REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL

Subpart D: Unsealed Byproduct Material - Written Directive Not Required

This subpart combines the requirements in the old Subpart D, “Uptake, dilution, and excretion” and old Subpart E, “Imaging and localization”

- The following sections were deleted:
  - §35.120 Possession of survey instrument
    - §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.
  - §35.205 Control of aerosol and gases
    - Part 35 licensees must comply with the occupational and public dose limits of Part 20
  - §35.220 Possession of survey instruments

§35.100 Use of unsealed byproduct material for uptake, dilution, and excretion studies for which a written directive is not required

- A licensee may use any byproduct material prepared for medical use for uptake, dilution, or excretion studies if:
  - Obtained from a manufacturer licensed under §32.72 or equivalent Agreement State requirements, or
  - Prepared by an ANP, or an AU who meets §35.290 or §35.390, or an individual under the supervision of an ANP or AU, or
  - Obtained from & prepared by 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 FDA, or
  - Prepared by the licensee for use in research in accordance with an RDRC approved application or an IND protocol

§35.190 Training for uptake, dilution, and excretion studies

- An AU under §35.100 will be a physician who:
  - 1) Is certified by a specialty board whose certification process has been recognized by NRC/Agreement States, or
  - 2) Is an AU under §35.290 (imaging & localization) or §35.390 (use of unsealed byproduct material, written directive required), or
  - 3) Has completed 60 hours of training and work experience (under the supervision of an AU who meets §35.190, §35.290, §35.390, or equivalent AS requirements), and
  - Has obtained a written certification by a preceptor AU who meets §35.190, §35.290, or §35.390

§35.200 Use of unsealed byproduct material for imaging and localization studies for which a written directive is not required

- A licensee may use any byproduct material prepared for medical use for imaging and localization studies if:
  - Obtained from a manufacturer licensed under §32.72 or equivalent Agreement State requirements, or
  - Prepared by an ANP, or AU who meets §35.290 or §35.390, or an individual under the supervision of an ANP or AU, or
  - Obtained from & prepared by 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 FDA, or
  - Prepared by the licensee for use in research in accordance with an RDRC approved application or an IND protocol

§35.204 Permissible molybdenum-99 concentration

- A licensee may not administer a radiopharmaceutical that contains more than 0.15 kilobecquerel of molybdenum-99 per megabecquerel of technetium-99m (0.15 microcurie of molybdenum-99 per millicurie of technetium-99m)

- A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of the first eluate after receipt of a generator

§35.290 Training for imaging and localization studies

- An AU under §35.200 will be a physician who:
  - 1) Is certified by a specialty board whose certification process has been recognized by NRC/Agreement States, or
  - 2) Is an AU under §35.390 (use of unsealed byproduct material, written directive required), or
  - 3) Has completed 700 hours of training and work experience (under the supervision of an AU who meets §35.290, §35.390, or equivalent AS requirements), and
  - Has obtained a written certification by a preceptor AU who meets §35.290, or §35.390