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.

ML023100622

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.

Donald A. Cool, Director Division of Industrial and Medical Nuclear Safety Office of Nuclear Material Safety and Safeguards

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1. List of recently issued NRC Regulatory Issue Summaries

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LIST OF RECENTLY ISSUED NRC REGULATORY ISSUE SUMMARIES

Regulatory Issue Summary No. Subject		Date of Issuance	Issued to			
2002-19	New Modalities to be Regulated Under 10 CFR 35.1000	10/21/2002	All medical licensees authorized to use byproduct material for therapeutic administration.			
2002-18	Issuance of Orders Imposing Additional Physical Protection Measures for the Transportation of Spent Nuclear Fuel Greater than 100 Grams	10/03/2002	All U.S. Nuclear Regulatory Commission specific power reactor licensees, research and test reactor licensees, independent spent fuel storage installation licensees, and special nuclear material licensees, who possess spent nuclear fuel; and general licensees under 10 CFR 70.20a who transport spent nuclear fuel greater than 100 grams.			
2002-14, Sup. 1	Proposed Changes to the Safety System Unavailability Performance Indicators	09/30/2002	All holders of operating licenses for nuclear power reactors, except those who have permanently ceased operations and have certified that fuel has been permanently removed from the reactor vessel.			
2002-17	Guidance on Performing Military Service Verification	09/19/2002	All holders of operating licenses for nuclear power reactors.			
2002-16	Current Incident Response Issues	09/13/2002	All holders of operating licenses for nuclear power plants.			
2002-15	NRC Approval of Commercial Data Encryption Systems for the Electronic Transmission of Safeguards Information	08/28/2002	All authorized recipients and holders of sensitive unclassified safeguards information (SGI).			
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