(b)(1) Has completed a structured educational program in basic radio-nuclide 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, 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) 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 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 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 individual is seeking authorization.


Subparts I–J [Reserved]

Subpart K—Other Medical Uses of Byproduct Material or Radiation From Byproduct Material

§ 35.1000 Other medical uses of byproduct material or radiation from byproduct material.

A licensee may use byproduct material or a radiation source approved for medical use which is not specifically addressed in subparts D through H of this part if—

(a) The applicant or licensee has submitted the information required by §35.12(b) through (d); and

(b) The applicant or licensee has received written approval from the Commission in a license or license amendment and uses the material in accordance with the regulations and specific conditions the Commission considers necessary for the medical use of the material.