Potential Changes to 10 CFR Part 35
ACMUI Meeting
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Donna-Beth Howe, Ph.D.

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

10 CFR 35.65 and 35.590 cont

10 CFR 35.204(b)

Problem: 35.204(b) permits licensees that elute Mo-99/Tc-99m generators to perform moly-breachthrough 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 kilo Becquerel 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 detector 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 administered 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 achieved RSO, AMP, AU, or ANP status under previous requirements they could not technically function 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.