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

February 5, 2004

NRC INFORMATION NOTICE 2004-02: STRONTIUM-90 EYE APPLICATORS: NEW CALIBRATION VALUES AND USE

Addressees:

All U.S. Nuclear Regulatory Commission (NRC) medical-use licensees and NRC master materials license medical-use permittees.

Purpose:

NRC is issuing this Information Notice (IN) to inform all medical-use licensees and permittees of information regarding the use of newly calibrated strontium-90 (Sr-90) eye applicators. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this IN are not new NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances:

This notice alerts medical-use licensees and permittees to discrepancies associated with new and older calibration values for Sr-90 eye applicators and effects this may have on their use under the regulatory requirements in 10 CFR Part 35, “Medical Use of Byproduct Material.”

Discussion:

NRC issued an IN, in 1994, on the calibration and use of Sr-90 eye applicators (IN 94-17, March 11, 1994) that, among other things, informed licensees that: (1) researchers at the National Institute of Standards and Technology (NIST) recognized large discrepancies among calibrated outputs assigned to Sr-90 eye applicators; (2) original manufacturer calibrations were expressed in older (traditional) units, which differed from the System Internationale (SI) units; (3) calibration values were not comparable for units from different manufacturers; and (4) discrepancies larger than 10 percent could exist when comparing output measurements between competent measurement laboratories using state-of-the-art techniques.

At that time, the Advisory Committee on the Medical Uses of Isotopes (ACMUI) advised the staff that calibration was not a critical factor in the use of Sr-90 eye applicators for treating pterygium because licensees treated for response rather than to tolerance. Members of the ACMUI recommended that the Sr-90 eye applicator licensees continue to treat patients as they had using the original manufacturer’s Sr-90 activity values and treatment times derived from decay correction charts. The ACMUI further recommended cautioning licensees that if they were to use an applicator other than the one currently in their possession, or if they were to buy a new one, their current technique might not be applicable to another device because of variances in stated and actual exposure rates for the different applicators.

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In 1991, NIST implemented major revisions to its method for performing these calibrations. The major changes involved using a collecting electrode smaller than the source being calibrated and restricting measurements to air gaps less than 0.2 millimeter (mm). These changes yielded current-versus-air-gap data that are linear and which extrapolate unambiguously at distances down to zero air gap. NIST reviewed additional changes in the recombination corrections, stopping-power averages, and corrections for electrode backscatter. NIST continues to review and refine its calibration calculations and techniques for Sr-90 eye applicators.

Before October 2002, if a medical-use licensee or permittee had a calibration certificate for its eye applicator, the licensee or permittee was not required to re-calibrate its eye applicators. Effective October 24, 2002, NRC amended its regulations at 10 CFR 35.432, "Calibration measurements of brachytherapy sources." This section of the regulations requires, among other things, that brachytherapy sources be calibrated before first medical use on or after the effective date of the rule. The effect of this requirement on Sr-90 eye applicator licensees and permittees was that they all had to have their applicators calibrated using the new techniques that more accurately measure the actual exposure rate for the eye applicator and provide the calibration results in SI units. Thus, the calibration values and units may be significantly different from those provided in the original manufacturer's calibrations or more recent calibrations.

NRC expects each Sr-90 eye applicator licensee and permittee to carefully review the results of the new calibration with its authorized medical physicist to assure proper interpretation of the calibration results. This review should include discussion of appropriate changes to the written directives so that the patient treatments are based on the new calibration information. As described below, the authorized user has several options and should select the best option, based on his/her medical judgment, for his/her practice. It is important for the licensee or permittee to keep in mind that, although the units and calibration values may be different, the actual amount of radioactive material (corrected for decreases from radioactive decay) contained in each applicator and its distribution in the applicator remains the same.

The written directive regulations for eye applicator procedures require that the licensee (or permittee) include the following information in the written directive:

- prior to implantation: treatment site, radionuclide, and dose;
- after implantation, but prior to completion of procedure: treatment site, radionuclide, number of sources, and total source strength and exposure time (or total dose).

Maintaining the same treatment regimen - revising total dose in the written directive.

