AEOD/

Preliminary
Case Study Report
on the
Rupture of an Iodine-125 Brachytherapy Source
at the University of Cincinnati Medical Center

by the

Office for Analysis and Evaluation of Operational Data

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This report documents the preliminary results of an ongoing study by the Office for Analysis and Evaluation of Operational Data (AEOD) with regard to a particular operating event. This report is issued for review and comment as part of the peer review process used for AEOD case studies. Since the study is ongoing, the content, findings, and recommendations are preliminary and may not represent the final positions of AEOD, the responsible program office, or the Nuclear Regulatory Commission.

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Executive Summary

The University of Cincinnati Medical Center reported to NRC (Region III), by telephone, the rupture of an iodine-125 seed (nominal activity of 40 millicuries). The seed, which was one of eight seeds being used by the University of Cincinnati Medical Center for brachytherapy treatment of brain tumors, was ruptured during removal of the seed from Heyer-Schulte coaxial catheters. These seeds, containing iodine-125 adsorbed on anion exchange resin spheres within a .05 mm thick welded titanium capsule, are manufactured by the 3M Company. The 3M Company specification sheet for the seeds indicates that the seeds can be used as removable brachytherapy implants. Because of this and the high activity of the seeds, the seeds can be used to treat several patients. Furthermore, users of the seeds are encouraged to consider reusing the seeds because of the relatively high cost of the seeds. This use is in contrast with the use of lower activity (0.1 to 1 millicurie), iodine-125 seeds also manufactured by the 3M Company, which are used as permanent implants (e.g., prostate cancer treatment).

The seeds are loaded into catheters for use in brachytherapy. Therefore, each reuse of the seeds involves removing them from old catheters and loading them into new ones. It was during this process of removing the seeds from old catheters using scissors, a razor blade, and a needle that one of the seeds was ruptured. The cause of the rupture was determined to be a cut by the scissors or one of the other sharp objects used to cut the catheters to free the seeds.

Licensee personnel were not immediately aware that one of the seeds had been ruptured.* Consequently, the seeds were loaded into new catheters and implanted in the scheduled patient. As a result, the patient received a thyroid burden and exposure of 557 microcuries and 2087 rads respectively.

A number of other persons also received uptakes of iodine-125. The removal of the seeds from the old catheters and loading of the seeds into the new catheters were done in the brachytherapy source room (BSR) in an area not ventilated by a fume hood. As a result, the BSR including the exhaust system, was contaminated (1000-1100 dpm/200 cm^2). Also, although the BSR exhaust system was on at least for a period of time before and after the seed rupture, the BSR apparently was under a positive pressure because of a blockage in the BSR exhaust system. This resulted in some iodine-125 being released to an area where a number of hospital personnel received uptakes of iodine-125. In total at least 60 hospital personnel, including personnel involved in the control and clean-up of the contamination, received thyroid uptake doses of .04 to 209 nanocuries.

Following the seed removal operation, the work area (in the BSR) and the tools used in the removal and loading of the seeds were surveyed with a survey meter normally capable of detecting low levels of iodine-125. However, the BSR had high background radiation which apparently masked the positive indication of contamination. The licensee did not perform wipe surveys normally done to detect low levels of contamination. After the contamination was discovered, licensee personnel took action to control and decontaminate the area.

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*During the period that the seed was ruptured, the seeds were removed from old catheters and loaded into new catheters on two separate occasions.

Because of the seed rupture event, the University of Cincinnati decided to terminate the use of high activity iodine-125 seeds until the safety and health physics aspects of these seeds are studied.

AEOD undertook a review of this incident to determine if there is a generic problem associated with the reuse of high activity iodine-125 seeds in brachytherapy implant protocols, and to assess any associated health and safety problems.

Based on our evaluation of this incident we found that:

1. The risk of an iodine-125 seed rupture is relatively high when the seeds are reused for several patients. The risk of a seed rupture is associated with:

   -- The susceptibility of the seeds to damage from typical tools used for removing the seeds (razor blade, scissors, etc.); and

   -- The discolored or stained condition of the catheters after use in therapy, making viewing of the seeds difficult.

