# SUMMARY OF 3M ACTIVITIES
# REGARDING
# LEAKING Cs-137 SOURCE INCIDENT
# MARY BIRD PERKINS CANCER CENTER

3M MEDICAL-SURGICAL DIVISION
January, 1989

## SOURCE CONSTRUCTION AND MANUFACTURE

The 3M Cesium-137 tube source involved in this incident consisted of an INNER stainless steel capsule (alloy no. 304) containing Cs-137 bound to ceramic microspheres, enclosed within an OUTER stainless steel capsule of the same alloy. Construction details of the source are depicted in ATTACHMENT 1 and described below.

Outer Capsule: As depicted in Attachment 1, the eyelet and color coding are located on the left side of the source. The right side of the outer capsule shows a plug which is press-fit and welded after the inner capsule has been added.

Inner Capsule: The inner capsule consists of a stainless steel tube containing Cs-137 microspheres with stainless steel balls press-fit into each end and welded.

Prior to 1986, the inner capsule consisted of a stainless steel rod drilled to contain Cs-137 loaded ceramic microspheres and sealed by one stainless steel ball welded in place (as depicted in Attachment 2). With this single exception, the two designs are identical.

The 3M Cesium-137 tube source involved in this incident (of the design shown in Attachment 1) was manufactured according to the following process.

1. Outer tubes are engraved with a serial number and color-coded with a heat and radiation-resistant paint.

2. One end of an inner tube is fitted with a stainless steel ball and welded.

3. Cs-137 microspheres (of a designated specific activity for a desired source strength) are scooped into the inner capsule.

4. The second end of the inner capsule is closed with a second stainless steel ball which is welded in place.

5. The completed inner capsule is cleaned, inspected, leak-tested in hot glycerin, soak-tested and assayed.

6. Acceptable inner capsules are dropped into an outer capsule and assayed again. A stainless steel plug is press fit into the neck of the capsule and welded.

7. The source is cleaned, inspected, leak-tested in hot glycerin, nickel-plated and soak-tested. The source is assayed for the final time just before shipment to a customer.

## 3M INVESTIGATION

Activities conducted by 3M and the Perkins Cancer Center during the investigation of this incident are listed in the "Chronology of Events - Leaking Cs-137 Source at Perkins Cancer Treatment Center," which is presented as Attachment 3. Also included in this chronology are references to related activities conducted by 3M to verify the integrity of 3M Cesium-137 sources and to preclude recurrence of this type of event.

Significant events from this chronology are excerpted below, followed by explanatory details.

**2/15/88** - D. Kubiatowicz from 3M visited Perkins and observed that 1) a wipe test of the 1504051 source produced a reading of 100 mR/h with a hand-held survey meter; 2) cleanup was progressing; 3) Cs source applicators were contaminated and needed cleaning; 4) room 174 was fairly clean but room 198 was contaminated.

DETAILS: The leaking source was viewed through a magnifying glass and nothing unusual was seen except a small crevice on the unpainted weld extending from the edge of the source to the center. It looked only like an indent and not a hole or fissure.

**2/25/88** - 3M evaluation indicated that the 15 mg Ra eq 3M source with serial number 1504051 (manufactured 1/27/86) was leaking and failed the hot glycerin bubble test. About 900 μCi of Cs-137 had been lost at Perkins.

DETAILS: 3M production and supervisory personnel examined the source from behind lead blocks immediately upon its return from Perkins, with the following observations:

1) Gross examination: The source did not appear as though it had been damaged in any way. The nickel plating on the source was shiny and intact. The engraved serial numbers appeared normal.

2) Eyelet and color coding end of source: The weld appeared normal. The color coding appeared normal, the eyelet was intact and appeared normal.

3) Opposite end of the source: The weld appeared shiny and normal except for the appearance of a tiny black pinpoint mark.

After determining that the source assayed about 2.7% less than its original certified activity corrected for 30.0 year decay, it was important to demonstrate whether the source was a 'leaker'. A hot glycerin bath was prepared, in which the source was placed. After approximately 20 seconds when the source was elevated in temperature, bubbles were observed coming off from the welded end of the source; it appeared that the bubbles were coming directly from the tiny black void in the weld.

3/7/88 - 3M evaluation of disassembled source indicated that the inner capsule of the source was also leaking.

DETAILS: A group of supervisory and production personnel met to observe the opening of the cesium source, serial no. 3M 1504051.

1) Source Cut Open

The end of the source was tightened in the chuck of a lathe and while the source was rotating, the sharp edge of a file was held to the center of the source, scoring the outer capsule nearly through the wall thickness.

A pliers was used to gently crack the remaining portion of the outer capsule. The half of the outer capsule containing the eyelet and color coding was easily pulled from the other half of the source, leaving half the inner capsule exposed. This exposed inner capsule was removed (with much difficulty) from the other half of the source having the defective weld. The length of the inner capsule was within specification.

The end of the inner capsule which was proximate to the defective weld appeared to have a bulkier weld compared to the other end of the inner capsule. In addition, the inner capsule was slightly bent which may possibly have been due to the difficult removal of the inner from the outer capsule.

2) Hot Glycerin Leak Test of Inner Capsule

Twenty seconds after immersing the inner capsule in hot glycerin, a very fine stream of bubbles was observed coming out of the end of the inner capsule that appeared to have the bulkier weld. There was no leakage whatsoever on the opposite end of the inner capsule.

The two halves of the outer source capsule were decontaminated, first with detergent and then nitric acid, for further examination. No attempt was made to clean the inner capsule for further examination, because of anticipated excessive exposure to the personnel involved. Thus, we did not determine precisely why the inner capsule leaked.

