REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart L: Records

This new subpart contains all the specific recordkeeping requirements necessary to implement the requirements in revised Part 35

- Note: Some new sections have been added as a result of new requirements, especially in Subpart H, that codify requirements for remote afterloaders and GSR units that are currently imposed by license conditions. The general requirements for record maintenance, such as electronic storage, are provided in §35.5

§35.2024 Records of authority and responsibilities for radiation protection programs

- Record of actions taken by the licensee's management must be retained for 5 years in accordance with §35.24(a)
  - Note: Record must include a summary of the actions taken and a signature of licensee management
- Retain copy of both the authority, duties, and responsibilities of the RSO according to §35.24(e), and signed copy of each RSO's agreements to be responsible for implementing the safety program as required by §35.24(b) for the duration of the license

§35.2026 Records of radiation program changes

- Licensee is required to retain a record of each radiation protection program change made in accordance with §35.26(a) for 5 years
  - Note: Record must include 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
  - The requirements in old §35.31 "Radiation Safety Program changes" to include the reasons for the program changes, and a summary of radiation safety matters that were considered before making the change, have been deleted

§35.2040 Records of written directives

- Requires the licensee to retain a copy of written directives required by new §35.40 “Written Directives” for 3 years

§35.2041 Records for procedures for administrations requiring a written directive

- Requires the licensee to retain a copy of the procedures required by §35.41(a) for the duration of the license

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

- Record of instrument calibrations performed in accordance with §35.60 must be maintained for 3 years. Must contain:
  - Model and serial number of the instrument;
  - Date of the calibration,
  - Results of the calibration; and
  - Name of the individual who performed the calibration
    - Requirement does not prohibit licensees from continuing to have the individual who performed the calibration sign the record
    - Deleted other prescriptive requirements for the record

§35.2061 Records of radiation survey instrument calibrations

- Record of radiation survey instrument calibrations performed in accordance with §35.61 must be maintained for 3 years. Record must contain:
  - Model and serial number of the instrument;
  - Date of the calibration,
  - Results of the calibration; and
  - Name of the individual who performed the calibration
    - Deleted the descriptions of the calibration procedure and the source used; the certified exposure rates from the source and the rates indicated by the instrument being calibrated; and the correction factors deduced from the calibration data

§35.2063 Records of dosage of unsealed byproduct material for medical use

- Record of dosage determinations required by §35.63 must be maintained for 3 years. Record must contain:
  - Radiopharmaceutical;
  - The patient's or human research subject's name, or identification number if one has been assigned;
  - Prescribed dosage, the determined dosage, or a notation that the total activity is less than 1.1 MBq (30 μCi);
  - Date and time of the dosage determination; and
  - Name of the individual who determined the dosage

§35.2063 Records of dosage of unsealed byproduct material for medical use (continuation)

- The term "dosage measurement" was replaced by the term "dosage determination" to be consistent with the changes made in §35.63

- Deleted the requirement to include the generic name, trade name, or abbreviation of the radiopharmaceutical; its lot number and expiration date; and the activity of the dosage at the time of measurement
  - Note: Expiration date was deleted because it is primarily related to drug stability and sterility, the rest of the requirements were deleted to make the rule less prescriptive

§35.2067 Records of leak tests and inventory of sealed sources and brachytherapy sources

- Record of leak tests and inventory required by §35.67(b) & (g) must be maintained for 3 years
- Leak test record must contain:
  - Model, and serial number (if assigned), of each source tested;
  - Identity of each source radionuclide and its estimated activity;
  - Results of the test;
  - Date of the test; and
  - Name of the individual who performed the test (before was RSO)
- Deleted the requirement to record the measured activity of each leak test sample and a description of the method used to measure each test sample

§35.2067 Records of leak tests and inventory of sealed sources and brachytherapy sources (cont.)

- Source inventory record must contain:
  - Model number of each source, and serial number if one has been assigned;
  - Identity of each source radionuclide and its nominal activity;
  - Location of each source; and
  - Name of the individual who performed the inventory (before was RSO)

§35.2070 Records of surveys for ambient radiation exposure rate

- Record of radiation surveys required by §35.70 must be maintained for 3 years. Record must contain:
  - Date of the survey;
  - Results of the survey;
  - Instrument used to make the survey; and
  - Name of the individual who performed the survey

- Deleted the need to record a plan of each area surveyed; the trigger level established for each area; and the detected dose rate at several points in each area expressed in millirem per hour or the removable contamination in each area expressed in dpm/100 square centimeters

§35.2075 Records of release of individuals containing unsealed byproduct material or implants containing byproduct material

- Record of patient release required by §35.75 must be maintained for 3 years
  - Note: No changes were made in the recordkeeping requirements
- 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 --
  - Using the retained activity rather than the activity administered;
  - Using an occupancy factor less than 0.25 at 1 meter;
  - Using the biological or effective half-life; or
  - Considering the shielding by tissue

§35.2075 Records of release of individuals containing unsealed byproduct material or implants containing byproduct material (cont.)

