

# **REVISED 10 CFR PART 35: MEDICAL USE OF BYPRODUCT MATERIAL**

## **Subpart C: General Technical Requirements**

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

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- 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

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- 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

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- 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)

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- 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

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- 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)

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- 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  $\mu$ Ci) or
  - ▶ **1000 times the quantities in Appendix B of Part 30**

## §35.67 Requirements for possession of sealed sources and brachytherapy sources

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- 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)

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- **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

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- 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

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- 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

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- 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)

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- 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

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- 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)

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- 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

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- 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