3) Microscopic Inspection of Defective Outer Weld

Examination of the defective weld on the decontaminated outer capsule took place on 3/11/88. The outside surface of the weld and capsule was rough due to the corrosive action of nitric acid used in decontaminating the source.

Under a microscope, there was only one single round crater-like hole, going down through the separation between the plug and the outer capsule. This single hole seemed to converge to a smaller size farther down below the surface of the weld joint. Attempts to demonstrate a light path through the hole from the opposite end of the plug were not successful, since there was no straight line hole to the inner cavity of the source. The diameter of the hole was estimated at 50 to 80 μm.

Additional examination did not show any other crack, fissure or separation. X-rays films of the capsule halves did not show useful detail.

4) Metallurgical Analysis of Defective Outer Weld

This work done was performed at 3M and summarized, as follows:

Transverse sectioning of the half of the outer source capsule containing the defective weld disclosed that the leak occurred in one of two dimples in the weld metal where the stainless steel plug was joined to the end of the outer capsule. 3M Materials Engineering examination showed that the leak path ran from the base of one dimple to the bottom of the plug, but because of the damaged incurred by the acid decontamination process, it was not possible to make an exact determination of the cause of the failure. It appeared that the leak was caused by the presence of slag or a blow hole which extended almost to the bottom of the weld penetration.

Impact loading in the field could have been sufficient to break the remaining weld and complete the leak path from the inside of the capsule.

3M Materials Engineering examined eight additional outer capsules typical of current production and noted that, whereas considerable variation existed in the depth of weld penetration of the outer capsule weld, no slag or other evidence of unsound weld metal was seen. The conclusion of the study was that failure of the Perkins Cs-137 source was an isolated occurrence.

Although it could not be proven that lack of adequate weld penetration into the plug contributed to the failure of the Perkins source, a recommendation was made that the weld thickness variability should be investigated to minimize the role such variability might play in the manufacture of the product.

**3/11/88** - Three production Cs-137 sources were autopsied by 3M Quality Assurance, found not leaking.

DETAILS: Three 15 mg Ra eq Cs-137 tube sources (of the design shown in Attachment 1) manufactured in June 1986 and April 1987 were opened and dissected in exactly the same manner as that described for the Perkins source opened 3/7/88. Inner capsules were straight, wipes tests of both inner and outer capsules were negative for Cs-137, leak testing in hot glycerin was negative for Cs-137.

**3/15/88** - 3M conducted prototype tests on 3 production Cs-137 sources. All passed.

DETAILS: The 3 Cs-137 sources (of the design shown in Attachment 1) manufactured in June 1986 and April 1987 were subjected to the following IAEA and DOT tests: a source drop of 30 ft, exposure to 800 degrees C temperature, and dropping a 1.4 kg weight on the source from the height of one meter. No Cs-137 contamination was removed from any of the sources following a 4-hour immersion in hot glycerin, overnight soak test in water, and seven-day soak test in water.

## FINAL SUMMARY AND RECOMMENDATIONS

We conclude that the leaking Perkins source was an isolated event, based on

1) our evaluation of the leaking Cs-137 source from Perkins Cancer Treatment Center in Baton Rouge, LA;

2) the successful wipe tests of field sources from the same production lot;

3) the successful autopsy of three additional production sources; and

4) the successful prototype tests of similar production sources.

We have ruled out the design change to the inner capsule as contributing to the Perkins source failure on the basis of defective inner capsules found during in-process manufacturing of the Cs-137 source. (See "Manufacture" step 5 in which "The completed inner capsule is cleaned, inspected, leak-tested in hot glycerin, soak-tested and assayed.")

Review of manufacturing data for the source design shown in Attachment 2 (1545 sources tested during January 1984 to November 6 1985) revealed NO inner capsule rejects and only 2 outer capsule rejects because of air bubbles seen during the hot glycerin leak test.

Similar review of manufacturing data for the source design shown in Attachment 1 (3410 sources tested during January 1986 to December 1987) revealed NO inner capsule rejects and 2 outer capsule rejects because of excessive Cs-137 found in the source soak tests. It should be noted that, if little free space exists after the inner capsule is sealed in the outer capsule, not enough air may be present to produce bubbles in a hot glycerin leak test to reveal a defective source. In this situation, the 16-hour soak test reveals a defective source.

### Recommendations

Based on our evaluations of the leaking Cs-137 source at Perkins and other sources, the following quality testing changes are being made to Cs-137 source production:

1) Statistical variability in raw materials from the vendor will be defined and tightened, if necessary.

2) All raw materials will be tested and/or audited for critical dimension control. All raw materials received will be identified with specific lot numbers.

3) Additional Go/No Go checks for part lengths, diameters and depths will be implemented, as needed.

4) In-process parts will receive additional inspection.

5) The metallurgical report suggested that weld thickness variability should be investigated (and minimized), even though studies on 8 sources showed that welding was sound in spite of this variability. Attempts will be made to produce more consistent welds, within the constraints that welding remains an art and is subject to variables such as humidity, which is difficult to control in a high air flow manufacturing area.

6) The welds on the finished source will receive close-up visual inspection.

7) An ultrasonic bath will be added to the soak test on the finished product so that sources can be sonicated for part of the 16-hour soak.

