

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

March 11, 1994

NRC INFORMATION NOTICE 94-17: STRONTIUM-90 EYE APPLICATORS:
SUBMISSION OF QUALITY MANAGEMENT
PLAN (QMP), CALIBRATION, AND USE

Addressees

All U.S. Nuclear Regulatory Commission Medical Use Licensees.

Purpose

The NRC is issuing this Information Notice to remind licensees authorized to possess Sr-90 for authorized uses described in 10 CFR 35.400(e) of the need to: (1) implement and submit a quality management plan (QMP) that includes policies and procedures to meet the requirements described in 10 CFR 35.32; and (2) inform all licensees of recent information regarding the use and calibration of Sr-90 eye applicators.

Description of Circumstances

There has been confusion as to the need for a QMP for Sr-90 eye applicators used for patient treatment procedures. The NRC's Office of the General Counsel advised the technical staff that because the QM program requirements in 10 CFR 35.32 apply to "any brachytherapy dose," the use of Sr-90 eye applicators, as described in 10 CFR 35.400(e), requires submission of a QMP. This Information Notice reminds Sr-90 eye applicator licensees of the requirement to submit and implement a QMP that meets the requirements of 10 CFR 35.32.

Additionally, this letter alerts licensees to possible discrepancies associated with the calibration of Sr-90 eye applicators and reminds licensees of the regulatory requirements associated with their calibration and use.

Discussion

Submission of a Quality Management Plan

If you are licensed for and using a Sr-90 eye applicator, the NRC's regulations require you to submit a QMP that meets the requirements of 10 CFR 35.32. The QMP should provide high confidence that radiation from the Sr-90 eye applicator will be administered as directed by the authorized user. The submitted QMP should include written policies and procedures that meet the five objectives, as described in 10 CFR 35.32(a):

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1. That prior to administration, a written directive, signed and dated by an authorized user, is prepared for each applicable administration.

(A written directive for Sr-90 eye-applicators means an order, in writing, for a specific patient, dated and signed by an authorized user prior to administration of radiation. It must include the radioisotope, the treatment site, source strength (corrected for decay), and exposure time (or equivalently, the total dose).

2. That prior to each administration, the patient is identified by more than one method as the individual named in the written directive.
3. That final plans of treatment and related calculations are in accordance with the respective written directive.
4. That each administration is in accordance with the written directive.
5. That any unintended deviation from the written directive is identified and evaluated, and appropriate action taken.

Additionally, to meet the requirements of 10 CFR 35.32(b), you need policies and procedures for conducting a review of the QMP to verify compliance of all aspects of the program at intervals no greater than 12 months. The review is to include a representative sample of patient administrations, all recordable events and all misadministrations, and any corrective actions taken.

Licensees may make modifications to their QMPs to increase the program's efficiency provided the program's effectiveness is not decreased. 10 CFR 35.32(e) requires licensees to submit modifications to their QMP to the appropriate NRC regional office within 30 days after the modification has been made.

If you are licensed for a Sr-90 eye applicator, but are not, or do not intend to use it, you may submit a "negative declaration" in lieu of a QMP. This written declaration must commit to your submission of a QMP to NRC prior to use of the Sr-90 eye applicator for patient treatment procedures.

Calibration and Use of Strontium-90 Eye applicators

The NRC staff has had discussions with and received correspondence from researchers at the National Institute of Standards and Technology (NIST) about large discrepancies among calibrated outputs assigned to Sr-90 eye applicators. The manufacturer's original calibrations may have been in units that are no longer used or have little relationship to System Internationale units in use today. Further, comparisons between units from different manufacturers may be meaningless and misleading. Finally, discrepancies larger than 10 percent still exist when comparing output measurements between competent measurement labs using state-of-the-art techniques.

The above information was provided to NRC's Advisory Committee on Medical Uses of Isotopes (ACMUI) at its November 1 and 2, 1993, meeting. The ACMUI members advised the staff that calibration was not a critical factor in the use of Sr-90 eye applicators for treating pterygium because licensees treat for response rather than to tolerance. The ACMUI recommended that NRC inform licensees of the potential problems associated with calibration of Sr-90 eye applicators. The Committee also recommended cautioning licensees that if they use an applicator, other than the one currently in their possession or buy a new one, their current technique may not be applicable to another device because of variances in stated and actual exposure rates for the different applicators.

