Medicine
Health Physics
Industrial Hygiene
Toxicology
Medical Department/3M

3M Center
St. Paul, Minnesota 55101
612/733 1110

June 9, 1982

FMB
6/28/82
June PG 9 Amend.
Exon
3M 6/29/82

RECEIVED
JUN 15 1982
U.S. NUCLEAR REGULATORY COMMISSION

Licensing Management Branch
Division of Fuel Cycle and Material Safety
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Gentlemen:

Subject: U.S. NRC License 22-00057-61

In accordance with the provisions of Condition 17 of the subject license, attached is a copy of the radiation survey report for the survey conducted by Atomic Energy of Canada Limited (AECL) personnel on May 27, 1982 at 3M's Brookings, South Dakota gamma sterilization facility subsequent to installation of an additional 196,000 curies of Cobalt-60. It is noted that external to the facility with the Cobalt-60 source rack in the irradiate position, (1) almost all of the radiation levels are less than 0.03 millirem per hour and (2) where detectable levels were observed, the maximum level is below the design criteria of 2 millirem per hour and the average is well below the design criteria of 0.25 millirem per hour. With the source rack in its storage position in the storage pool, it is noted that radiation levels in the sterilization room are less than 0.03 millirem per hour.

The above survey information was confirmed in an independent, comprehensive survey performed on May 28, 1982 by J. A. Bauhs of 3M Health Physics Services. Details of this survey along with a copy of AECL's survey report are being maintained in the 3M Health Physics Services files in St. Paul, Minnesota and in the 3M Plant Radiation Safety Officer files in Brookings, South Dakota.

Should you have any questions regarding the radiation survey report, please contact Duane C. Hall of our office at 612/733-7316.

Sincerely,

Robert G. Wissink

Robert G. Wissink
Licensing Administrator
Radioactive Materials

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FEE EXEMPT

RGW:cr
attachment
cc: U. S. Nuclear Regulatory Commission
Office of Inspection and Enforcement, Region III
Atomic Energy of Canada Limited
E. C. Seydel - 3M Medical Products - Brookings, South Dakota

Irradiator survey see attached memo

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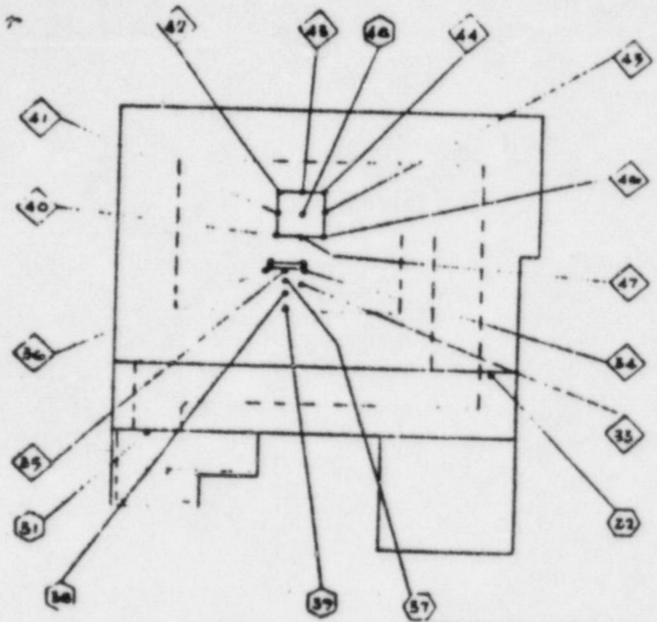
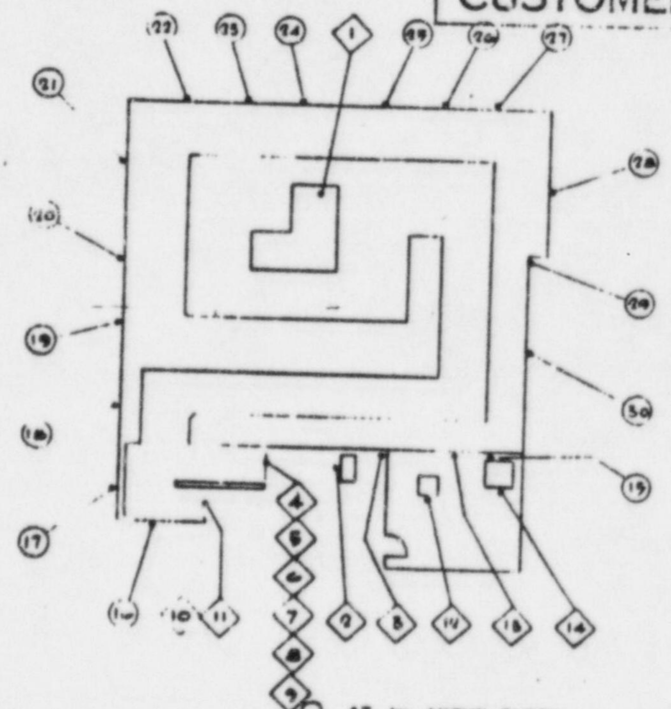
G-8