ATTACHMENT 1

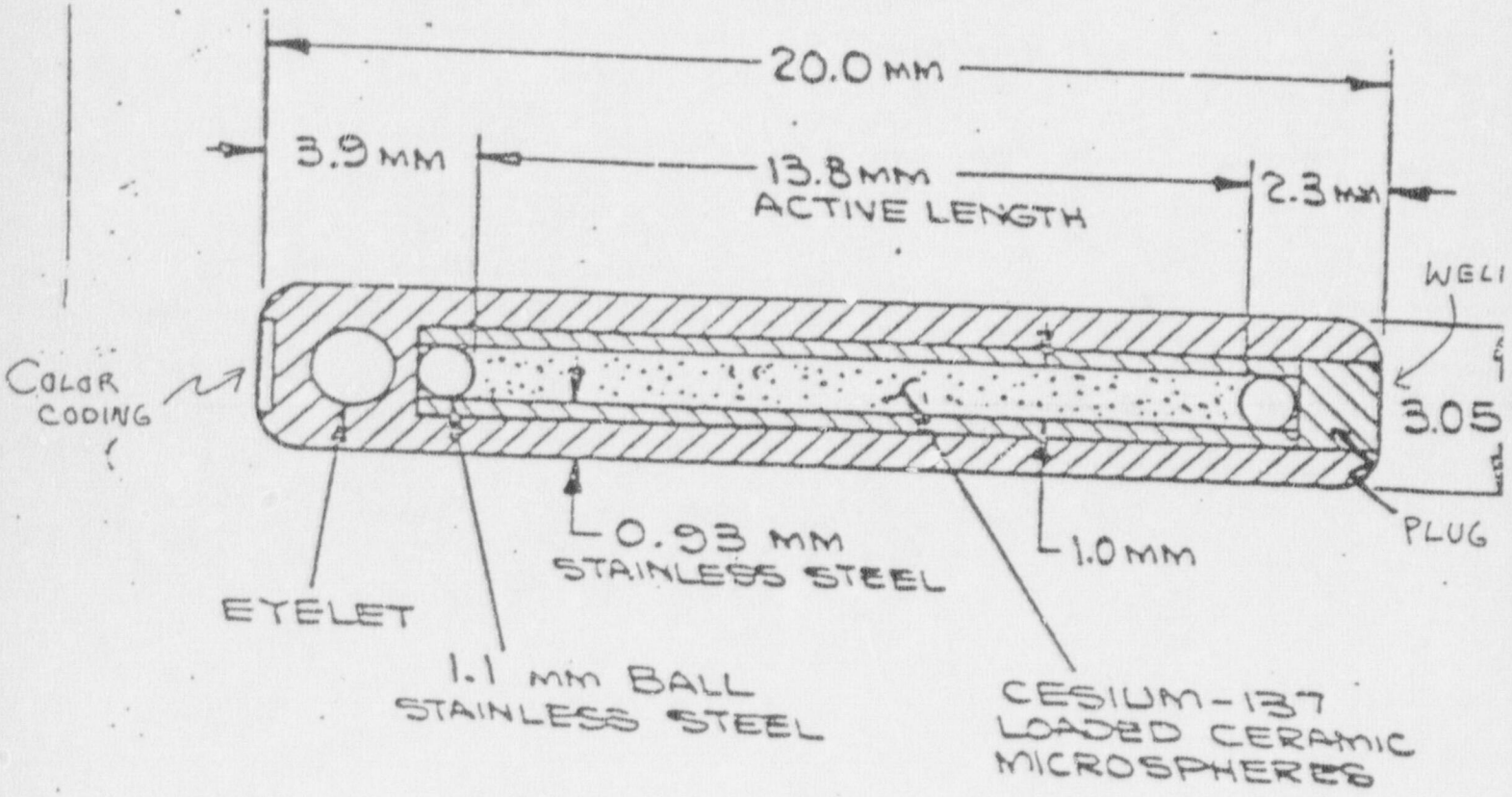
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES

SAFETY EVALUATION OF SOURCE

(AMENDED IN ITS ENTIRETY)

NO. NR-460-S-137-S DATE:

JUN 25 1985



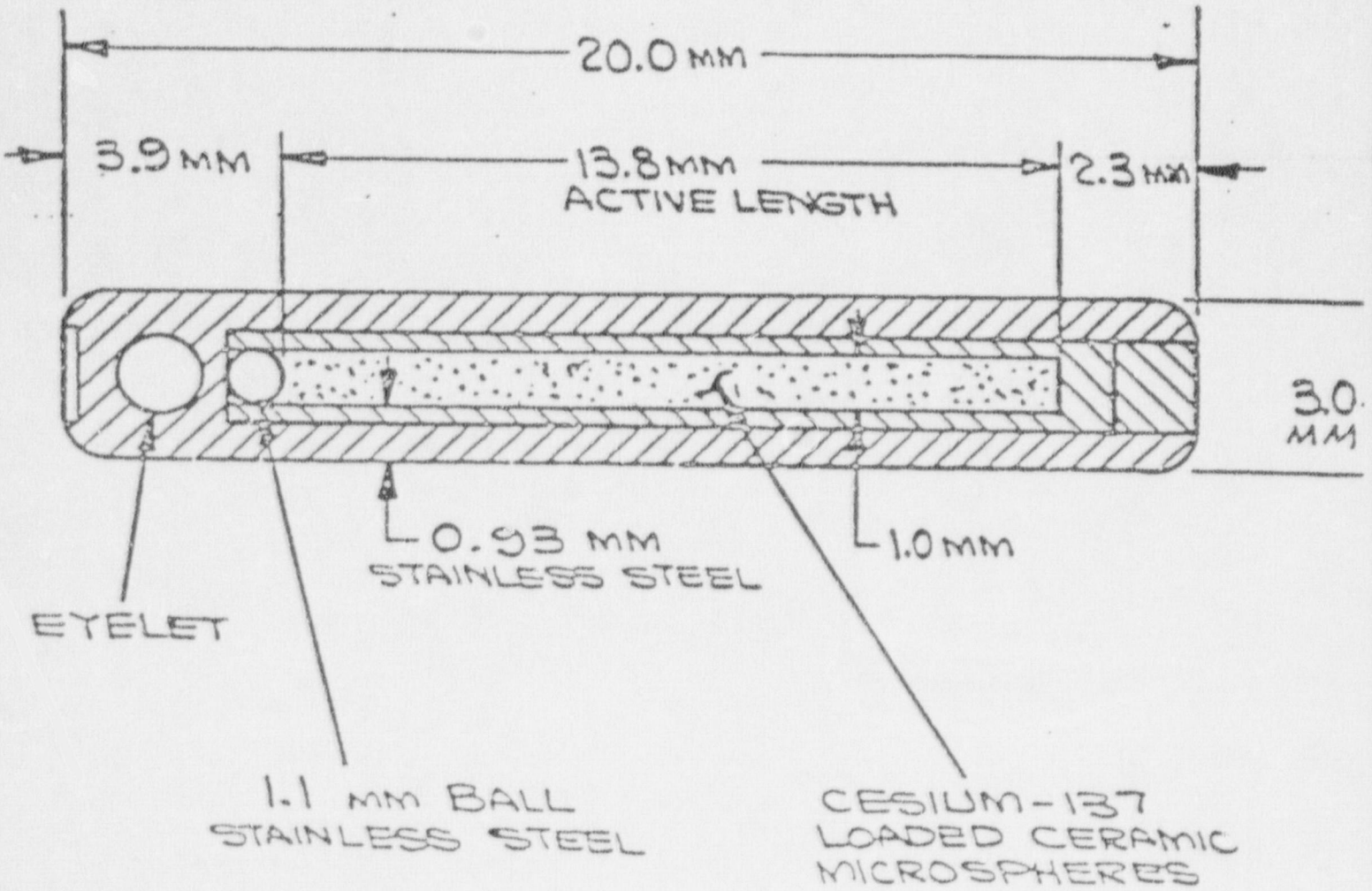

Schematic Diagram of Modified 3M Cesium-137 Source, Series 6500

ATTACHMENT 2

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SOURCE
(AMENDED IN ITS ENTIRETY)

NO. NR-460-S-137-S DATE: JUN 25 1985

3M old source design



ATTACHMENT 3

# CHRONOLOGY OF EVENTS - LEAKING Cs137 SOURCE AT PERKINS CANCER TREATMENT CENTER

| DATE | OCCURRENCE |
|---|---|
| March 1986 | Perkins Cancer Treatment Center in Baton Rouge, LA was shipped 29 Cs-137 sources (10, 15, 20, 25 mg RaEq). Sources shipped in 5 lead pigs. |
| December 1987 | Personnel at Perkins removed some sources from the 5 lead pigs put into use combined with older 3M sources. New sources were not wipe tested but assayed. |
| Wed 2/10/88 | Lead safe was moved from Perkins Room 198 to 174. Wipe test of safe near 174 showed contaminated surface and inside. |
| Thu 2/11/88 | Bill Kubricht, Physicist at Perkins, called Duane Hall, Health Physicist at 3M, to report a leaking Cs-137 source. |
| Fri 2/12/8 | Calls between Bill Kubricht and several people at 3M indicated a possibility that a 3M source was leaking. Bill Kubricht indicated that they and colleagues were unequipped to handle Cs-137 cleanup.<br><br>The sources had been used in some patients in 3 hospitals, but all the hospitals rooms were clean. Status of the patients was unknown.<br><br>At 3M's suggestion, a Health Physics consultant DR. MAX SCOTT from LSU was hired to identify the source of the contamination at Perkins. By 11 p.m. Dr. Scott had traced the contamination to 3M shipping pig No. 5 which contained 4 sources, two 15 mg and two 25 mg. |
| Sat 2/13/88 | Dr. Scott hired a technician to help him perform wipe and leak tests. During the day they isolated a leaking 15 mg source 1504051. |
| Mon 2/15/88 | D. Kubiatowicz from 3M visited Perkins' and observed that 1) a wipe test of the 1504051 source produced a reading of 100 mR/h 2) cleanup was progressing; 3) Cs source applicators were contaminated and needed cleaning; 4) room 174 was fairly clean but room 198 was contaminated. |
| Thu 2/18/88 | 3M reported incident to the NRC Region III, which had prior knowledge of incident. Bill Kubricht had been in constant contact with the State of LA.<br><br>Perkins sent leaking Cs-137 source back to 3M in contaminated lead pig No. 5. |
| Mon 2/22/88 | Bill Kubricht reported that some of the women treated with this source had been checked and were found to have vaginal vaults contaminated with some isotope. |