- 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)
  - Note: There is an intentional difference between the potential dose to the infant/child at which written instructions are required (>0.1 rem) and the potential dose at which a written record of the instructions are required (>0.5 rem)

§35.2080 Records of mobile medical services

- Requires the licensees to:
  - Maintain a copy of each letter that permits the use of byproduct material at a client's address of use for 3 years after the last provision of service; and
  - Retain the records of the surveys for 3 years
- Record of each survey must contain:
  - Date of the survey; result of the survey; instrument used to make a survey; and name of the individual who performed the survey
- Deleted the requirements to record a plan of each area that was surveyed and the measured dose rate at several points in each area of use expressed in millirem per hour

§35.2092 Records of decay-in-storage

- Record of the disposal of licensed material required by §35.92 must be maintained for 3 years. Must contain:
  - Date of the disposal;
  - Survey instrument used;
  - Background radiation level;
  - Radiation level measured at surface of each waste container; and
  - Name of the individual who performed the survey

- Deleted the requirement to record the date that the material was placed in storage and the radionuclides because the requirement to store material for 10 half-lives was deleted

§35.2204 Records of molybdenum-99 concentrations

- Record of molybdenum-99 concentration tests required by §35.204(b) must be maintained for 3 years. Must include:
  - For each elution of Tc-99m, the ratio for the measures expressed as kBq of Mo-99 per MBq of Tc-99m (μCi of Mo per mCi of Tc);
  - Time and date of the measure; and
  - Name of the individual who performed the survey
- Deleted the requirements to record the measured activity of the technetium expressed in mCi and the measured activity of the molybdenum expressed in μCi

§35.2310 Records of safety instructions

- Record of radiation safety instructions required by §35.310, §35.410, and §35.610 must be maintained for 3 years
  - List of the topics covered;
  - Date of the instruction;
  - Name(s) of the attendee(s); and
  - Name of the individual who provided the instruction

- Deleted the term "description of the instruction"
  - Note: Replaced with the term "topics covered" to make clear that the record should contain the topics, e.g., patient, visitor, waste, or contamination control

§35.2404 Records of surveys after source implant or removal

- Requires the licensee to maintain a record of the surveys required by §35.404 and §35.604 for 3 years. Each record must include:
  - Date and results of the survey;
  - Survey instrument used;
  - Name(s) of the attendee(s); and
  - Name of the individual who made the survey

- Deleted the requirement to record the dose rate from the patient or the human research subject expressed as millirem per hour and measured at 1 meter from the patient of human research subject

§35.2406 Records of brachytherapy source accountability

- Requires the licensee to maintain a record as required by §35.406 for 3 years

- Records for temporary implants must include:
  - Number and activity of sources removed from and returned to storage;
  - Time and date they were removed from and returned to storage;
  - Name(s) of the individual(s) who removed them from and returned them to storage; and
  - Location of use

§35.2406 Records of brachytherapy source accountability (continuation)

- Records for permanent implants must include:
  - Number and activity of sources removed from storage;
  - Number and activity of sources permanently implanted in the patient or human research subject;
  - Number and activity of sources not implanted;
  - Date they were removed from & returned to storage; and
  - Name(s) of the individual(s) who removed them from and returned them to storage
- Deleted names of the individuals permitted to handle the sources; name and room number of the patient or the human research subject receiving the implant; number and activity of the sources in storage after the removal; and the number and activity of sources in storage after the return

§35.2432 Records of calibration measurements of brachytherapy sources

- Requires the licensee to maintain a record as required by §35.432 for 3 years after the last use of the source

- The record must contain:
  - Date of the calibration;
  - Manufacturer's name, model number, and serial number for the source and instruments used to calibrate the source;
  - Source output or activity;
  - Source positioning accuracy within the applicators;
  - Signature of individual performing calibration.

§35.2433 Records of decay of strontium-90 sources for ophthalmic treatments

- Requires the licensee to maintain a record as required by §35.433, for the life of the source
- The records for each Sr-90 source must include:
  - Date and initial activity of the source as determined under §35.432; and
  - For each decay calculation, the date and the source activity as determined under §35.433

§35.2605 Records of installation, maintenance, adjustment, and repair of remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery units

- Requires the licensee to maintain a record as required by §35.605 for 3 years
- The records must include date, description of the service, and name(s) of the individual(s) who performed the work
  - Note: Previously, licensees were not required to keep records of installation, maintenance, adjustment, and repair. A record is necessary to document that the units are properly installed, maintained, adjusted, and repaired; to establish trends in unit performance; and to establish a service history that may be used in evaluation of generic equipment problems

§35.2610 Records of safety procedures

- A licensee shall retain a copy of the procedures required by §35.610(a)(4) and (d)(2) until the licensee no longer possesses the remote afterloader, teletherapy unit, or gamma stereotactic radiosurgery unit

§35.2630 Records of dosimetry equipment used with remote afterloader units, teletherapy units, and gamma stereotactic radiosurgery

- Requires the licensee to retain a record of the calibration, intercomparison, and comparisons of its dosimetry equipment done in accordance with §35.630 for the duration of the license. Record must include:
  - Date;
  - Manufacturer's name, model and serial numbers of the instruments that were calibrated, intercompared, or compared as required by paragraphs (a) and (b) of §35.630;
  - Correction factor that was determined from the calibration or comparison or the apparent correction factor that was determined from an intercomparison; and
  - Names of the individuals who performed the calibration, intercomparison, or comparison

