduct material before it is administered to each patient or human research subject.

(b) A licensee shall calibrate the instrumentation required in paragraph (a) of this section in accordance with nationally recognized standards or the manufacturer’s instructions.

(c) A licensee shall retain a record of each instrument calibration required by this section in accordance with §35.2060.

§ 35.61 Calibration of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part and 10 CFR part 20 before first use, annually, and following a repair that affects the calibration. A licensee shall—

(1) Calibrate all scales with readings up to 10 mSv (1000 mrem) per hour with a radiation source;

(2) Calibrate two separated readings on each scale or decade that will be used to show compliance; and

(3) Conspicuously note on the instrument the date of calibration.

(b) A licensee may not use survey instruments if the difference between the indicated exposure rate and the calculated exposure rate is more than 20 percent.

(c) A licensee shall retain a record of each survey instrument calibration in accordance with §35.2061.

§ 35.63 Determination of dosages of unsealed byproduct material for medical use.

(a) A licensee shall determine and record the activity of each dosage before medical use.

(b) For a unit dosage, this determination must be made by—

(1) Direct measurement of radioactivity; or

(2) A decay correction, based on the activity or activity concentration determined by—

(i) A manufacturer or preparer licensed under §32.72 of this chapter or equivalent Agreement State requirements; or

(ii) An NRC or Agreement State licensee for use in research in accordance with a Radioactive Drug Research Committee-approved protocol or an Investigational New Drug (IND) protocol accepted by FDA; or

(iii) A PET radioactive drug producer licensed under §30.32(j) of this chapter or equivalent Agreement State requirements.

(c) For other than unit dosages, this determination must be made by—

(1) Direct measurement of radioactivity;

(2) Combination of measurement of radioactivity and mathematical calculations; or

(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.