NIST offers a service for the calibration of Sr-90 eye applicators that provides: (1) the calculation of the emission rate, and (2) a mapping of the Sr-90 distribution across the face of the applicator in order to ascertain uniformity of dose. For further information on the NIST calibration service, contact either Dr. Christopher Soares at (301) 975-5589 or Dr. Bert Coursey at (301) 975-5584. Although NIST is, to the best of the staff's knowledge, the only provider of such a service, there may be others. NRC is not requiring that licensees participate in the NIST program, and accepts calculations of exposure time based on the original vendor's calibration, corrected for radioactive decay.

Since 10 CFR 35.400(e) identifies the Sr-90 eye applicator as a brachytherapy device, licensees are reminded that 10 CFR 35.59, "Requirements for possession of sealed sources and brachytherapy sources," does apply to Sr-90 eye applicators. Specifically, licensees must perform applicable leak tests and surveys described in 10 CFR 35.59. Additionally, 10 CFR 35.400(e) limits the use of Sr-90 eye applicators to "treatment of superficial eye conditions." Licensees are reminded that NRC authorization for use of a Sr-90 eye applicator for patient procedures does not authorize its use on treatment sites other than the eye.

This Information Notice requires no specific action or written response. If you have questions about the information in this notice, please contact the appropriate technical contact listed below.

Carl J. Paperiello, Director
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

Technical contacts: Jim Dwyer, RI (215) 337-5309
 Jacqueline Burks, RIV (817) 860-8132
 John Pelchat, RII (404) 331-5083
 James Montgomery, RV (510) 975-0249
 Cassandra Frazier, RIII (708) 790-5704
 Sally L. Merchant, NMSS (301) 504-2637

Attachments:

1. List of Recently Issued NMSS Information Notices
2. List of Recently Issued NRC Information Notices

* See previous concurrence

OFC	IMAB	IMAB	IMAB	TechEd*	IMOB*	IMOB
NAME	SMerchant	LWCamper	JEGlenn	EKraus	KRamsey	FCombs
DATE	02/24/94	02/24/94	02/24/94	12/29/93	01/13/94	02/20/94
OFC	OGC	IMNS	IMNS			
NAME	STreby	WBrach	CPaperiello			
DATE	02/04/94	02/07/94	03/10/94			

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LIST OF RECENTLY ISSUED
NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
94-16	Recent Incidents Resulting in Offsite Contamination	03/03/94	All U.S. Nuclear Regulatory Commission material and fuel cycle licensees.
94-15	Radiation Exposures during an Event Involving a Fixed Nuclear Gauge	03/02/94	All U.S. Nuclear Regulatory Commission licensees authorized to possess, use, manufacture, or distribute industrial nuclear gauges.
94-09	Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas due to Presence of Patients Containing Radioactivity Following Implementation of Revised 10 CFR Part 20	02/03/94	All U.S. Nuclear Regulatory Commission medical licensees.
94-07	Solubility Criteria for Liquid Effluent Releases to Sanitary Sewerage under the Revised 10 CFR Part 20	01/28/94	All byproduct material and fuel cycle licensees with the exception of licensees authorized solely for sealed sources.
93-100	Reporting Requirements for Bankruptcy	12/22/93	All U.S. Nuclear Regulatory Commission licensees.
93-80	Implementation of the Revised 10 CFR Part 20	10/08/93	All byproduct, source, and special nuclear material licensees.
93-77	Human Errors that Result in Inadvertent Transfers of Special Nuclear Material at Fuel Cycle Facilities	10/04/93	All nuclear fuel cycle licensees.

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94-14	Failure to Implement Requirements for Biennial Medical Examinations and Notification to the NRC of Changes in Licensed Operator Medical Conditions	02/24/94	All holders of OLs or CPs for nuclear power and non-power reactors and all licensed reactor operators and senior reactor operators.
92-36, Supp. 1	Intersystem LOCA Outside Containment	02/22/94	All holders of OLs or CPs for nuclear power reactors.
94-13	Unanticipated and Unintended Movement of Fuel Assemblies and Other Components due to Improper Operation of Refueling Equipment	02/22/94	All holders of OLs or CPs for nuclear power reactors.
94-12	Insights Gained from Resolving Generic Issue 57: Effects of Fire Protection System Actuation on Safety-Related Equipment	02/09/94	All holders of OLs or CPs for nuclear power reactors.
94-11	Turbine Overspeed and Reactor Cooldown during Shutdown Evolution	02/08/94	All holders of OLs or CPs for nuclear power reactors.

OL = Operating License
 CP = Construction Permit

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