UNITED STATES NUCLEAR REGULATORY COMMISSION OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS WASHINGTON, D.C. 20555-0001

November 7, 2002

NRC REGULATORY ISSUE SUMMARY 2002-20 CLARIFICATION OF REQUIREMENTS UNDER 10 CFR 35.432, "CALIBRATION MEASUREMENTS OF BRACHYTHERAPY SOURCES"

ADDRESSEES:

All medical licensees.

INTENT:

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to provide clarification to addressees concerning the requirements under 10 CFR 35.432, "Calibration of measurements of brachytherapy sources." No specific action or written response is required.

BACKGROUND:

The requirements governing calibration of manual brachytherapy sources are contained in 10 CFR 35.432, and the associated record-keeping requirements are contained in 10 CFR 35.2432. It has recently been identified that 10 CFR 35.2432(b)(5) states that "The signature of the authorized medical physicist" is part of the required record for 10 CFR 35.432 calibrations. However, there is no corresponding requirement, in 10 CFR 35.432, to have an authorized medical physicist (AMP) perform calibrations of manual brachytherapy sources.

The requirement for an AMP's signature was intended to be associated with 10 CFR 35.2433, "Records of decay of strontium-90 sources for ophthalmic treatments." An AMP is required, under 10 CFR 35.433 (the requirement associated with 10 CFR 35.2433), to calculate the activity of each strontium-90 source that is used to determine the treatment times for ophthalmic treatments.

SUMMARY OF ISSUE:

An AMP is not required to perform the calibration of manual brachytherapy sources. NRC plans to exercise enforcement discretion in not citing licensees whose records of calibration measurements of manual brachytherapy sources do not contain an AMP's signature. This policy will remain in effect while NRC evaluates a revision to the record-keeping requirements in 10 CFR 35.2432 and 35.2433.

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This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the technical contact listed below or the appropriate regional office.

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Attachment:

1. List of recently issued NRC Regulatory Issue Summaries