

**§ 35.2024**

(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.

**Subpart L—Records**

**§ 35.2024 Records of authority and responsibilities for radiation protection programs.**

(a) A licensee shall retain a record of actions taken by the licensee's management in accordance with §35.24(a) for 5 years. The record must include a summary of the actions taken and a signature of licensee management.

(b) The licensee shall retain a copy of both authority, duties, and responsibilities of the Radiation Safety Officer as required by §35.24(e), and a signed copy of each Radiation Safety Officer's agreement to be responsible for implementing the radiation safety program, as required by §35.24(b), for the duration of the license. The records must include the signature of the Radiation Safety Officer and licensee management.

**§ 35.2026 Records of radiation protection program changes.**

A licensee shall retain a record of each radiation protection program change made in accordance with §35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

**§ 35.2040 Records of written directives.**

A licensee shall retain a copy of each written directive as required by §35.40 for 3 years.

**§ 35.2041 Records for procedures for administrations requiring a written directive**

A licensee shall retain a copy of the procedures required by §35.41(a) for the duration of the license.

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**§ 35.2060 Records of calibrations of instruments used to measure the activity of unsealed byproduct material.**

A licensee shall maintain a record of instrument calibrations required by §35.60 for 3 years. The records must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

**§ 35.2061 Records of radiation survey instrument calibrations.**

A licensee shall maintain a record of radiation survey instrument calibrations required by §35.61 for 3 years. The record must include the model and serial number of the instrument, the date of the calibration, the results of the calibration, and the name of the individual who performed the calibration.

**§ 35.2063 Records of dosages of unsealed byproduct material for medical use.**

(a) A licensee shall maintain a record of dosage determinations required by §35.63 for 3 years.

(b) The record must contain—

- (1) The radiopharmaceutical;
- (2) The patient's or human research subject's name, or identification number if one has been assigned;
- (3) The prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30  $\mu$ Ci);
- (4) The date and time of the dosage determination; and
- (5) The name of the individual who determined the dosage.

**§ 35.2067 Records of leaks tests and inventory of sealed sources and brachytherapy sources.**

(a) A licensee shall retain records of leak tests required by §35.67(b) for 3 years. The records must include the model number, and serial number if one has been assigned, of each source tested; the identity of each source by radionuclide and its estimated activity; the results of the test; the date of the test; and the name of the individual who performed the test.

(b) A licensee shall retain records of the semi-annual physical inventory of

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sealed sources and brachytherapy sources required by §35.67(g) for 3 years. The inventory records must contain the model number of each source, and serial number if one has been assigned, the identity of each source by radionuclide and its nominal activity, the location of each source, and the name of the individual who performed the inventory.

### § 35.2070 Records of surveys for ambient radiation exposure rate.

A licensee shall retain a record of each survey required by §35.70 for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

### § 35.2075 Records of the release of individuals containing unsealed by-product material or implants containing byproduct material.

(a) A licensee shall retain a record of the basis for authorizing the release of an individual in accordance with §35.75, if the total effective dose equivalent is calculated by—

- (1) Using the retained activity rather than the activity administered;
- (2) Using an occupancy factor less than 0.25 at 1 meter;
- (3) Using the biological or effective half-life; or
- (4) Considering the shielding by tissue.

(b) A licensee shall retain a record that the instructions required by §35.75(b) were provided to a breast-feeding female if the radiation dose to the infant or child from continued breast-feeding could result in a total effective dose equivalent exceeding 5 mSv (0.5 rem).

(c) The records required by paragraphs (a) and (b) of this section must be retained for 3 years after the date of release of the individual.

### § 35.2080 Records of mobile medical services.

(a) A licensee shall retain a copy of each letter that permits the use of by-product material at a client's address, as required by §35.80(a)(1). Each letter must clearly delineate the authority and responsibility of the licensee and

the client and must be retained for 3 years after the last provision of service.

(b) A licensee shall retain the record of each survey required by §35.80(a)(4) for 3 years. The record must include the date of the survey, the results of the survey, the instrument used to make the survey, and the name of the individual who performed the survey.

### § 35.2092 Records of decay-in-storage.

A licensee shall maintain records of the disposal of licensed materials, as required by §35.92, for 3 years. The record must include the date of the disposal, the survey instrument used, the background radiation level, the radiation level measured at the surface of each waste container, and the name of the individual who performed the survey.

### § 35.2204 Records of molybdenum-99 concentrations.

A licensee shall maintain a record of the molybdenum-99 concentration tests required by §35.204(b) for 3 years. The record must include, for each measured elution of technetium-99m, the ratio of the measures expressed as kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (or microcuries of molybdenum per millicurie of technetium), the time and date of the measurement, and the name of the individual who made the measurement.

### § 35.2310 Records of safety instruction.

A licensee shall maintain a record of safety instructions required by §§ 35.310, 35.410, and 35.610 for 3 years. The record must include a list of the topics covered, the date of the instruction, the name(s) of the attendee(s), and the name(s) of the individual(s) who provided the instruction.

### § 35.2404 Records of surveys after source implant and removal.

A licensee shall maintain a record of the surveys required by §§ 35.404 and 35.604 for 3 years. Each record must include the date and results of the survey, the survey instrument used, and the name of the individual who made the survey.