§ 35.491 Training for ophthalmic use of strontium-90.

Except as provided in §35.57, the licensee shall require the authorized user of strontium-90 for ophthalmic radiotherapy to be a physician who—

(a) Is an authorized user under §35.490 or equivalent Agreement State requirements; or

(b)(1) Has completed 24 hours of classroom and laboratory training applicable to the medical use of strontium-90 for ophthalmic radiotherapy. The training must include—

(i) Radiation physics and instrumentation;

(ii) Radiation protection;

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

(iv) Radiation biology; and

(2) Supervised clinical training in ophthalmic radiotherapy under the supervision of an authorized user at a medical institution, clinic, or private practice that includes the use of strontium-90 for the ophthalmic treatment of five individuals. This supervised clinical training must involve—

(i) Examination of each individual to be treated;

(ii) Calculation of the dose to be administered;

(iii) Administration of the dose; and

(iv) Follow up and review of each individual’s case history; and

(3) Has obtained written attestation, signed by a preceptor authorized user who meets the requirements in §§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.

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§ 35.610 Safety procedures and instructions for remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units.

(a) A licensee shall—
(1) Secure the unit, the console, the console keys, and the treatment room when not in use or unattended;
(2) Permit only individuals approved by the authorized user, Radiation Safety Officer, or authorized medical physicist to be present in the treatment room during treatment with the source(s);
(3) Prevent dual operation of more than one radiation producing device in a treatment room if applicable; and
(4) Develop, implement, and maintain written procedures for responding to an abnormal situation when the operator is unable to place the source(s) in the shielded position, or remove the patient or human research subject from the radiation field with controls from outside the treatment room. These procedures must include—
   (i) Instructions for responding to equipment failures and the names of the individuals responsible for implementing corrective actions;
   (ii) The process for restricting access to and posting of the treatment area to minimize the risk of inadvertent exposure; and
   (iii) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer to be contacted if the unit or console operates abnormally.

(b) A copy of the procedures required by paragraph (a)(4) of this section must be physically located at the unit console.

(c) A licensee shall post instructions at the unit console to inform the operator of—
   (1) The location of the procedures required by paragraph (a)(4) of this section; and
   (2) The names and telephone numbers of the authorized users, the authorized medical physicist, and the Radiation Safety Officer.