REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart F: Manual Brachytherapy

New Subpart F replaces the requirements in the old Subpart G, “Sources for Brachytherapy”

- The following section was deleted:
  - §35.420 Possession of survey instruments
    - §20.1501 requires the licensee to make surveys to demonstrate compliance with Part 20, and requires the licensee to ensure that instruments and equipment used to show compliance with Part 20 are periodically calibrated. In addition, §30.33(a)(2) requires the licensee to have adequate instrumentation.

§35.400 Use of sources for manual brachytherapy

- A licensee shall use only brachytherapy sources for therapeutic medical uses:
  - As approved in the Sealed Source & Device Registry; or
  - In research in accordance with an active Investigational Device Exemption (IDE) application accepted by FDA
- Deleted reference of specific sources and its medical uses
  - Cs-137, Co-60, Au-198, Ir-192, Sr-90, I-125, & Pd-103

§35.404 Surveys after source implant and removal

- Immediately after implanting sources the licensee shall make a survey to locate and account all sources that have not been implanted
  - Note: This survey may be a visual or a radiation survey
- Immediately after removing the last temporary implant source, the licensee shall make a radiation survey of the patient to confirm that all sources have been removed
- Deleted the requirement that a licensee may not release a patient or a human research subject treated by temporary implant until all sources have been removed

§35.406 Brachytherapy sources accountability

- A licensee shall maintain accountability at all times for all brachytherapy sources in storage or use

- Deleted the majority of the prescriptive requirements and associated recordkeeping requirements

§35.410 Safety instruction

- Revised to state that instruction requirements in §35.410 are in addition to the training requirements in §19.12
- Safety instruction must be provided initially and at least annually to personnel caring for patients who cannot be released in accordance with §35.75
  - Must include visitor and patient control, safe handling/shielding
- Personnel should notify the RSO, or his or her designee, and the AU if the patient has a medical emergency or dies

§35.410 Safety instruction (continuation)

- Visitor control:
  - Routine visitation to hospitalized individuals must be in accordance with §20.1301(a)(1) [Limit to members of the public: 100 mrem/year], and
  - Visitation authorized must be in accordance with §20.1301(c)
    - §20.1301(c): Licensee may permit visitors to individuals who cannot be released, under §35.75, to receive dose greater than 100 mrem if:
    - a) Radiation dose received does not exceed 500 mrem, and
    - b) The AU has determined before the visit that it is appropriate

§35.415 Safety precautions

- Revised to clarify that the requirements in this section only apply if a patient or human research subject cannot be released in accordance with §35.75
- Amended to clarify that a patient or human research subject who is receiving brachytherapy can only share a room with another brachytherapy patient
- Requires to have emergency response equipment available near each treatment room to respond to:
  - A source dislodged from the patient; and
  - Lodged within the patient following removal of the source applicators

§35.415 Safety precautions (continuation)

- Require that the patient's room be visibly posted
- Deleted the following because they are radiation protection requirements that are covered under Part 20:
  - The licensee shall authorize visits by individuals under age 18 on a case by case basis with approval of RSO and AU
  - After implanting the material, measure dose rate in contiguous restricted & unrestricted areas to show compliance with Part 20
  - Retain for 3 years record of survey that includes area surveyed, measured dose rates in mrem/hour, instrument used to make survey, and initials of individual who make the survey

§35.432 Calibration measurements of brachytherapy sources

- Requires calibration measurements on brachytherapy sources before the first medical use of the source(s) after the effective date of the rule

- Allows the licensee to rely on the output measurement provided by the source manufacturer or by a calibration laboratory accredited by the American Association of Physicists in Medicine, as long as the calibration was conducted in accordance with a published protocol accepted by a nationally recognized body and appropriately calibrated equipment was used

§35.433 Decay of strontium-90 sources for ophthalmic treatments

- Requires that only an AMP may calculate the activity of a Sr-90 source that is used to determine the treatment times for ophthalmic treatments
- Decay must be based on the activity determined under §35.432

§35.457 Therapy-related computer systems

- Licensee shall perform acceptance testing on the treatment planning system of therapy-related computer systems in accordance with published protocols accepted by nationally recognized bodies

- Acceptance testing must include verification of:
  - Source-specific input parameters required by the dose calculation algorithm;
  - Accuracy of dose, dwell time, and treatment time calculations at representative points;
  - Accuracy of isodose plots and graphic displays; and
  - Accuracy of the software used to determine sealed source positions from radiographic images

§35.490 Training for use of manual brachytherapy sources

- Licensee shall require this AU to be a physician who:
  - 1) Is certified by a medical specialty board, or
  - 2) Has completed 200 hours of classroom & laboratory training, and 500 hours of work experience under the supervision of an AU who meets §35.490, or equivalent AS requirements, at a medical institution, and
  - Three years of supervised clinical experience in radiation oncology under the supervision of an AU who meets §35.490, and
  - Has obtained a written certification by a preceptor AU who meets §35.490, or equivalent AS requirements

§35.491 Training for ophthalmic use of strontium-90

- Licensee shall require this AU to be a physician who:
  - 1) Is an AU under §35.490 or equivalent AS requirements, or
  - 2) Has completed 24 hours of classroom & laboratory training, and supervised clinical training in ophthalmic radiotherapy under the supervision of an AU at a medical institution that includes the use of Sr-90 for the ophthalmic treatment of five individuals, and
  - Has obtained a written certification by a preceptor AU who meets §35.490, §35.491, or equivalent AS requirements