| | |
|---|---|
| Tue 2/23/88 | 3M submitted a Medical Device Report to the FDA describing the incident. |
| Thu 2/25/88 | 3M evaluation indicated that 1504051 source was leaking and failed the hot glycerin bubble test. About 900 uCi of Cs-137 had been lost at Perkins. |
| Fri 2/26/88 | Radiation Management Corporation, a cleanup crew from Philadelphia, was hired by Perkins to clean up the facility. |
| Mon 2/29/88 | 3M retained Roger Linnemann, MD from Radiation Management Consultants in Philadelphia, to advise physicians at Perkins about possible radiation risk to treated patients. |
| Tue 3/1/88 | Dr. Scott advised 3M that women tested at Perkins were found NOT to be contaminated with Cs-137. Contaminating isotope not yet identified.<br><br>Cleanup crew from Radiation Management Corporation arrived at Perkins. |
| Wed 3/2/88 | Hospitals and rooms retested and found not to be contaminated. |
| Thu 3/3/88 | Six of twelve patients checked at Perkins and found not to be contaminated with Cs-137.<br><br>Review meeting at 3M resulted in following action plan:<br><br>1. stop Cs-137 source manufacture and shipment for 2 weeks;<br>2. to request customers having Cs sources from same lot to wipe test sources;<br>3. to evaluate leaking Cs source;<br>4. to audit production records<br>5. to evaluate integrity of Cs source design. |
| Fri 3/4/88 | 3M contacted 9 customers with Cs-137 sources from same lot as leaker. |
| Mon 3/7/88 | 3M evaluation indicated that leaking source was disassembled and inner capsule was also leaking.<br><br>Eight of twelve women treated at Perkins found to be clean of Cs-137. |
| Tue 3/8/88 | Arrangements made by 3M for ADCO (Illinois) to pick up five 55-gallon waste drums at Perkins on March 14, liquid waste to be picked up later. |

| | |
|---|---|
| Wed 3/9/88 | Cleanup crew completed work at Perkins. |
| Fri 3/11/88 | Three production Cs-137 sources were autopsied by 3M Quality Assurance, found not leaking. |
| Tue 3/15/88 | 3M conducted prototype tests on 3 production Cs-137 sources. All passed. |
| Thu 3/17/88 | Five 55-gallon barrels of radioactive waste picked up at Perkins. |
| Fri 3/18/88 | Results of 3M customer survey tallied. Eleven of twelve customers having 47 of 59 Cs-137 sources from the lot which produced the leaking source called to say new wipe tests were negative. Twelfth customer is in Panama; response to wipe test query is unlikely. |
| Mon 3/21/88 | 3M resumed Cs-137 source manufacture and shipment. Replacement 15 MgRaEq Cs-137 source shipped to Perkins, along with two others shipped back to 3M with the leaking 3M 1504051.<br><br>Eleven of twelve women treated at Perkins found to be clean of Cs-137. |
| Wed 4/6/88 | Liquid Cs-137 waste solidified at Perkins (30-gallon drum). This will be picked up by ADCO next time through Baton Rouge.<br><br>Dr. Scott writing report. Other reports forthcoming. |
| Wed 4/13 | Dr. Linnemann advised 3M that all patients have been seen, all found NOT to be contaminated with Cs-137. |

## INCIDENT INVESTIGATION

| | | |
|---|---|---|
| LICENSEE: | Mary Bird Perkins Cancer Center<br>4950 Essen Lane<br>Baton Rouge, Louisiana 70809 | INSPECTION DATE:<br>February 16, 1988 |
| LICENSE NO.: | LA-2651-L01 | REPORT DATE: |
| INSPECTED BY: | Robert D. Funderburg, Manager<br>Licensing & Registration Section | April 6, 1988 |
| | David A. Zaloudek<br>Licensing Coordinator | PERSONS INTERVIEWED:<br>William Kubricht, Carrie Rudolf<br>Oscar Hidalgo, Mike Martin, |
| REPORT BY: | Robert D. Funderburg | Dr. George Mills, & Dr. Max Scott |

---

On February 11, 1988, Mr. William Kubricht informed the Louisiana Nuclear Energy Division of a possible problem with a leaking or contaminated Cesium-137 brachytherapy source at the Mary Bird Perkins Cancer Center. He had found removable contamination on a wipe test in the storage area in the Cancer Center that was identified as Cesium-137. He suspected that the problem was one (1) or more of 44 sources manufactured by the 3M Company in Minnesota. He had contacted the manufacturer, who retained Dr. Max Scott, Radiation Safety Officer at L.S.U., to assist in finding the source of the contamination. On Wednesday, February 16, 1988, an inspection was conducted at the Mary Bird Perkins Cancer Center to investigate the incident. The following were present at the discussion: William Kubricht, RSO; Carrie Rudolf, Oscar Hidalgo, Medical Physicists; Mike Martin, Executive Officer of Mary Bird Perkins Cancer Center; Dr. George Mills, RSO at Our Lady of the Lake Hospital; and Dr. Max Scott, Consultant for the 3M Corporation. Mr. Kubricht gave a short history of the events as follows:

In May, 1986, a shipment of Cesium-137 brachytherapy sources was received by Mr. Kubricht at Mary Bird Perkins and placed in a small, leadlined storage vault. Sometime between October 15 and December 29, 1987, Mr. Kubricht decided to relocate his source storage area and placed the sources in another vault with other Cesium sources already being used for brachytherapy treatment. During the week of February 8, 1988, Mr. Kubricht moved the empty storage vault and made a survey of the empty vault to assure that all sources had been transferred. He found residual radiation levels. A contamination swipe confirmed that there was removable radioactive material on the empty storage vault. At first, it was assumed that there was some other type of contamination, such as residual Iridium-192 or Iodine-131. The swipe was sent to the Nuclear Medicine Department where it was confirmed to be Cesium-137.

Leak tests had not been performed on the Cesium sources since their receipt. The manufacturer had provided a leak test certificate that indicated the sources were leak tested in May, 1986. There was no removable activity at that time and a three (3) year interval was approved as a leak test procedure. (Louisiana Radiation Regulations require six (6) month leak tests on all medical brachytherapy sources.)

Mr. Kubricht was unable to ascertain which and how many of the sources were the cause of the contamination. He contacted the manufacturer who retained Dr. Max Scott, RSO at L.S.U., to determine the extent of the problem with the leaking

sources. Wipe tests performed by Dr. Scott found removable activity on all of the brachytherapy sources. One (1) source was particularly identified has having an appreciably greater amount of removable radioactivty. Later tests confirmed that this source was leaking.

