§ 35.652 Radiation surveys.

(a) In addition to the survey requirement in §20.1501 of this chapter, a person licensed under this subpart shall make surveys to ensure that the maximum radiation levels and average radiation levels from the surface of the main source safe with the source(s) in the shielded position do not exceed the levels stated in the Sealed Source and Device Registry.

(b) The licensee shall make the survey required by paragraph (a) of this section at installation of a new source and following repairs to the source(s) shielding, the source(s) driving unit, or other electronic or mechanical component that could expose the source, reduce the shielding around the source(s), or compromise the radiation safety of the unit or the source(s).

(c) A licensee shall retain a record of the radiation surveys required by paragraph (a) of this section in accordance with §35.2652.

§ 35.655 Five-year inspection for teletherapy and gamma stereotactic radiosurgery units.

(a) A licensee shall have each teletherapy unit and gamma stereotactic radiosurgery unit fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first, to assure proper functioning of the source exposure mechanism.

(b) This inspection and servicing may only be performed by persons specifically licensed to do so by the Commission or an Agreement State.

(c) A licensee shall keep a record of the inspection and servicing in accordance with §35.2655.

§ 35.657 Therapy-related computer systems.

The licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies. At a minimum, the acceptance testing must include, as applicable, verification of:

(a) The source-specific input parameters required by the dose calculation algorithm;

(b) The accuracy of dose, dwell time, and treatment time calculations at representative points;

(c) The accuracy of isodose plots and graphic displays;

(d) The accuracy of the software used to determine sealed source positions from radiographic images; and

(e) The accuracy of electronic transfer of the treatment delivery parameters to the treatment delivery unit from the treatment planning system.

§ 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) 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 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)(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.