

§ 35.33

10 CFR Ch. I (1-1-01 Edition)

management program has been implemented along with a copy of the program.

[56 FR 34121, July 25, 1991, as amended at 59 FR 61783, Dec. 2, 1994]

§ 35.33 Notifications, reports, and records of misadministrations.

(a) For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center² no later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the appropriate NRC Regional Office listed in 10 CFR 30.6 within 15 days after discovery of the misadministration. The written report must include the licensee's name; the prescribing physician's name; a brief description of the event; why the event occurred; the effect on the individual who received the misadministration; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not; and if there was notification, what information was provided. The report must not contain the individual's name or any other information that could lead to identification of the individual. To meet the requirements of this section, the notification of the individual receiving the misadministration may be made instead to that individual's responsible relative or guardian, when appropriate.

(3) The licensee shall notify the referring physician and also notify the individual receiving the misadministration of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the individual or that, based on medical judgement, telling the individual would be harmful. The licensee is not required to notify the individual without first consulting the referring physician. If the referring physician or the individual receiving the misadministration cannot be reached within 24 hours, the licensee shall notify the individual as soon as possible

²The commercial telephone number of the NRC Operations Center is (301) 816-5100.

thereafter. The licensee may not delay any appropriate medical care for the individual, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the individual was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the individual by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the individual, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

(b) Each licensee shall retain a record of each misadministration for 5 years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the individual who received the misadministration, and that individual's referring physician, if applicable), the individual's social security number or other identification number if one has been assigned, a brief description of the 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 the dose calibrator, the calculated activities, the measured activities, the date of the test, and the identity of the individual performing the test.

(4) For paragraph (b)(4) of this section, the model and serial number of the dose calibrator, the configuration of the source measured, the activity measured for each volume measured, the date of the test, and the identity of the individual performing the test.

[51 FR 36951, Oct. 16, 1986, as amended at 53 FR 19247, May 27, 1988; 59 FR 61783, Dec. 2, 1994]

§ 35.51 Calibration and check of survey instruments.

(a) A licensee shall calibrate the survey instruments used to show compliance with this part before first use, annually, and following repair. The licensee shall:

(1) Calibrate all scales with readings up to 1000 millirem per hour with a radiation source;