#16

Potential Changes to 10 CFR Part 35

ACMUI Meeting

October 28, 2008

Donna-Beth Howe, Ph.D.

10 CFR 30.35(b)

- **Problem:** 30.35(b) requires a certificate of financial assurance for decommissioning for licensees authorized for the possession and use of sealed sources including Co-60 with a half-life greater than 120 days and in quantities exceeding 10,000 but less than 1,000,000 curies for Co-60. Most medical use licensees do not exceed these limits and require financial assurance for sealed sources unless they possess multiple gammaknife units. However, a medical use licensee with a single gammaknife unit that has not gone through a complete half life of decay that changes the sources may exceed the limit for the short period of time that the sources are exchanged or a new replacement unit is installed. The financial assurance requirements should not apply to short term (60 day period) in which the limits are exceeded because of source exchange.
- **Recommend: Revise 30.35(b) to read:**

  (b) Each applicant for a specific license authorizing possession and use of byproduct material of half-life greater than 120 days and in quantities specified in paragraph (d) of this section (except licensees that exceed these limits for 60 days due to source exchange) shall either–

10 CFR 35.40

- Problem: The authorized user (AU) is required to date and sign the written directive. 35.40(b)(6) requires a two part written directive for "all other brachytherapy, including low, medium, and pulsed dose rate remote afterloaders." The two part written directive involves before implantation and after implantation but before completion of the procedure. The proposed Part 35 rulemaking clarifies that the AU needs to sign and date the additional information provided after implantation but before completion of the procedure. However, this rulemaking only addressed permanent manual brachytherapy and not all the brachytherapy modalities in 35.40(b)(6).
- Recommend: Revise 10 CFR 35.40 to clarify that the AU needs to sign and date both the before administration and after implantation parts of the written directive for all modalities with two part written directives.

10 CFR 35.65 and 35.590

- **Problem:** 35.65 authorizes medical use licensees to use byproduct material for transmission sources as well as check, calibration, and reference use. All the other sources are used for quality control and quality assurance test when evaluating the function of equipment traditionally found in medical use facilities. These sources are not used to produce radiation for use on humans.

  The transmission source on the other hand is used in medical procedures to irradiate patients and human research subjects as part of the imaging process and therefore a medical use. Although a medical use source, it is the only type of medical use source that is not included under one of the types of medical use and associated with a specific type of authorized user. For consistency with other medical uses, the transmission sources when used to irradiate human subjects (as opposed to phantoms) should be moved into 35.500 and authorized for use by AU's meeting the requirements of 35.590 or 35.290.

10 CFR 35.65 and 35.590 cont

Recommend:

Revise 35.65 to clarify it does not apply to sources used for medical use, i.e., the intentional external administration of radiation from byproduct material to patients or human research subjects.

"Any person authorized by § 35.11 for medical use of byproduct material may receive, possess, and use any of the following byproduct material for check, calibration, transmission, and reference use provided the byproduct material is not used to intentionally administer radiation from byproduct material to patients or human research subjects."

Revise 35.590 to permit the use of transmission sources under 35.500 by authorized users meeting the training and experience requirements of 35.590 or 35.290.

Except as provided in § 35.57, the licensee shall require the authorized user of a diagnostic sealed source for use in a device authorized under § 35.500 to be a physician, dentist, or podiatrist who–

(a)…; or

(c) Has completed training in the use of the device for the uses requested; or

(d) Is an authorized user under § 35.290 requesting use of a transmission source for administering radiation to a patient or human research subject."

10 CFR 35.204(b)

- **Problem: 35.204(b) permits licensees that elute Mo-99/Tc-99m generators to perform moly-breakthrough measurements on the first generator eluate to demonstrate compliance with the requirement that a licensee may not administer to humans 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).**

  Before the 2002 revision to Part 35, licensees were required to measure moly-breakthrough at each elution to show compliance with the Mo-99 administration requirement. Experience at that time indicated a defective generator would always fail the test on the first elution. However, recent information from a major generator manufacturer shows that there are generator defects that are only detectable by moly-breakthrough measurements performed during later elutions. Therefore, compliance with the limits of Mo-99 that can be administration to humans cannot be made by simply measuring moly-breakthrough on the first elution.

10 CFR 35.204(b) cont.

Revise **35.204(b)** to read

(b) A licensee that uses molybdenum-99/technetium-99m generators for preparing a technetium-99m radiopharmaceutical shall measure the molybdenum-99 concentration of each eluate after receipt of a generator to demonstrate compliance with paragraph (a) of this section.

10 CFR 35.50, 35.51, ..., 35.690

- Problem: All the training and experience requirements in 10 CFR Part 35 that include supervised work experience and attestations require the supervising individual and the attestation preceptor to meet the training and experience requirements of that section. The effect of this is if an individual acchieved RSO, AMP, AU, or ANP status under previous requirements they could not technically funtion as the supervising individual or preceptor.

10 CFR 35.50, 35.51, ..., 35.690

Recommend

Revise each section requiring supervised work experience and preceptor statements to either:

(1) include individuals meeting the criteria under 35.57 for that particular use, or

(2) permit individuals identified on a license as an RSO, AMP, ANP, or AU for that particular use

to be the supervising individual or provide the attestation.