CUSTOMER



○ AT 1m ABOVE FLOOR
⬡ AT FLOOR OR ON ROOF
◇ ON NAMED FEATURE (SURVEYOR TO ADD AS NECESSARY)

ALL READINGS IN mrem/h
'ADINGS LESS THAN 0.03 mrem/h SHOWN THUS *

NO	READING	REMARKS
1	*	POOL SURFACE
2	*	CONTROL CONSOL
3	*	FLOOR OVER DUCT
4	*	ABOVE RES DOOR
5	*	RES DOOR OPEN
6	*	RES DOOR CLOSE
7	0.06	LEFT DOOR BOUND
8	*	RIGHT DOOR BOUND
9	*	CRACK AT FLOOR
10	*	UPPER CONV
11	*	LOWER CONV
12	*	AIR FILTER
13	*	FLOOR TRENCH
14	*	DEIONIZER
15	*	
16	*	
17	*	
18	*	
19	*	
20	*	
21	*	
22	*	
23	*	
24	*	
25	*	
26	*	
27	*	
28	*	
29	*	
30	*	
31	*	
32	*	
33	*	AIR LINE
34	0.05	GUIDE CABLE
35	0.65	HOIST CABLE
36	*	GUIDE CABLE
37	*	
38	*	
39	*	
40	1.6	PLUM CRACK
41	0.55	PLUM CRACK
42	0.1	PLUM CRACK
43	0.65	PLUM CRACK
44	0.08	PLUM CRACK
45	0.1	PLUM CRACK
46	0.18	PLUM CRACK
47	0.75	PLUM CRACK
48	*	
49		
50		
51		
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57		
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59		
60		

MAXIMUM RADIATION DESIGN LEAKAGE SO THAT NO ONE SHALL RECEIVE MORE THAN 10 mrem IN A 40 HOUR WORK WEEK WITH 3×10^6 CURIES OF COBALT-60 INSTALLED.

OCCUPANCY HOURS/WEEK	DOSE RATE IN mrem/h IN AREA	
	MAXIMUM	AVERAGE
40	2.0	0.25

SURVEY PERFORMED BY GLEESON
DATE MAY 27/82

SURVEY INSTRUMENT MODEL BERTH RATO F
SERIAL NO 52352 / CALIBRATION DATE 82004-28
SOURCE CONTENT 626495 CURIES
ON DATE JUNE 1/82

ATOMIC ENERGY OF CANADA LIMITED
OTTAWA COMMERCIAL PRODUCTS CANADA

RADIATION SURVEY REPORT
AFTER SOURCE INSTALLATION NO 4
IN IR100 3M COMPANY
BROOKINGS S.D.

SHEET 0

ENCLOSURE 1

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D. C. 20555

JUN 3 0 1982

MEMORANDUM FOR: John G. Davis, Director
Office of Nuclear Material Safety
and Safeguards

FROM: Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety
Office of Nuclear Material Safety
and Safeguards

SUBJECT: AEOD REVIEW OF IODINE-125 SOURCE LEAKAGE INCIDENTS

We have reviewed the AEOD report enclosed with Mr. Michelson's memorandum dated May 25, 1982, discussing iodine-125 sealed source leakage incidents.

As discussed in the AEOD report, NMSS wrote to 3M in July, 1981 concerning the leakage incidents, and as a result 3M added a warning notice for users of the iodine-125 seeds. To our knowledge, no incidents have been identified since the warning notice was added. However, it is entirely possible that incidents have occurred, but were not recognized by the licensees. In any case, we still consider this to be an unresolved problem.

Our preliminary evaluation is as follows:

1. The iodine-125 seeds are inherently fragile, and the leaks were probably caused by rough handling. However, we have not ruled out the possibility that a manufacturing defect is involved. We agree with AEOD that the test data provided by 3M is not conclusive.

2. The seeds may need to be inherently fragile, in order to be medically effective. Therefore, if 3M is required to make the seeds stronger, the medical effectiveness could be reduced.

3. A leaking seed can deliver a dose of up to 100 rads to the cancer patient's thyroid. This potential risk must be balanced against the medical benefit of the cancer therapy. There is also the risk of laboratory contamination prior to implantation of the seeds.

4. For perspective, a diagnostic thyroid scan using I-131 delivers 65 to 90 rads to the thyroid. Treatment of hyperthyroidism involves doses in excess of 1000 rads to the thyroid.

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In order to resolve these issues, we plan to take the following actions:

1. As recommended by AEOD, we will coordinate with IE to develop a supplemental information notice for medical licensees.

2. We will inform 3M of our preliminary evaluation, and request supplemental information and comments as to their evaluation of the problem.

3. As suggested by AEOD, we will obtain a medical consultant to assist in our independent evaluation. Dr. Peter Almond of the Anderson Hospital and Tumor Institute has informed us that he is available to provide this assistance. Dr. Almond is presently under contract to NRC as a consultant in medical physics.

4. After obtaining appropriate information and recommendations, we will complete our risk/benefit analysis, and identify what requirements, if any, should be imposed upon 3M and/or medical licensees.

