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

December 13, 1996

NRC INFORMATION NOTICE 96-66: RECENT MISADMINISTRATIONS CAUSED BY INCORRECT CALIBRATIONS OF STRONTIUM-90 EYE APPLICATORS

Addressees

All U.S. Nuclear Regulatory Commission Medical Use Licensees authorized to use strontium-90 (Sr-90) eye applicators.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to alert addressees to recent misadministrations caused by incorrect source strength determinations of Sr-90 eye applicators. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not NRC requirements; therefore, no specific action nor written response is required.

Description of Circumstances

The primary causes of two recent events have been problems with calibration and calculation of the dose rates from Sr-90 applicators. As a result, the administered doses were not within 20 percent of the prescribed dose.

Case 1. In October 1995, during an inspection of a licensee authorized to use a Sr-90 eye applicator in Mayagüez, Puerto Rico, it was determined that the calibration record for the licensee's Sr-90 eye applicator was missing. A previous owner of the source lost the original calibration certificate, and his medical physics consultant performed a check of the source strength. This check was performed with an inappropriate measurement instrument and resulted in an incorrect determination of the source strength as 0.24 Gray (Gy)/sec (24 rad/sec). The licensee obtained the source in 1994 and relied on the erroneous source strength determination during treatments. Also, the source had not been decay-corrected by either owner since 1990. NRC urged the licensee to have the eye applicator recalibrated and to be instructed in the proper method to calculate the decay of the source.

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The licensee subsequently had the eye applicator recalibrated by the National Institute of Standards and Technology. The resultant recalibration revealed a dose rate of 0.53 Gray (53 rad)/sec rather than the 0.24 Gy (24 rad)/sec used by the licensee. The licensee had prescribed a total dose of between 10 to 25 Gy (1000 to 2500 rad) for approximately

70 patients, but actually administered about twice this amount. An NRC medical consultant has reviewed the cases and has recommended that the patients be evaluated for any adverse effects.

Case 2. In November 1995, while reviewing treatment records during a routine NRC inspection of a licensee authorized to use a Sr-90 eye applicator in Honolulu, Hawaii, an NRC inspector determined that the licensee had incorrectly calculated the decay of the strength of a Sr-90 eye applicator and subsequently delivered doses 20 percent over the prescribed doses to 16 patients. The root cause of this event was the licensee improperly calculating the decay of the Sr-90 source. Specifically, the licensee linearly decayed the strength of the source instead of logarithmically decaying the source strength of the eye applicator. Before May 1995, a technologist had correctly calculated the decay of the source; however, when this technologist left, the physician incorrectly calculated the source decay based on a linear decay from the previous calculations. In addition, the incorrect half-life of Sr-90 was used in the calculation.

Following a correct determination of the source strength, the licensee determined that 17 misadministrations involving 16 patients occurred, from May 6, 1995 to November 16, 1995, including one patient who was treated on both eyes. The delivered doses range from 21.1 to 22.7 percent greater than the prescribed dose of 40 Gy (4000 rad).

Discussion

10 CFR 35.32, "Quality Management Program," requires licensees to develop written procedures to meet five objectives associated with any brachytherapy dose, including assurance that the prescribed dose is the administered dose. A necessary part of this is to ensure that the dose rate emitted from an applicator is correct. If the manufacturer's certificate of calibration or original activity/dose rate name plate is missing, the licensee should arrange with a qualified expert to determine the dose rate from the Sr-90 source. (For additional details, see NRC IN 94-17, "Sr-90 Eye Applicators: Submission of Quality Management Plan, Calibration and Use," dated March 11, 1994.) Failure to implement the Quality Management Rule and make required reports may subject a licensee to orders, civil penalties, and notices of violation.

In view of the nature of the cited events, it appears worthwhile to review some of the properties of Sr-90 eye applicators and the related processes for decay correction over time. New Sr-90 eye applicators typically contain a 2 gigabecquerel (GBq) [54 millicurie(mCi)] source, exhibiting a surface dose rate of about 0.50 Gy (50 rad)/sec. The half-life of the parent Sr-90 is 28.5 yrs [maximum beta energy equal to 0.54 mega-electron volts (MeV)], and the yttrium-90 (Y-90) daughter half-life is 64.2 hrs (beta-max, 2.27 MeV); therefore, both isotopes are in equilibrium on the eye applicator. Since Sr-90 and Y-90 are in equilibrium, emissions from both isotopes must be accounted for in dosimetry calculations.

