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UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, DC 20555

May 30, 2002

NRC INFORMATION NOTICE 02-017: MEDICAL USE OF STRONTIUM-90 EYE APPLICATORS: NEW REQUIREMENTS FOR CALIBRATION AND DECAY CORRECTION

Addressees:

All U.S. Nuclear Regulatory Commission (NRC) medical licensees that use strontium-90 (Sr-90) eye applicators.

Purpose:

NRC is issuing this Information Notice (IN) to inform licensees about new requirements in the revised 10 CFR Part 35, "Medical Use of Byproduct Material," pertaining to the calibration and decay correction of Sr-90 eye applicators and related issues. It is expected that recipients will review the information for applicability to their facilities and consider actions, as appropriate, to assure compliance with the new NRC requirements. However, no specific action or written response is required by this notice.

Description of Circumstances:

NRC's complete revision of Part 35, "Medical use of byproduct material," issued on April 24, 2002, may be viewed through the NRC website under the Electronic Reading Room link (http://ruleforum.llnl.gov/cgi-bin/downloader/final_lib/280-0161.pdf). The effective date of the revision is October 24, 2002. This letter discusses the revised requirements related to the calibration and decay correction of Sr-90 eye applicators.

Discussion:

A previous 1996 Sr-90 eye applicator IN (IN 96-66) discussed two cases in which problems with the calibration and calculation of dose rates for Sr-90 eye applicators resulted in 87 misadministrations. Additional misadministrations have occured since 1996. There have been an additional 670 misadministrations for six different licensees in events that occurred between 1990 and 2000.

The new Part 35 has new requirements in 10 CFR 35.432, "Calibration measurements of brachytherapy sources," and 10 CFR 35.433, "Decay of strontium-90 sources for ophthalmic treatments," that apply to the use of Sr-90 eye applicators, as follows:

1. Under 10 CFR 35.432(a), the source output or activity must be determined using a dosimetry system that meets the requirements of 10 CFR 35.630(a). This regulation states that the dosimetry system must have been calibrated using a system or source traceable to the National Institute of Science and Technology (NIST) and published

protocols accepted by nationally recognized bodies, or calibrated by a calibration laboratory accredited by the American Association of Physicists in Medicine (AAPM). Under 10 CFR 35.432 (b), the licensee is allowed to use measurements provided by the source manufacturer, or by a calibration laboratory accredited by the AAPM, that are made in accordance with the requirements of 10 CFR 35.432(a). Most licensees possessing Sr-90 eye applicators do not have their applicators calibrated to these current standards. It should be noted that NIST-traceable calibrations of Sr-90 eye applicators preceding August of 1990 do not meet the revised criteria of 10 CFR 35.432 within the new Part 35. In August of 1990, NIST implemented a new Sr-90 eye applicator calibration procedure that established the currently accepted national standards. Any NIST-traceable calibrations performed after this date should ensure compliance.

2. Under 10 CFR 35.433, only an authorized medical physicist can calculate the activity of each Sr-90 source that is used to determine the treatment times for ophthalmic treatments. The authorized medical physicist must have the qualifications specified in 10 CFR 35.51, "Training for an authorized medical physicist," 10 CFR 35.57, "Training for experienced Radiation Safety Officer, teletherapy or medical physicist, authorized user, and nuclear pharmacist," or 10 CFR 35.961, "Training for an authorized medical physicist." The decay must be based on the activity determined under 10 CFR 35.432.

Medical licensees who use Sr-90 eye applicators should check calibration records and take steps now to assure that they will be in compliance with these new requirements by the effective date of October 24, 2002.

This IN requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical individuals listed below or the appropriate regional office.

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Attachments:
1. IN 96-66
2. List of Recently Issued NMSS Information Notices
3. List of Recently Issued NRC Information Notices

UNITED STATES
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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.

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 (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:

D. t = D. o · (e-■t)
(F1)

where e, the base of the natural logarithm (2.718), is raised to the power -■t and is referred to as the "decay factor" (df), where -■ = -0.693/T½, T½ is the half-life of the isotope, and t is the elapsed time. For Sr-90, T½=28.5 years; therefore, ■ = (0.693)/(28.5 yrs) = 0.0243 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:

D. t = D. o · df
(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 (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:

D. t = D. o · df

D. 18 years = (0.75 Gy/sec)(0.646)

D. 18 years = 0.485 Gy/sec (48.5 rad/sec)

Table 1 may be extended using formula F1 and the value ■ = 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.

This information notice requires no specific action nor written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below or the appropriate regional office.

signed by

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Attachments:
1. Table 1

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