If the licensee's or permittee's medical experience with its Sr-90 treatment regimen before the October 2002 required recalibration indicated that the treatments provided appropriate medical results, the authorized user may elect to administer the same amount of radiation to the

treatment site and provide the same medical results after recalibration, as before. Even though the units and calibration values may be different from those of an earlier calibration, the actual exposure rate (corrected for decreases from radioactive decay) remains the same.

Therefore, to administer the same amount of radiation from a specific eye applicator, the authorized user should keep the treatment time the same and adjust the total dose to a new value, based on the new calibration exposure rate.

For example, based on the original manufacturer's calibration data, the authorized user believes that the exposure rate is 0.42 gray per second (Gy/sec), but the exposure rate based on the new calibration certificate is really 0.55 Gy/sec, a value 31 percent higher. The authorized user's medical experience is that the treatment times used in the past provided good medical results. To achieve the same medical results, the authorized user would keep the administration time the same and increase the value of the total dose documented in the written directive by 31 percent. The treatment times will change with time, because of the normal radioactive decay of the Sr-90.

Changing the treatment regimen - retaining the same written directive total dose value.

Although the authorized user's medical experience with his/her Sr-90 treatment regimen before the October 2002 required calibration indicated that the treatments provided appropriate medical results, the authorized user decides he/she wants to keep the value of the total dose the same in future written directives. In this case, the authorized user will adjust the treatment time so that the total dose value recorded in the written directive does not change. Because the treatment regimen is changed, the authorized user should monitor his/her patients to see if the expected medical results stay the same or change.

For example, based on the original manufacturer's calibration data, the authorized user believes that the exposure rate is 0.42 Gy/sec, but the exposure rate based on the new calibration certificate is really 0.55 Gy/sec, a value 31 percent higher. In this example, the authorized user decides to keep the total dose value the same in the written directive. To achieve the same value for the total dose, the authorized user would have to reduce the administration time by 31 percent.

This IN requires no specific action nor written response. If you have questions about the information in this notice, please contact the appropriate technical contact listed below.

/RA/ PKHolahan for

Charles L. Miller, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Technical contacts: Donna-Beth Howe, Ph.D., NMSS
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1. List of Recently Issued NRC Information Notices
2. List of Recently Issued NMSS Information Notices

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Information Notice No.	Subject	Date of Issuance	Issued to
2004-01	Auxiliary Feedwater Pump Recirculation Line Orifice Fouling - Potential Common Cause Failure	01/21/2004	All holders of operating licenses or construction permits for nuclear power reactors, except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor.
2002-26, Sup 2	Additional Failure of Steam Dryer After A Recent Power Uprate	01/09/2004	All holders of an operating license or a construction permit for nuclear power reactors, except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor.
2003-11, Sup 1	Leakage Found on Bottom-Mounted Instrumentation Nozzles	01/08/2004	All holders of operating licenses or construction permits for nuclear power reactors, except those that have permanently ceased operations and have certified that fuel has been permanently removed from the reactor.
2003-22	Heightened Awareness for Patients Containing Detectable Amounts of Radiation from Medical Administrations	12/09/2003	All medical licensees and NRC Master Materials License medical use permittees.
2003-21	High-Dose-Rate-Remote-Afterloader Equipment Failure	11/24/2003	All medical licensees.

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OL = Operating License
CP = Construction Permit

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2003-21	High-Dose-Rate-Remote-Afterloader Equipment Failure	11/24/2003	All medical licensees.
2003-20	Derating Whiting Cranes Purchased Before 1980	10/22/2003	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; applicable decommissioning reactors, fuel facilities, and independent spent fuel storage installations.
2003-16	Icing Conditions Between Bottom of Dry Storage System and Storage Pad	10/06/2003	All 10 CFR Part 72 licensees and certificate holders.
2003-12	Problems Involved in Monitoring Dose to the Hands Resulting from the Handling of Radiopharmaceuticals	08/22/2003	All holders of 10 CFR Parts 32, 33, and 35 licenses.
2003-10	Criticality Monitoring System Degradation at BWX Technologies, Inc., Nuclear Products Division, Lynchburg, VA	08/04/2003	All U.S. Nuclear Regulatory Commission (NRC) licensees authorized to possess a critical mass of special nuclear material.

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