2. The consequence of the seed rupture at the University of Cincinnati--involving patient and other personnel uptakes and the facility contamination--could have been mitigated by adequate radiation surveys of the work area and the tools used to remove the seeds from the catheter, and/or by performing a leak test of

the seeds. Additionally, personnel uptakes other than the patient and the facility contamination could have likely been prevented if the seed removal operation had been performed under a fume hood.

3. As a result of the iodine-125 seed rupture event at the University of Cincinnati, the 3M Company now voluntarily includes a "warning notice" with the packaging of iodine-125 seeds that implies that the seeds should not be reused. If the wording of this "warning notice" is clarified to state explicitly that seeds are not to be reused and the 3M Company license is amended to require the inclusion of the "warning notice" with the packaging of iodine-125 seeds, then "Group Byproduct Material Licensees" would be prohibited by regulations from reusing the sources. "Broad Scope Material Licensees" are not required to follow the source manufacturer's recommendations for safety and handling and thus would not be prohibited from reusing the seeds.

In addition to the specific findings stated above, we believe that attention should be called to one other matter related to the incident:

-- The University of Cincinnati's licensed program represents a large research and medical use isotope program that typically employs a full-time health physics staff that is generally familiar with a wide variety of uses of radioisotopes. In this event, however, it appears that licensee personnel failed to appreciate or understand the potential for a seed

to be ruptured by the seed removal operation or the consequence of such a rupture, in that the protocol describing procedures to be followed for temporary implants did not require (1) that the seed removal operation be conducted in a fume hood; or (2) that wipes survey and/or leak test* be performed to verify the integrity of the seeds before the sources were reused.

Based on our findings, we recommend that:

-- The Office of Inspection and Enforcement (IE) send an Information Notice to the affected licensees describing the event at the University of Cincinnati and describing the action taken by the licensee and the source manufacturer (3M Company) to prevent the recurrence of similar events.

-- The Region III office amend the 3M Company's distribution license to make the inclusion of a "warning notice" in the packaging of iodine-125 seeds a part of the license requirements. This amendment should ensure that the 3M Company's recommendation that the seeds not be reused is clearly stated in the "warning notice."

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*NRC regulations do not require such a leak test.

-- The Office of Nuclear Material Safety and Safeguards (NMSS) determine whether further regulatory actions should be undertaken by NRC to ensure that "Broad Scope Byproduct Material Licensees" will not reuse the high intensity iodine-125 seeds.

1.0 INTRODUCTION

The University of Cincinnati reported to NRC/Region III by telephone that an iodine-125 brachytherapy source was found to be leaking. The licensee later submitted a written report giving an account of the circumstances surrounding the source rupture (Ref. 1).

In the month following the event, inspection personnel from the NRC/Region III office conducted a special inspection to review the facts surrounding the source rupture. The results of this inspection are documented in Region III Inspection Report No. 30-02764/84-02 (Ref. 2).

The University of Cincinnati's medical isotope program is licensed under 10 CFR Part 33, "Broad Scope Byproduct Material License". A "Broad Scope Byproduct Material License," among other things, authorizes licensees to employ a radiation safety committee to conduct safety evaluations of proposed uses (including human use) of byproduct material (e.g., review facilities and equipment, operating or handling procedures, training and experience of users, etc.) and approve such uses in lieu of requesting from NRC approval of proposed uses. The other type of byproduct material license for human use issued by NRC is a "Group Byproduct Material License" authorized under 10 CFR Part 35. This license, among other things, differs from the "Broad Scope Byproduct Material License" in that specific isotopes and their authorized uses are listed in the license and any changes in authorization must be approved by NRC before the changes are implemented.

In regard to the use or reuse of high intensity iodine-125 seeds, the following observations are made relative to licensing:

-- The "Broad Scope Byproduct Material License" authorizes the use of the seeds through the mechanism of approval of uses of byproduct material by the medical isotope committee.

-- The "Group Byproduct Material License" authorizes the use of the seeds through 10 CFR Part 35.100(f)(8) which states, "Iodine-125 as seeds for interstitial treatment of cancer".