There were several other brachytherapy sources stored in the same vault manufactured by another company. These sources were tested and subsequently found to have removable contamination but not considered leaking sources. Mr. Kubricht could not positively confirm if the one leaking brachytherapy source had been used in patients between December 29, 1987, and the date of the inspection. He did confirm that there were 11-12 patients treated during that interval of time. After-loading devices were checked and found to be contaminated; this contamination was later attributed to the procedures for placing the after-loading devices in a disinfectant after patient treatment. Mr. Kubricht and Dr. Scott made contamination surveys and found the storage areas in an unused accelerator room and the normal storage and loading room to be contaminated. Several spots on the corridor floor and carpet were identified as having contamination. These had been isolated in attempts made to remove the contamination. Mr. Kubricht isolated the storage areas and attempted to clean up the spots under Dr. Scott's supervision.

The inspectors made the following requests:

A. All brachytherapy sources are to be wiped and tested for removable contamination (this should include the additional five (5) sources that were manufactured by another company plus the 44 sources originally mentioned. Dr. Scott stated that a limit should be established to identify removable activity from the sources in order to designate them as "clean". A guide of twice normal background was established. This level is assuming proper instrumentation sensitive enough to detect 200 dpm.

B. All brachytherapy patient treatment should cease until specific approval is authorized by the Division. Patients already scheduled for treatment could be treated with new or cleaned equipment. Dr. Mills outlined a procedure to be followed for checking patients for contamination. All patients had been given directions for sanitary cleansing of the vaginal areas before being discharged from the hospital and were scheduled for a recheck in the next two (2) to three (3) weeks when contamination could be checked at that time. Any suspected contamination would then be followed-up with a special procedure using a pencil probe capable of identifying hot spots in patients. However, this probe would not be available for at least one (1) week. In the meantime contamination swabs could be counted by using a well-counter available at the Baton Rouge Pharmacy. Areas of contamination should be isolated and procedures established to ensure that contamination is confined. Mr. Kubricht and Dr. Scott stated that the areas had already been isolated and an attempt would be made to clean the carpets. The alleged leaking source should be sent back to the 3M Company for analysis. It should be properly packaged in the appropriate containers and labeled.

At this time it was brought to the attention of the Perkins Administration that previous requests sent by the Division for additional information to support the application have not been answered. A review of the history in the license file revealed that information had been promised for renewal of the license two (2) years ago that, to date, had not been received (see letter dated March 1, 1987). Requests were made by the inspectors to have this information submitted as soon as possible.

On Friday, Febuary 18, 1988, Mr. Kubricht informed the Louisiana Nuclear Energy Division that additional areas of contamination were discovered in the main corridor of the accelerator area and attempts had been made to vacuum and shampoo the carpets. It appeared that the activity was fixed in the carpets and measured to be 1 to 3 times normal background. Mr. Kubricht was instructed to cover the areas with plastic material to prevent further spread of contamination. Two (2) patients had been checked for contamination and a swab of one was found to be positive. The swab had been counted at the Baton Rouge Pharmacy. This patient was going into surgery for a hysterectomy on the week of February 21, 1988, and Dr. Mills assured the inspectors that proper precautions would be taken and that a study would be made to detect contamination levels in the patient. It was later determined that the contamination found on the one (1) swab could have conceivably been from a contaminated pair of tongs and not the patient. Further investigation showed that the activity was not Cesium-137.

During the week of February 22, inspectors visited the Mary Bird Perkins Cancer Center daily to discuss progress in isolation of the contamination areas, further identification of patient contamination, and cleanup. The following is a dissertation of items that were accomplished during this and subsequent weeks:

All 48 sources were decontaminated and retested. The leaking source was sent back to the 3M Company and confirmed to be leaking. Six (6) of the 11 patients were checked and found to be free of contamination. The one (1) patient found to be contaminated was deemed to be cleaned. The contamination was thought to have come from mishandling of the swab. Radiation Management Corporation was retained to provide cleanup of the source storage room and the general storage room. Decontamination Levels were established to be values used in NRC Regulation Guide 8.6. which is 5000 dpm/100 cm2

During the week of February 29 and March 4, 1988, inspectors observed the cleanup operation conducted by Radiation Management Corporation. Mr. Lee Booth was the supervisor of the crew of three (3) helpers. Personnel dosimeters, badges, and calibrated survey equipment were all provided. Mr. Booth described procedures used for surveying the decontaminations which were approved by the inspectors.

Week of March 7 through 11, 1988: The decontamination operation was completed and the accelerator room and the after-loading room were checked for contamination and cleared by the inspectors. Radioactive waste that was produced during cleanup operation was placed in four (4) barrels to be transferred to ADCO for subsequent transfer to a radioactive waste disposal site. All 11 patients had been surveyed and determined to be free of any contamination. Information received from Mr. Kubricht was reviewed and found to still be deficient, and Mr. Kubricht agreed to provide that additional information.

March 22, 1988: Mr. Kubricht informed the Louisiana Nuclear Energy Division that three (3) patients had been scheduled for brachytherapy and requested approval. At this time more information was needed relating to the license and there had been no report received on the incident. Mr. Kubricht was told that authorization would be given if the attending physician would stipulate that it was in the patients' best interest for the brachytherapy procedures to occur. These letters were received, and authorization given for the three (3) patients.