§35.2632 Records of teletherapy, remote afterloader, and gamma stereotactic radiosurgery full calibrations

- Requires the licensee to maintain a record as required by §35.632, 35.633, and 35.635 for 3 years
- Recordkeeping requirements were reduced to:
  - Date of the calibration;
  - Manufacturer's name, model number, and serial number for the unit, source and instruments used to calibrate the unit;
  - Results and assessment of the calibration;
  - Results of the autoradiograph required for low dose-rate remote afterloader units; and
  - Signature of the AMP who performed the full calibration

§35.2642 Records of periodic spot-checks for teletherapy units

- Requires the licensee to retain a record as required by §35.642 for 3 years. Record must include:
  - Date of the spot-check;
  - Manufacturer's name, model number, and serial number of the teletherapy unit, source and instrument used to measure the output of the teletherapy unit;
  - Assessment of timer linearity and constancy;
  - Calculated on-off error;
  - Determination of the coincidence of the radiation field and the field indicated by the light beam localizing device;
  - Determined accuracy of each distance measuring and localization device;

§35.2642 Records of periodic spot-checks for teletherapy units (continuation)

- Difference between the anticipated output and the measured output;
- Notations indicating the operability of each entrance door electrical interlock, each electrical or mechanical stop, each source exposure indicator light, and the viewing and intercom system and doors; and
- Name of the individual who performed the periodic spot-check and the signature of the authorized medical physicist who reviewed the record of the spot-check

- A licensee shall retain a copy of the spot check procedures required by §35.642(b) until the licensee no longer possesses the teletherapy unit

§35.2643 Records of periodic spot-checks for remote afterloader units

- Requires the licensee to retain a record as required by §35.643 for 3 years. Record must include:
  - Date of the spot-check;
  - Manufacturer's name, model and serial number for both the remote afterloader unit and source;
  - Assessment of timer accuracy;
  - Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, clock and decayed source activity in the unit's computer; and
  - Name of the individual who performed the periodic spot-check and the signature of the AMP who reviewed the record

§35.2643 Records of periodic spot-checks for remote afterloader units (continuation)

- A licensee shall retain a copy of the spot check procedures required by §35.643(b) until the licensee no longer possesses the remote afterloader unit

§35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units

- Requires the licensee to retain a record as required by §35.645 for 3 years. Record must include:
  - Date of the spot-check;
  - Manufacturer's name, model and serial number for the GSR unit and the instrument used to measure the output of the unit;
  - Assessment of timer linearity and accuracy;
  - Calculated on-off error;
  - Determination of trunnion centricity;
  - Difference between the anticipated output and measured output;
  - Assessment of source output against computer calculations;

§35.2645 Records of periodic spot-checks for gamma stereotactic radiosurgery units (cont.)

- Record must include:
  - Notations indicating the operability of radiation monitors, helmet microswitches, emergency timing circuits, emergency off buttons, electrical interlocks, source exposure indicator lights, viewing and intercom systems, timer termination, treatment table retraction mechanism, stereotactic frames and localizing devices (trunnions); and
  - Name of the individual who performed the periodic spot-check and signature of the AMP who reviewed the periodic spot-check

- A licensee shall retain a copy of the spot check procedures required by § 35.645(b) until the licensee no longer possesses the gamma stereotactic radiosurgery unit

§35.2647 Records of additional technical requirements for mobile remote afterloader units

- Requires the licensee to retain a record as required by §35.647 for 3 years. Record must include:
  - Date of the check;
  - Manufacturer's name, model and serial number for the unit;
  - Notations accounting for all sources before departing from a facility;
  - Notations indicating the operability of each entrance door electrical interlock, radiation monitors, source exposure indicator lights, viewing and intercom system, applicators, source transfer tubes, and transfer tube applicator interfaces, and source positioning accuracy; and
  - Signature of the individual who performed the check

§35.2652 Records of surveys of therapeutic treatment units

- Requires the licensee to retain a record as required by §35.652 for the duration of use of the unit. Must include:
  - Date of the measurements;
  - Manufacturer's name, model and serial number of the treatment unit, source, and instrument used to measure radiation levels;
  - Each dose rate measured around the source while the unit is in the off position and the average of all measurements; and
  - Signature of the individual who performed the surveys
- Deleted requirements to maintain a plan of the areas surrounding the treatment room that were surveyed, the measured dose rate at several points expressed in mrem/hour, and the calculated maximum quantity of radiation over a period of 1 week for each restricted and unrestricted area

§35.2655 Records of 5-year inspection for teletherapy and gamma stereotactic radiosurgery units

- Requires the licensee to retain a record as required by §35.655 for the duration of use of the unit. Must include:
  - Inspector's radioactive materials license number;
  - Date of inspection;
  - Manufacturer's name, model and serial number for both the treatment unit and source;
  - List of components inspected and serviced, and the type of service; and
  - Signature of the inspector
- Deleted the requirement to maintain a record of the components replaced