-- The "Group Byproduct Material License" requires the licensee to follow the radiation safety and handling instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer in the leaflet or brochure that accompanies the source. (This will be discussed further in Section 4.)

AEOD's review and analysis of the incident was undertaken to determine whether there is a generic problem with the reuse (treating several patients with the same set of seeds) of high activity iodine-125 seeds, and to assess any associated health and safety problems. This review is primarily based on information obtained from the licensee's report, the NRC/Region III inspection report and a telephone conversation with University of Cincinnati personnel involved with the radiation therapy program.

Section 2 is a description of the source rupture event; Section 3 is an analysis of the event; Section 4 discusses the licensee's and the source manufacturer's actions following the event; Section 5 gives the findings of the study; and Section 6 contains the conclusions and recommendations from the study. Appendix A is a copy of the licensee's protocol for the use of iodine-125 seed in brachytherapy; Appendix B is the manufacturer's specification sheet for the iodine-125 seeds; Appendix C is the manufacturer's specification sheet for the Heyer-Schulte coaxial catheters; and Appendix D is the manufacturer's specification sheet for the MiniMonitor 125 radiation survey meter.

2.0 DESCRIPTION OF THE EVENT

2.1. General

The source rupture event at the University of Cincinnati involved the rupture of a high activity (40 millicurie) iodine-125 seed. The seed was one of eight seeds being used as a temporary implant in the brachytherapy treatment of brain tumors. The seeds were manufactured by the 3M Company. Because the seeds could be used as temporary brachytherapy implants and because of the high activity and relatively high cost of the seeds, the University of Cincinnati was using the same set of seeds to treat several patients. This reuse of the seeds involved removing the seeds from catheters and loading them into new catheters. This was a new procedure at the University of Cincinnati.* Previous uses of

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*The protocol describing procedures to be followed for temporary brain implants received radiation safety committee approval prior to use of the seeds (Appendix A).

iodine-125 seeds involved the use of low activity iodine-125 seeds (0.1-1 millicurie) as permanent brachytherapy implants.

2.2 Chronology of Events

The following excerpt from the Region III inspection report gives a chronology of licensee actions leading to the rupture of the iodine-125 source. (For further details see Ref. 2)

(1) On Friday (day 1), the Radiation Safety Office received 400 millicuries of iodine-125 brachytherapy seeds. A total of 10 seeds, 40 millicuries each, were inventoried.

(2) On Monday (day 4), eight of the ten seeds were prepared and implanted.

(3) On Friday (day 8), the seeds were removed from the first patient.

(4) On Monday (day 11), the eight seeds were removed from the original catheters. Five seeds were prepared for treatment of patient 2, however, this treatment was cancelled.

(5) On Monday (day 18), the five seeds were removed from the catheter and eight seeds were prepared and implanted into patient 3.

(6) On Tuesday (day 19), a wipe test of a shipping container revealed iodine-125 contamination. Source of contamination was traced to the brachytherapy source storage room.

(7) On Wednesday (day 20), a wipe test of the patient's head and bandage revealed no contamination.

(8) On Thursday (day 21), a thyroid count on the technician who prepared the seeds revealed a 209 nanocurie uptake.

(9) On Friday (day 22), air flow rates in the brachytherapy source storage room were determined. Urine bioassays of personnel working with the seeds revealed nanocurie amounts of iodine-125.

(10) On Saturday (day 23), the seeds were removed from patient 3. After explant, a survey of the patient's neck revealed a radiation level of 1.5 mR/hr at two inches from the thyroid. The patient was discharged.

(11) On Tuesday (day 26), a urine bioassay from the patient revealed 57.6 microcuries of iodine-125. The NRC in Region III was notified.

(12) On Wednesday (day 27), a thyroid bioassay on patient 3 revealed a burden of 557 microcuries.

(13) On Thursday (day 28), determination of area contamination continued.

(14) On Friday (day 29), the NRC Region III was informed of current conditions and actions taken. Decontamination of the storage room continued.

(15) On Monday (day 32), the exhaust system in the storage room was modified to increase flow rates.

(16) On Tuesday (day 33), evaluation of contaminated areas continued.

(17) On Wednesday (day 34), the condition of the patient was determined. The walls in the storage room were painted to "fix" the contamination.

