AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

misadministration, why it occurred, the effect on the individual, improvements needed to prevent recurrence, and the actions taken to prevent recurrence.

(c) Aside from the notification requirement, nothing in this section affects any rights or duties of licensees and physicians in relation to each other, to individuals receiving misadministrations, or to that individual's responsible relatives or guardians.

[56 FR 34122, July 25, 1991, as amended at 59 FR 14086, Mar. 25, 1994; 60 FR 48626, Sept. 20, 1995]

§ 35.49 Suppliers for sealed sources or devices for medical use.

A licensee may use for medical use only:

(a) Sealed sources or devices manufactured, labeled, packaged, and distributed in accordance with a license issued pursuant to 10 CFR part 30 and 10 CFR 32.74 or the equivalent requirements of an Agreement State; or

(b) Teletherapy sources manufactured and distributed in accordance with a license issued pursuant to 10 CFR part 30 or the equivalent requirements of an Agreement State.

[59 FR 61783, Dec. 2, 1994]

Subpart C—General Technical Requirements

§ 35.50 Possession, use, calibration, and check of dose calibrators.

(a) A licensee shall possess and use a dose calibrator to measure the activity of dosages of photon-emitting radionuclides prior to administration to each patient or human research subject.

(b) A licensee shall:

(1) Check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. To satisfy the requirement of this paragraph, the check must be done on a frequently used setting with a sealed source of not less than 10 microcuries of radium-226 or 50 microcuries of any other photon-emitting radionuclide;

(2) Test each dose calibrator for accuracy upon installation and at least annually thereafter by assaying at least two sealed sources containing different radionuclides whose activity the manufacturer has determined within 5 percent of its stated activity, whose activity is at least 10 microcuries for radium-226 and 50 microcuries for any other photon-emitting radionuclide, and at least one of which has a principal photon energy between 100 keV and 500 keV;

(3) Test each dose calibrator for linearity upon installation and at least quarterly thereafter over a range from the highest dosage that will be administered to a patient or human research subject to 1.1 megabecquerels (30 microcuries); and

(4) Test each dose calibrator for geometry dependence upon installation over the range of volumes and volume configurations for which it will be used. The licensee shall keep a record of this test for the duration of the use of the dose calibrator.

(c) A licensee shall also perform appropriate checks and tests required by this section following adjustment or repair of the dose calibrator.

(d) A licensee shall mathematically correct dosage readings for any geometry or linearity error that exceeds 10 percent if the dosage is greater than 10 microcuries and shall repair or replace the dose calibrator if the accuracy or constancy error exceeds 10 percent.

(e) A licensee shall retain a record of each check and test required by this section for three years unless directed otherwise. The records required in paragraphs (b)(1) through (b)(4) of this section must include:

(1) For paragraph (b)(1) of this section, the model and serial number of the dose calibrator, the identity of the radionuclide contained in the check source, the date of the check, the activity measured, and the initials of the individual who performed the check;

(2) For paragraph (b)(2) of this section, the model and serial number of the dose calibrator, the model and serial number of each source used, the identity of the radionuclide contained in the source and its activity, the date of the test, the results of the test, and the identity of the individual performing the test.

(3) For paragraph (b)(3) of this section, the model and serial number of