March 29, 1988: Mr. Kubricht provided the incident report, and the additional information needed for the license renewal. He informed the Louisiana Nuclear

Energy Division that treatment of one (1) of the three (3) patients previously approved had been postponed and another patient was treated instead. This was not deemed to be acting in good faith, since approval was given for three specific patients.

April 5, 1988: A letter was written authorizing the licensee to treat patients on a routine basis.

SUMMARY:

The main cause of the incident was the leaking Cesium source. The Radiation Safety Officer failed to conduct a leak test prior to utilization. Had this been done, this contamination of the facility might not have occurred. The manufacturer listed a leak test interval of three (3) years and the Radiation Safety Officer believed that he did not have to do the leak test for three (3) years. The Louisiana Radiation Regulations require six (6) month leak tests for medical sources. It was undetermined when the contamination of the facility occurred, but from information obtained, it is assumed that contamination occurred after December 29, 1987. Inventory records and utilization logs should be improved to provide better documentation of source use. (Finally, all sources should be wiped for residual activity prior to being returned to storage.)

RDF:cwr

Mary Bird Perkins
CANCER CENTER
Accredited by the American College of Radiology

MICHAEL H. MARTIN
Executive Director

INCIDENT REPORT

TO: The State of Louisiana
Nuclear Energy Division

PREPARED BY: William Kubricht, Jr., Chief
Department of Clinical Physics
Mary Bird Perkins Cancer Center

DATE: March 28, 1988

## I N T R O D U C T I O N

On 10/15/87, a decision was made to relocate the storage area of our radioactive materials to a more centrally located area of the center. This relocation involved substantial renovations to the room in question in preparation for actual moving of the radioactive sources.

Upon completion of these renovations, the source transfer was initiated 2/10/88. Lead safes, L-blocks and other shielding equipment normally used with the sources were transported. At the time of transportation the sources were in place in the secured safes. Two safes were involved, one having the old inventory and the other containing the newer inventory which had been recently partially unpacked and calibrated. The newer inventory had been in storage for almost two years. They had not been unpacked and put into use due to indecision about where they would be stored. Upon unpacking, there was no wipe test performed due to two reasons; first, they had remained stored in the original sealed containers and, secondly, all sources were

4950 Essen Lane P.O. Box 43457
Baton Rouge, LA 70895-6457 504-767-0867

well within the NRC requirement of wipe testing every three years. This was in direct violation of Louisiana law which requires wipe tests of cesium sources every six months, as is the custom with Radium.

As the transfer of the two safes containing the old and new inventories was completed, it was decided to attempt to load all sources into a single safe and survey the surrounding area in hopes that one safe could be done away with. The drawers of the safe chosen to hold all sources were sent to our machinist (Mr. Allen Young) for modification.

The modification employed the addition of additional shielding in the void of the drawer of the safe which would then be appropriately drilled to the correct depth and diameter to contain the individual sealed sources. It was felt that the additional shielding would permit the additional sources being contained within the same safe. In addition, provision was made by drilling each drawer with two separate groups of holes so that the old inventory could be distinguished from the new.

Late that afternoon, all sources were transferred to the modified safe. Prior to initiating a survey of the room and adjacent areas, the empty safe was surveyed to confirm that it was in fact empty. This was done by opening each drawer individually and

inserting the probe of a Geiger-Mueller tube into the drawer without contacting the drawer. The second drawer examined exhibited an extremely high degree of radioactivity, giving the impression that a source was remaining in the drawer. The drawer was examined; no source was found.

At that time it was apparent that contamination remained in the drawer though it was not appreciated that it might be cesium. Over the past several decades doubly encapsulated cesium sources have been in use in this country and such an incident has not occurred. Consideration was given to the possibility that a graduate student may have brought in some other isotope from the outside, something of a short half life nature such as iodine, though careful questioning of all who had access to the area revealed nothing.

At that point, consideration was given to cesium. On 2/11/88 Dr. George Mills, who has access to sophisticated counting equipment was contacted and asked for assistance. A wipe sample from a known contaminated area was placed in a multichannel analyser and a distinct peak at 662 KeV was demonstrated.

With this information on hand, a call was placed to the Nuclear Energy Division informing them (Mr. Ronald Wascom) of the distinct possibility that a significant degree of contamination

had been demonstrated. The actual source of the contamination, e.g. arriving as external contamination on a source or contamination due to a leaking source, had not been determined. The same information was forwarded to 3M who planned an immediate site visit (Mr. Dave Kubitowitz). A site visit was also initiated the following day (and several subsequent days) by members of the Nuclear Energy Division (Messrs. Robert Funderburg, David Zaloudek and James Miller).

On the morning of 2/12/88, a meeting was held with Mr. Mike Martin and Mesdames Pat Summers and Brenda Truxillo to inform them of the situation. A meeting was scheduled for that same day at noon to inform the entire staff of the situation and to give the staff some information about the events that would be coming in the immediate future.

At that time a committee comprised of Mr. William Kubricht, Dr. Oscar Hidalgo, Ms. Carrie Rudolf and Dr. George Mills was formed to act as the committee that would evaluate and deal with the problem at hand. The actions of this committee, its results and future plans are outlined in the balance of this document.

## STATEMENT OF THE PROBLEM

Late in the evening of 2/10/88, contamination was found in one of the drawers of the cesium storage safe in which sources from the most recent shipment had been placed. Additional contamination was found on the L-block mort used in the handling of these sources. As previously noted, it was not appreciated at that time that the contamination was cesium. The contaminated area on the L-block appeared to be liquid form, leading us to believe at the time that the possibility existed for iodine. That notion was quickly dispelled.