(18) On Thursday (day 35), air samples taken from the storage room revealed no detectable activity.

3.0 ANALYSIS OF THE EVENT

3.1 Seed Rupture

A review of the manufacturer's specification sheet for the iodine-125 seeds shows that the seeds consist of a welded titanium capsule containing iodine-125 adsorbed on anion exchange resin spheres (Appendix B). The titanium capsule thickness is .05 mm. The capsule is a cylinder .8 mm in diameter and 4.5 mm long. The catheters used at the University of Cincinnati were Heyer-Schulte coaxial after-loading teflon catheters. They consist of an inner and an outer catheter, 16.5 cm long and 15 cm long respectively (Appendix C). The catheter manufacturer specifies that the catheters are recommended for "single

use only," therefore, reuse of the iodine-125 seeds contained in the catheters requires removing the seeds from the old catheter and loading them into a new catheter.

The technique used for removing the seeds from the catheters at the University of Cincinnati consisted of first cutting the ends off of the catheters using scissors and then using a razor blade to shear the plastic tubing longitudinally in such a manner as to expose the bare seed from the catheter enough so that forceps could grasp the seed. This same technique was reportedly used for removing the seeds on both day 11 and day 18. The protocol describing procedures to be followed for using the high activity iodine-125 seeds for temporary implants did not address how to remove the seeds from the catheters. The technologist involved in the seed removal feels that the seed was likely ruptured by the scissors when the ends of the catheters were cut off. This view of the cause of the rupture is consistent with the findings of the manufacturer, 3M Company who analyzed the leaking seed.

An excerpt from the 3M Company report states: (Ref. 3)

> In conclusion, of the ten high-activity I-125 seeds returned to 3M for inspection following discovery of radioactive contamination at your institution, only one seed (seed #2) released I-125. In our estimation this release was caused by structural damage to the titanium shell of the seed in the form of a transverse cut near the weld end. The cut may have been caused by a scissors or wire cutter, etc., used to free seeds from the catheters prior to loading them into new catheters.

The technologist involved in the seed removal feels that this cut had likely occurred during removal of the seeds on day 11. The seeds removed at that time were contained in catheters that were stained from having been implanted

in a tumor thus making it difficult to see the seeds in the catheter. In addition, the technologist indicated that the inner catheter and outer catheter were stuck together and could not be separated, further hindering visibility of the seeds. By contrast, the seeds that were removed from the catheters on day 18 had not been used (therapy cancelled); therefore, the catheters were clear and allowed greater visibility of the seeds.

3.2 Contamination and Personnel Uptakes

The removal of the seeds on both day 11 and day 18 was done in the brachytherapy source room (BSR) in an open area that was not ventilated by a fume hood. Also, the BSR apparently was under a slight positive pressure at the time because of a blockage in the room's exhaust system (a damper was partially closed) that reduced the exhaust flow rate to less than the exhaust flow rate for the area outside of the BSR.*

Licensee personnel stated that both times the seeds were removed, radiation surveys of the work area and the tools used in removing the seeds were made and that these surveys revealed no contamination. The surveys were done with a Nuclear Associate's MiniMonitor 125 which, according to the manufacturer's specification sheet, has a minimum range of 0-500 counts per minute (cpm) (Appendix D). The Region III inspection report noted that the background radiation level in the BSR was normally high because of the proximity of other brachytherapy sources. This made it difficult to detect contamination

*Following the discovery or contamination in the BSR, it was closed off using plastic over the door. It was noted that the plastic was ballooned outward, indicating a positive pressure in the BSR.

using a survey meter. Wipe surveys, which involve wiping suspected contaminated areas with cotton swabs or similar material and later counting the wipes, were not done. Good health physics practices and NRC regulatory requirements indicate that, under the circumstances, wipe surveys should have been performed to look for contamination.* In addition, good health physics practices indicate that, since removal of the seeds from catheters involved non-routine handling of the seeds which increased the risk that seeds could be damaged, the seeds should have been leak-tested following removal of the seeds from the catheters. The protocol describing procedures to be followed for using the high activity iodine-125 seeds for temporary implants did not address making wipe surveys or leak testing of the seeds.