The dose rate ($\dot{D}_t$) at a time (t) can be calculated from the initial dose rate (D_o) at the time of the most recent calibration with the following formula:

$$\dot{D}_t = \dot{D}_o \cdot (e^{-\lambda t}) \qquad \text{(F1)}$$

where e, the base of the natural logarithm (2.718), is raised to the power $-\lambda t$ and is referred to as the "decay factor" (df), where $-\lambda = -0.693/T_{½}$, $T_{½}$ is the half-life of the isotope, and t is the elapsed time. For Sr-90, $T_{½}$=28.5 years; therefore, $\lambda = (0.693)/(28.5 \text{ yrs}) = 0.0243 \text{ yr}^{-1}$. The values for df can be used to determine the fraction of original activity remaining after t years. These values can then be used to calculate dose rates by using the following formula:

$$\dot{D}_t = \dot{D}_o \cdot df \qquad \text{(F2)}$$

The fraction of activity remaining after a given number of years from the original measurement date is given in Table 1 (Attachment 1).

For example

An eye applicator calibrated by the manufacturer on January 1, 1978, delivered an initial dose rate ($\dot{D}_o$) of 0.75 Gy/sec (75 rad/sec) on contact. If, on January 1, 1996, the eye applicator needs to be used, the elapsed time (in years) since calibration is 18, and from Table 1, df = 0.646 for Sr-90. Using formula F2:

$$\dot{D}_t = \dot{D}_o \cdot df$$

$$\dot{D}_{18 \text{ years}} = (0.75 \text{ Gy/sec})(0.646)$$

$$\dot{D}_{18 \text{ years}} = 0.485 \text{ Gy/sec}$$

$$(48.5 \text{ rad/sec})$$

Table 1 may be extended using formula F1 and the value $\lambda = 0.0243\ yr^{-1}$ for Sr-90. Other values of df that need to be evaluated by licensees will need to be re-calculated by using the appropriate half-life for that isotope. Alternatively, a semi-logarithmic plot of the above data will yield a straight line, which may be extended beyond 25 years.

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Attachments:
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2. List of Recently Issued NRC Information Notices

Attachment filed in Docket

TABLE 1

FRACTION (EXPRESSED AS DECIMAL) OF ORIGINAL SR-90 ACTIVITY REMAINING AFTER (t) YEARS

Years (t)	df	Years (t)	df	Years (t)	df	Years (t)	df
.25	0.994	6.5	0.854	12.75	0.734	19	0.63
.5	0.988	6.75	0.849	13	0.729	19.25	0.626
.75	0.982	7	0.844	13.25	0.725	19.5	0.623
1	0.976	7.25	0.838	13.5	0.72	19.75	0.619
1.25	0.97	7.5	0.833	13.75	0.716	20	0.615
1.5	0.964	7.75	0.828	14	0.712	20.25	0.611
1.75	0.958	8	0.823	14.25	0.707	20.5	0.608
2	0.953	8.25	0.818	14.5	0.703	20.75	0.604
2.25	0.947	8.5	0.813	14.75	0.699	21	0.6
2.5	0.941	8.75	0.808	15	0.695	21.25	0.597
2.75	0.935	9	0.804	15.25	0.69	21.5	0.593
3	0.93	9.25	0.799	15.5	0.686	21.75	0.589
3.25	0.924	9.5	0.794	15.75	0.682	22	0.586
3.5	0.918	9.75	0.789	16	0.678	22.25	0.582
3.75	0.913	10	0.784	16.25	0.674	22.5	0.579
4	0.907	10.25	0.78	16.5	0.67	22.75	0.575
4.25	0.902	10.5	0.775	16.75	0.666	23	0.572
4.5	0.896	10.75	0.77	17	0.662	23.25	0.568
4.75	0.891	11	0.765	17.25	0.658	23.5	0.565
5	0.886	11.25	0.761	17.5	0.654	23.75	0.562
5.25	0.88	11.5	0.756	17.75	0.65	24	0.558
5.5	0.875	11.75	0.752	18	0.646	24.25	0.555
5.75	0.87	12	0.747	18.25	0.642	24.5	0.551
6	0.864	12.25	0.743	18.5	0.638	24.75	0.548
6.25	0.859	12.5	0.738	18.75	0.634	25	0.545