We anticipate that the IE information notice will be sent to licensees within 30 days, and that input can be obtained from 3M and our consultant within 60-9 days. Within 30 days thereafter, we should be able to identify the requiremen which should be imposed, if any. However, this schedule depends on our ability to use Dr. Almond within current limits placed on "full time equivalents".

Richard E. Cunningham, Director
Division of Fuel Cycle and
Material Safety
Office of Nuclear Material Safety
and Safeguards

KBlack JJoiner
LCobb KBarr
GTerry WAxelson.
BSinger DChapell
RHall FWenslawski
DThompson, FDA
FCML r/f FC Central File
NMSS r/f JHickey
VLMiller PVacca

File: License 22-00057-59MD

DEC 22 1983

ATTACHMENT B

MEMORANDUM FOR: Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety

FROM: Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and Material Safety

SUBJECT: LEAKING 3M I-125 SEEDS

This memorandum closes out our review of several reports of leaking iodine-125 seeds manufactured by 3M Company (See Enclosure 1, Memorandum to Mr. Davis dated June 30, 1982). As discussed in Enclosure 2, we have concluded that the primary cause of these incidents was rough handling by medical licensees as opposed to manufacturer's defects.

The only additional action we recommend is for 3M to improve the instructions to licensees who receive the iodine seeds. The 3M distribution license No. 22-00057-59MD is currently being renewed, and the instructions can be improved as part of the renewal.

We have discussed the case with FDA. They performed an independent inspection in 1981, and are satisfied that the seeds are being manufactured properly. FDA does not plan any further action. No leakage incidents were reported in 1982 or 1983. If 3M agrees to improve its instructions to users as part of its license renewal, we will consider this case closed (unless additional incidents occur).

Original Signed By
VANDY L. MILLER

Vandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:
1. Memorandum to Mr. Davis dated June 30, 1982
2. Supplemental Evaluation of Leaking Iodine Seeds

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1p

FCML	FCML					
JHickey/sc	VLMiller					
12/ /83	12/22/83	12/22/83				

DEC 22 1983

ENCLOSURE 2

SUPPLEMENTAL EVALUTION OF LEAKING IODINE SEEDS

Contact: John Hickey, NMSS
FTS 427-4093
December 13, 1933

BACKGROUND

During 1980 and 1981, several incidents occurred where cancer therapy seeds containing iodine-125 leaked, resulting in exposures of up to tens of rads to the patients' thyroids.

An IE Information Notice was issued on October 10, 1980. Nevertheless, additional incidents occurred in July, 1981, and 3M added a stronger warning notice to the seeds. AEOD identified the incidents as a potential generic problem in May, 1982. NMSS worked with IE to issue a second Information Notice in October, 1982.

NMSS retained a medical physics consultant to review the case, and his report was completed in January, 1983. NMSS visited 3M with Region III in August, 1983. We have also discussed the case with FDA, who reviewed the problem and inspected 3M in February, 1981. FDA did not identify any manufacturing problems.

No leakage incidents for iodine-125 seeds were reported in 1982 or 1983.

DISCUSSION

The results of our follow-up actions are:

1. The FDA inspection in February, 1981 did not identify any problems related to the incidents. Subsequent discussions with FDA indicate that they do not plan any further regulatory action.

2. Our medical physics consultant, Dr. Peter Almond of M.D. Anderson Hospital and Tumor Institute, concluded that the problem lies more with the users of the seeds than with the supplier. He raises the question as to whether the applicator used to insert the seeds into patients is at fault. He also recommends that patient bioassay be considered if difficulties are encountered during implantation.

3. We talked to Felix Mick of New York, who supplies an applicator commonly used with the iodine seeds. He acknowledged that the old-style Mick applicator could jam if not tightly assembled, and he has modified the design to eliminate this problem. All of his customers have been notified in writing of availability of the new design. We conclude that both devices are adequate if properly used, and no further action is necessary.

CC ▶							
NAME ▶							

4. We discussed the case with 3M, and Dr. William Walker accompanied Region III on an inspection in August, 1983. They concluded that the seeds are being manufactured properly, and that no further regulatory action is necessary.

CONCLUSION

The seeds are being properly manufactured and should not leak or rupture if normal care in handling is exercised. However, the instructions to users can be improved to emphasize the need to avoid rough handling.

RECOMMENDATION

As part of renewal of 3M license number 22-00057-59MD, 3M should be requested to improve instructions to users as follows:

1. Add a statement to the instructions, stating that patient bioassay and thyroid blocking procedures should be considered in cases where difficulties are encountered in implants, or where surgery is performed in the implant area within 120 days after seeds are implanted.

2. Modify warning to read as follows: Do not force iodine-125 seeds into or out of any implant tube, needle or cartridge. Do not exert excess forcep pressure or other crushing force. Such rough handling may damage seeds and cause release of iodine-125 into body fluids if the seed is implanted. If a seed is damaged in any way, discard it immediately to radioactive waste and check the area for radioactive contamination. Never implant a damaged seed.