On day 19, the day after the sources were implanted in a patient, the licensee discovered iodine-125 contamination on a source storage/transport bucket for iridium-192 that had been stored in the brachytherapy source room. The iodine-125 contamination which was discovered during routine wipe surveys of the bucket (being prepared for shipment) averaged approximately 625 dpm/200 cm^2. The contamination was traced to the brachytherapy source room. The BSR was sealed off and decontamination was begun. Wipe testing of the brachytherapy source room revealed contamination levels of 1000-11000 dpm/200 cm^2.

The day following the discovery of iodine-125 contamination in the BSR, licensee personnel wipe tested the patient's lead hat and bandage to check for

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*The licensee was cited by NRC/Region III for being in violation of 10 CFR 20.201(b), which requires licensees to make surveys as necessary and reasonable under the circumstances to evaluate the radiation hazards.

contamination. No contamination was found. Later, after it was determined that the source of the iodine-125 contamination was the implanted seeds, a medical decision was made to leave the sources implanted for the prescribed period of the therapy (Ref. 4).*

The implanted seeds were removed from the patient on day 23. The catheters containing the seeds were placed in a lead-shielded container and taken to the radiation safety laboratory and placed in a fume hood. The catheters containing the seeds were later sent to the 3M Company for evaluation. A survey of the patient's room with a survey meter revealed no contamination. However, a survey of the patient revealed a radiation level of 1.5 millirem per hour 2 inches from the thyroid gland. The patient was released from the hospital on day 25. On day 27, the patient returned to the hospital for a bioassay and the results indicated a thyroid burden and exposure of 557 microcuries and 2087 rads, respectively.

The positive pressure in the BSR, which existed for several days following the discovery of iodine-125 contamination in the room, aided the airborne migration of the iodine-125 into adjacent areas. This resulted in numerous personnel who frequented these areas receiving uptakes of iodine-125. Other personnel involved in the control and cleanup of the contamination also

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*Because a medical evaluation and decision was made to leave the implanted sources in place, the iodine-125 uptake by the patient was not deemed by NRC to be a medical misadministration as defined in 10 CFR 35.41.

received iodine-125 uptakes. Bioassay results for these personnel indicated that:

-- The technician who prepared the iodine-125 seeds had a thyroid uptake of 209 nanocuries; and

-- Sixty hospital personnel and a friend of the patient had thyroid uptakes that ranged from .04 to 209 nanocuries.

The maximum permissible body burden (MPBB) for iodine-125 is 500 nanocuries.

Although the contamination of the BSR was extensive, wipe surveys and air samples revealed that the contamination was essentially limited to the BSR. Wipe tests taken in the brachytherapy source room showed contamination levels that ranged from 160-3900 dpm/200 cm^2 for the wall and floor to 1900 dpm/200 cm^2 on the lowered-ceiling tiles. A maximum total of 25 microcuries of iodine-125 was estimated to be in the paint on the walls. Air samples taken in the BSR showed air concentrations of 52 to 125 dpm/20 ft^3, (less than the maximum permissible concentrations for restricted areas). Air samples taken outside of the BSR showed negligible concentrations. However, contamination (approximately 7700 dpm) was found on the total surface area of the BSR exhaust vent at the point of release.

The University of Cincinnati successfully decontaminated the BSR or fixed the contamination by repainting the walls.

4.0 LICENSEE AND SOURCE MANUFACTURER ACTIONS

4.1 Licensee Actions

As a result of the source rupture, the University of Cincinnati suspended the use of high intensity iodine-125 seeds pending the investigation of the event (Ref. 5).* The University of Cincinnati, in their response to the NRC Notice of Violation,** expressed concern that there was a likelihood of other occurrences of source ruptures involving the reuse of high intensity iodine-125 seeds.

An excerpt from the University of Cincinnati's response is as follows:

> The sealed source was opened by a radiation safety technologist under conditions of poor visibility. This accident could have happened at any installation in the country where the seeds would have been placed in plastic tubing which becomes discolored from use and an attempt made to retrieve the seeds and reutilize them because of their cost. These concerns have been shared with the manufacturer of the seeds who has agreed that it would be unwise for any of the high activity iodine-125 (40 mCi) seeds to be reutilized within a hospital since this problem could occur again anywhere.