Once it was determined that cesium was the isotope with which we were dealing, a more extensive survey was performed. Again, instrumentation was borrowed from Our Lady of the Lake Hospital though none of the instrumentation that we had on hand at that time proved to be the ideal choice.

The contamination was limited to places in which the sources were normally handled -- the L-block, the work surfaces, the brachytherapy calibration chamber, forceps, source carriers used for transportation; all contained some level of contamination. In addition, the general area about the calibration instrumentation yielded low level contamination. Surveys of both the old and new areas yielded some degree of contamination.

At this point, it was determined that the contamination seemed to be well localized in the back corner of the unfinished treatment room and the old photographic lab, which had been converted to the new storage area. Both areas were restricted and appropriately posted, with gloves and shoe covers being made available for entry to both areas.

By 2/12/88 the decision had been made to attempt to continue our clinical program of the treatment of patients. Prior to this, however, wipe tests were performed on the cesium tube sources, and the Heyman sources. One cesium tube was found to have outside contamination; the Heyman sources surveyed as clean.

Careful examination of instruments used for GYN implants disclosed contamination in four source holders. Other applicators or portions of applicator sets were found to have very low level contamination, probably transferred in the washing process and these systems were removed from service.

Two additional patients were treated during this time frame, between February 10th and February 19th. Subsequent treatments were discontinued due to the continuing doubtful nature of our applicators. At one time, either during the period of time that the original contaminated safe was being moved, or during the period of evaluation of the contamination, the opportunity for

transpo ing contamination occurred and a distinct set of "footprints" could be found leaving the old storage area and moving in the direction of the new area. The contamination was obviously on one shoe and it decreased in intensity as the contaminated shoe moved along its path to the new storage area.

By the fifth day, the extent of the contamination was ell understood. All areas were restricted and confined; cleanup activities began at that point in earnest.

## ACTIONS TAKEN

On 2/12/88, Dr. Max Scott, Consulting Health Physicist for 3M, visited the site in preparation for evaluation for cleanup. During the initial assessment, one of the original shipping containers was found to be contaminated having higher levels of radioactivity than any previously encountered. All sources were wiped, with sources 1 through 6 being condemned. The balance, through No.33, were cleared for use. Records of patients treated subsequent to the opening of the new sources on 12/29/87 were pulled and evaluated. The rooms which these patients had used at Our Lady of the Lake, Woman's or Earl K. Long were evaluated for contamination and found to be negative.

Since the carpet in the treatment area had been contaminated, it was assumed that the possibility existed that contamination could have been tracked by individuals normally working in that area to their homes. Extensive evaluation of homes were made at that time. In addition, as appropriate, cars were checked for contamination, not only for individuals transporting sources but for any individuals who thought the possibility might exist that they had accidentally tracked contamination. As noted in previous correspondence, twelve (12) patients were evaluated for

contamination of the vaginal mucosa and subsequently found to be negative and at background levels. Evaluation was performed with a transvaginal scintillation detector and by wipe test of the vaginal mucosa. Wipe tests were counted in a well counter at the Central Pharmacy Lab. All counting procedures were confirmed by Dr. Scott at the Nuclear Science Center.

A cleaning company was brought in to effect cleanup of the carpet in the treatment area immediately after confirming contamination in the carpet. The cleaning procedure was considered successful even though all contamination was not removed. Since we had a a tenfold decrease in the level of contamination in these areas of the carpet, it was felt that at least all of the removable contamination was removed and hence one would not expect the possibility of tracking to continue. The actual time that was involved in which there was contamination in the carpet available for tracking was held to a minimum. The areas were then covered with film.

On 2/20/88, Radiation Management Corporation (RMC) was called to make arrangements for them to effect the cleanup, which was undertaken on 2/29/88. The entire cleanup was supervised by the Physics staff here at Perkins in conjunction with 3M's representative, Dr. Max Scott. All easily transported materials were

shipped under the supervision of Dr. Scott. The only remaining contaminated items were in a confined area in the unfinished treatment room. A decision on the disposition of these items will be made at a later date in conjunction with 3M. All old applicators have been pulled from service and have been replaced with new systems by 3M Corporation. The contaminated applicators will be evaluated though none will be returned to service unless all contamination can be removed. No attempt will be made to clean a system that has already been replaced. At this juncture our only interest in salvaging old applicators is a 15 and 30 degree square handled Fletcher-Delclos colpostat which cannot be replaced. An attempt will be made to clean these instruments.

## FUTURE PLANS

It becomes obvious, as we review this entire event, that normal operating procedures at any hospital in this country which follow a six-month wipe test routine would not have caught a leaking source until obviously six months at the maximum of when it had started leaking.

Obviously a wipe test upon receipt of these sources, prior to putting them into use, would have precluded such an event.

As the procedures for the radioactive material license were rewritten in conjunction with the cleanup of the contamination, various procedures were incorporated that would not have ordinarily found their way into common use. They are described in detail in the Policy and Procedures submitted in support of our license application. Philosophically, however, these detailed attempts will be made at confirming the integrity of sources prior to their clinical use on a regular basis. The instrumentation for such a program has been purchased and is being put in place as this document is drafted.

In addition, more concise methods of maintaining inventory control over these sources to the extent that a serial number source can be immediately earmarked at any given position in a gynecological system during the entire duration of the patient's treatment will be conducted. These records become a part of the permanent record of the patient and constitute also the record of our source, transfer and inventory.

Ultimately, all sources at Perkins within the next few weeks will be, in all probability, replaced by 3M Corporation as the final move in effecting a worthwhile resolution of this incident. In addition to the above, a system of routine wipe test of all sources in the work area will be effected in accordance with the Policy and Procedures Manual.

WK/eom