REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart C: General Technical Requirements

§35.60 Possession, use, and calibration of instruments used to measure the activity of unsealed byproduct material

- Addresses calibration of all instruments used to measure the activity of all unsealed byproduct materials,
  - No longer refers to dose calibrators and instruments used to measure dosages of alpha- or beta-emitting radionuclides
- Instrument calibration in accordance with nationally recognized standards or with the manufacturer's instructions
- No longer contains prescriptive requirements such as constancy, linearity, accuracy, and geometry tests

§35.61 Calibration of survey instrument

- Requires calibration of survey instruments used to show compliance with Part 35 & Part 20 before first use, annually, and following repairs that affect calibration
- Requires that survey instruments be removed from use if the indicated exposure rate differs from the calculated exposure rate by more than 20 percent
- No longer includes requirements such as:
  - Note on instrument the apparent exposure rate from a dedicated source as determined at the time of calibration
  - Attachment of correction chart or graph to instruments
  - Perform daily check of instrument with dedicated source to determine proper operation

§35.63 Determination of dosages of unsealed byproduct material for medical use

- Requires licensees to determine and record the activity of each dosage before medical use
- If licensee uses only unit dosages, then dosage must be determined by:
  - Direct measurement of radioactivity, or
  - A decay correction based on the activity or activity concentration determined by a manufacturer or preparer licensed under §32.72 or equivalent Agreement States requirements, or
  - An NRC or AS licensee for use in research in accordance with a Radioactive Drug Research Committee (RDRC)-approved protocol or an Investigational New Drug (IND) protocol accepted by the Food and Drug Administration

§35.63 Determination of dosages of unsealed byproduct material for medical use (continuation)

- For other than unit dosages, the licensee must determine the dosage by:
  - Direct measurement of radioactivity, or
  - Combination of direct measurement of radioactivity and mathematical calculations; or
  - By combination of volumetric measurements & mathematical calculations based on the measurement made by a manufacturer or preparer licensed under §32.72 or equivalent AS requirements

- A licensee may not use a dosage if
  - the dosage does not fall within the prescribed dosage range, or
  - if the dosage differs from the prescribed dosage by more than 20%

§35.65 Authorization for calibration, transmission, and reference sources

- Allows receipt, possession, and use of sealed sources if they do not exceed 1.11GBq (30 mCi) each and they are manufactured and distributed by a person licensed under §32.74 or equivalent AS regulations
- Allows redistribution of the above sealed sources by a licensee authorized to redistribute the sealed sources, providing the redistributed sealed sources are in the original packaging and shielding and are accompanied by the manufacturer's approved instructions
- Deleted the possession limit for Tc-99m

§35.65 Authorization for calibration, transmission, and reference sources (continuation)

- Allows possession of calibration and reference sources with half-lives not longer than 120 days in individual amounts not to exceed 0.555 GBq (15 mCi)

- Allows possession of any byproduct material with a half-life longer than 120 days in individual amounts that do not exceed the smaller of the following two values:
  - 7.4 MBq (200 μCi) or
  - 1000 times the quantities in Appendix B of Part 30

§35.67 Requirements for possession of sealed sources and brachytherapy sources

- Leak test of source before first use (unless certificate from the supplier show test was done within 6 months) and leak test of source at intervals not to exceed 6 months or at other intervals approved in the Sealed Source and Device Registry (SSDR)

- Allow leaking sources to be withdrawn from use and stored, repaired or disposed

§35.67 Requirements for possession of sealed sources and brachytherapy sources (continuation)

- Semi-annual source inventory
  - Note: Gamma stereotactic radiosurgery sources are exempted from the requirement of physical inventory
- Deleted the requirement to maintain the instructions for the duration of source use
- Deleted the requirements on how to satisfy the leak test
- Deleted the requirements for the quarterly ambient dose rate survey and its recordkeeping

§35.69 Labeling of vials and syringes

- Requires that syringes and vials containing unsealed byproduct material be labeled to identify the radioactive drug
- Also requires that syringe shields and vial shields be labeled unless the label on the syringe or vial is visible when shielded
- Licensees are still required to show compliance with the labeling requirements in 10 CFR Part 20

- Deleted reference to shielding of vials and syringes

§35.70 Ambient exposure rate surveys

- Perform radiation survey (end of each day of use) of all areas where unsealed byproduct material requiring a written directive was prepared for use or administered except areas:
  - Where patients are confined & cannot be released under §35.75

- This section no longer contains requirements such as:
  - Weekly surveys of storage and waste storage areas, ability to detect 0.1 mrem/hr, and establishing radiation dose trigger levels
  - Weekly surveys for removable contamination, ability to detect 2000 dpm, and establishing contamination trigger levels

§35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material

- Allows the release from licensee control of any individual who has been administered unsealed byproduct material or implants containing byproduct material if the total effective dose equivalent to any other individual from exposure to the released individual is not likely to exceed 5 mSv (0.5 rem)
- Must provide the released individual or to the individual's parent or guardian, with written instructions to maintain doses ALARA if the TEDE to any other individual is likely to exceed 1 mSv (0.1 rem)

§35.75 Release of individuals containing unsealed byproduct material or implants containing byproduct material (continuation)

- Must provide to an individual written instructions to maintain doses ALARA if the TEDE to a nursing infant or child could exceed 1 mSv (0.1 rem)
- Instructions must include information on potential consequences, if any, of failure to follow the guidance
- Reference of NUREG-1556 Vol. 9 in footnote instead of Regulatory Guide 8.39 "Release of Patients Administered Radioactive Materials"

§35.80 Provision of mobile medical service

- Must obtain a letter from its client that permits the use of byproduct material at the client's address
- Must check the instruments used to measure the activity of unsealed byproduct materials for constancy before medical use at each address of use or on each day of use, whichever is more frequent
- Must check survey instruments for proper operation with a dedicated check source, before use, at each client's address

§35.80 Provision of mobile medical service (continuation)

- Requires survey of all areas of use to ensure compliance with the dose limits in Part 20 before leaving each client's address
- Does not allow byproduct material to be delivered from the manufacturer or the distributor to the client, unless the client has a license allowing possession
- Deleted the requirements for a licensee to:
  - Transport to each address of use only syringes or vials containing prepared radiopharmaceuticals, or for reconstitution
  - Bring into each address of use all byproduct material to be used; and before leaving, remove unused material and waste
  - Secure or keep under surveillance and control all material

§35.92 Decay-in-storage

- Allow decay-in-storage for byproduct material with a physical half-life of less than 120 days before disposal
- Remove or obliterate all radiation labels, except for radiation labels on materials that are within containers and that will be managed as biomedical waste after they have been released from the licensee
- This section no longer contains a requirement to hold materials for 10 half-lives, and to separate and monitor each generator column