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*As of the date of this report the University of Cincinnati has not resumed the practice of reusing the seeds to treat multiple patients.

**The University of Cincinnati was in noncompliance with the License Condition 15, which states that sealed sources shall not be opened, and 10 CFR 20.210, failure to make adequate radiation surveys.

4.2 Source Manufacturer Actions

After the seed rupture event at the University of Cincinnati, the 3M Company notified NRC that they are now including a "warning notice" with 3M brand I-125 seeds which states:

> WARNING:
>
> Do not force I-125 seeds into (or out of) any implant tube, needle, or cartridge. Doing so may damage the wall or end welds of the seed potentially causing release of I-125 into body fluids if the seed is implanted. If an I-125 seed has been visibly damaged in any way, discard it immediately to radioactive waste and check the area for contamination. Under no circumstances should a visibly damaged seed be implanted.

Although this "warning notice" does not explicitly state that the seeds not be reused, the 3M Company indicated in a letter to NRC (to Darrell Wiedeman, Chief, Materials Radiation Protection Section, Region III, from Robert G. Wissink, Manager, Health Physics Services) that this notice implies that the seeds should not be reused (Ref. 6).

The 3M Company voluntarily began including this "warning notice" with the packaging of iodine-125 seeds but this action has not been made a part of the requirements of the 3M Company's distribution license for iodine-125 seeds. 10 CFR 35.14(5)(iv) requires that "Group Byproduct Material Licensees," who are authorized to use sources and devices containing byproduct material, to "follow the radiation safety and handling instructions approved by the Nuclear Regulatory Commission or an Agreement State and furnished by the manufacturer on the label attached to the source, device or permanent container thereof, or in the leaflet or brochure that accompanies the source or device, etc."

Thus, if the inclusion of a "warning notice" in the packaging of iodine-125 seeds (specifying that the iodine-125 seed not be reused) is made part of requirements of the 3M Company license to distribute these sources then the "Group Byproduct Material Licensees" (licensed under 10 CFR 35) would be prohibited by regulations from reusing the seeds.

On the other hand, "Broad Scope Material Licensees," the other group of medical licensees authorized to use the iodine-125 seeds, are not required by regulations to follow the source manufacturer's recommendations for safety and handling, therefore, this group of licensees would not be required by regulations not to reuse the seeds.

5.0 FINDINGS

1. The risk of iodine-125 seed rupture is relatively high when the seeds are reused for several patients. The risk of seed rupture is associated with:

   -- The susceptibility of the seeds to damage from typical tools used for removing the seeds (razor blade, scissors, etc.); and

   -- The discolored or stained condition of the catheters after use in therapy, making viewing of the seeds difficult.

2. The consequence of the seed rupture at the University of Cincinnati--involving patient and other personnel uptakes and the facility contamination--could have been mitigated by adequate radiation surveys of the work area and the tools used to remove the seeds from the catheter, and/or by performing a leak test of the seeds. Additionally, personnel uptakes other than the patient and the facility contamination could have likely been prevented if the seed removal operation had been performed under a fume hood.

3. As a result of the iodine-125 seed rupture event at the University of Cincinnati, the 3M Company now voluntarily includes a "warning notice" with the packaging of iodine-125 seeds that implies that the seeds should not be reused. If the wording of this "warning notice" is clarified to state explicitly that seeds are not to be reused and the 3M Company license is amended to require the inclusion of the "warning notice" with the packaging of iodine-125 seeds, then "Group Byproduct Material Licensees" would be prohibited by regulations from reusing the sources. "Broad Scope Material Licensees" are not required to follow the source manufacturer's recommendations for safety and handling and thus would not be prohibited from reusing the seeds.

