§ 35.633 Full calibration measurements on remote afterloader units.

(a) A licensee authorized to use a remote afterloader unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;

(2) Before medical use under the following conditions:

(i) Following replacement of the source or following reinstallation of the unit in a new location outside the facility; and

(ii) Following any repair of the unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding 1 quarter for high dose-rate, medium dose-rate, and pulsed dose-rate remote afterloader units with sources whose half-life exceeds 75 days; and

(4) At intervals not exceeding 1 year for low dose-rate remote afterloader units.

(b) To satisfy the requirement of paragraph (a) of this section, full calibration measurements must include, as applicable, determination of:

(1) The output within ±5 percent;

(2) Source positioning accuracy to within ±1 millimeter;

(3) Source retraction with backup battery upon power failure;

(4) Length of the source transfer tubes;

(5) Timer accuracy and linearity over the typical range of use;

(6) Length of the applicators; and

(7) Function of the source transfer tubes, applicators, and transfer tube-applicator interfaces.

(c) A licensee shall use the dosimetry system described in §35.630(a) to measure the output.

(d) A licensee shall make full calibration measurements required by paragraph (a) of this section in accordance with published protocols accepted by nationally recognized bodies.

(e) In addition to the requirements for full calibrations for low dose-rate remote afterloader units in paragraph (b) of this section, a licensee shall perform an autoradiograph of the source(s) to verify inventory and source(s) arrangement at intervals not exceeding 1 quarter.

(f) For low dose-rate remote afterloader units, a licensee may use measurements provided by the source manufacturer that are made in accordance with paragraphs (a) through (e) of this section.

(g) A licensee shall mathematically correct the outputs determined in paragraph (b)(1) of this section for physical decay at intervals consistent with 1 percent physical decay.

(h) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (g) of this section must be performed by the authorized medical physicist.

(i) A licensee shall retain a record of each calibration in accordance with §35.2632.

§ 35.635 Full calibration measurements on gamma stereotactic radiosurgery units.

(a) A licensee authorized to use a gamma stereotactic radiosurgery unit for medical use shall perform full calibration measurements on each unit—

(1) Before the first medical use of the unit;
§ 35.642 Periodic spot-checks for tele-therapy units.

(a) A licensee authorized to use tele-therapy units for medical use shall perform output spot-checks on each tele-therapy unit once in each calendar month that include determination of—

(1) Timer accuracy, and timer linearity over the range of use;
(2) On-off error;
(3) The coincidence of the radiation field and the field indicated by the light beam localizing device;
(4) The accuracy of all distance measuring and localization devices used for medical use;
(5) The output for one typical set of operating conditions measured with the dosimetry system described in § 35.630(b); and
(6) The difference between the measurement made in paragraph (a)(5) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(b) A licensee shall perform measurements required by paragraph (a) of this section in accordance with written procedures established by the authorized medical physicist. That individual need not actually perform the spot-check measurements.

(c) A licensee shall have the authorized medical physicist review the results of each spot-check within 15 days. The authorized medical physicist shall notify the licensee as soon as possible in writing of the results of each spot-check.

(d) A licensee authorized to use a tele-therapy unit for medical use shall perform safety spot-checks of each tele-therapy facility once in each calendar month and after each source installation to assure proper operation of—