LIST OF RECENTLY ISSUED NMSS INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-63	Potential Safety Issue Regarding the Shipment of Fissile Material	12/05/96	All U.S. Nuclear Regulatory Commission licensees authorized to possess special nuclear material in unsealed quantities greater than a critical mass
96-57	Incident-Reporting Requirements Involving Intakes, During a 24-Hour Period that May Cause a Total Effective Dose Equivalent in Excess of 0.05 Sv (5 rem)	10/30/96	All U.S. Nuclear Regulatory Commission licensees
96-54	Vulnerability of Stainless Steel to Corrosion When Sensitized	10/17/96	All material licensees
96-53	Retrofit to Amersham 660 Posilock Radiography Camera to Correct Inconsistency in 10 CFR Part 34 Compatibility	10/15/96	All industrial radiography licensees
96-52	Cracked Insertion Rods on Troxler Model 3400 Series Portable Moisture Density Gauges	09/26/96	All U.S. Nuclear Regulatory Commission portable gauge licensees and vendors
96-51	Residual Contamination Remaining in Krypton-85 Handling System After Venting	09/11/96	All material licensees

LIST OF RECENTLY ISSUED NRC INFORMATION NOTICES

Information Notice No.	Subject	Date of Issuance	Issued to
96-65	Undetected Accumulation of Gas in Reactor Coolant System and Inaccurate Reactor Water Level Indication During Shutdown	12/11/96	All holders of OLs or CPs for nuclear power reactors
96-64	Modifications to Containment Blowout Panels Without Appropriate Design Controls	12/10/96	All holders of OLs or CPs for nuclear reactors
96-63	Potential Safety Issue Regarding the Shipment of Fissile Material	12/05/96	All U.S. Nuclear Regulatory Commission licensees authorized to possess special nuclear material in unsealed quantities greater than a critical mass
96-62	Potential Failure of the Instantaneous Trip Function of General Electric RMS-9 Programmers	11/20/96	All holders of OLs and CPs for nuclear power plants
96-61	Failure of a Main Steam Safety Valve to Reseat Caused by an Improperly Installed Release Nut	11/20/96	All holders of OLs or CPs for nuclear power reactors
96-60	Potential Common-Mode Post-Accident Failure of Residual Heat Removal Heat Exchangers	11/14/96	All holders of OLs or CPs for nuclear power reactors

OL = Operating License
CP = Construction Permit

Table 1 may be extended using formula F1 and the value $\lambda = 0.0243\ yr^{-1}$ for Sr-90. Other values of df that need to be evaluated by licensees will need to be re-calculated by using the appropriate half-life for that isotope. Alternatively, a semi-logarithmic plot of the above data will yield a straight line, which may be extended beyond 25 years.

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Official Record Copy S:\jsmith\imns5350.JAS

OFC	IMAB	E	IMAB		IMAB		IMOB		Tech Ed	
NAME	JASmith		SLMerchant		LWCamper ⊙		JMPiccone ⊙		EKraus ⊙	
DATE	11/26/96		11/26/96		10/28/96		10/29/96		8/01/96	

OFC	OE		OGC		DD/IMNS		D/IMNS	
NAME	JLieberman⊙		SATreby ⊙		FCCombs⊙		DACool	
DATE	08/07/96		11/07/96		11/12/96		11/29/96	

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DATE	11/16/96		11/18/96		10/28/96		10/29/96		8/01/96	

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$$\dot{D}_{18\ years} = (0.75\ Gy/sec)(0.646)$$

$$\dot{D}_{18\ years} = 0.485\ Gy/sec$$

Table 1 may be extended using formula F1 and the value $\lambda = 0.0243\ yr^{-1}$. Alternatively, a semi-logarithmic plot of the above data will yield a straight line, which may extended beyond 20 years.

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DATE	8/7/96		8/7/96 8/14		8/23/96		1/96		8/01/96	

OFC	OE		DD/IMNS	8/26/96	D/IMNS			
NAME	JLieberman		FCCombs		DACool			
DATE	8/19/96		1/96					

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