In addition to the specific findings stated above, we believe that attention should be called to one other matter related to the incident:

-- The University of Cincinnati's licensed program represents a large research and medical use isotope program that typically employs a full-time health physics staff that is generally familiar with a wide variety of uses of radioisotopes. In this event, however, it appears that licensee personnel failed to appreciate or understand the potential for a seed to be ruptured by the seed removal operation or the consequence of such a rupture, in that the protocol describing procedures to be followed for temporary implants did not require (1) that the seed removal operation be conducted in a fume hood; or (2) that wipes survey and/or leak test* be performed to verify the integrity of the seeds before the sources were reused.

6.0 CONCLUSIONS AND RECOMMENDATIONS

Based on our findings, we recommend that:

-- The Office of Ins tion and Enforcement (IE) send an Information Notice to the affected licensees describing the event at the University of Cincinnati and describing the action taken by the licensee and the source manufacturer (3M Company) to prevent the recurrence of similar events.

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*NRC regulations do not require such a leak test.

-- The Region III office amend the 3M Company's distribution license to make the inclusion of a "warning notice" in the packaging of iodine-125 seeds a part of the license requirements. This amendment should ensure that the 3M Company's recommendation that the seeds not be reused is clearly stated in the "warning notice."

-- The Office of Nuclear Material Safety and Safeguards (NMSS) determine whether further regulatory actions should be undertaken by NRC to ensure that "Broad Scope Byproduct Material Licensees" will not reuse the high intensity iodine-125 seeds.

7.0 REFERENCES

(1) Letter from Eugene L. Saenger, M.D., to NRC.

(2) Region III Inspection Report Number 30-02764/84-02 (DRSS).

(3) Letter from David Kubiatowicz, Medical Products Division, 3M Company to Peter Ho, M.D., Department of Radiation Therapy, University of Cincinnati Hospital General.

(4) Letter from Eugene L. Saenger, M.D., Chairman, Radiation Safety Committee, University of Cincinnati Medical Center, to William Axelson, NRC (Region III).

(5) Memorandum from Eugene L. Saenger, M.D., University of Cincinnati Medical Center to Bernard S. Arin, M.D. and Peter Y. C. Ho, M.D., University of Cincinnati Medical Center.

(6) Letter from Robert G. Wissink, Manager, Health Physics Services, 3M Company to Darrell Wiedeman, Chief, Materials Radiation Protection Section, NRC (Region III).

Protocol for the use of ^{125}I sealed sources for implant into patient's tumor:

1. Upon receiving ^{125}I shipment

   A. A wipe test is first made inside the source container bottle by Radiation Safety to detect possible leakage of the sealed source.

   B. Calibration of each shipment of sealed sources is done by Radiation Oncology with a dose calibrator using an NBS standard source (available late 1983).

2. Preparation for implants

   A. The ^{125}I seeds are loaded into shielded cartridges or afterloading devices by Radiation Oncology technologist/staff/residents with special tools designed for handling the seeds standing behind a lead shield or wearing a lead apron.

   B. Afterloading, the instrumnnts used for handling the ^{125}I seeds will be checked with a thin window counter to check for leakage contamination due to possible mechanical damage to the seeds.

   C. The shielded cartridges or afterloading devices are gas sterilized for 24 hours or steam sterilized for 10 minutes.

3. During implant in patients and immediately post implant

   A. The instruments used in the implant should be monitored with a thin window counter after the implant to check for leakage contamination due to possible mechanical damage to the seeds.

   B. The suction apparatus, tubing and traps, including the Foley bag are checked for loose ^{125}I seeds and removed appropriately for disposal by Radiation Oncology or Radiation Safety.

4. Post implant monitoring - per Radiation Safety regarding exposure to personnel

5. If leakage is discovered

   A. Upon receiving shipment - container is to be sealed and disposed appropriately by Radiation Safety.

   B. During handling of seeds - all personnel or patients involved are to have their urine checked and undergo thyroid counting to monitor exposure.

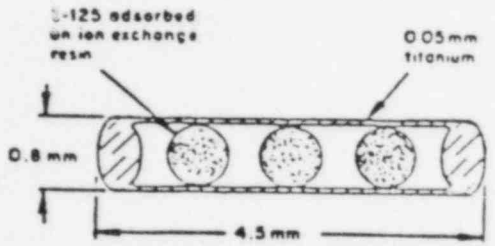
6. All unused ^{125}I seeds are to be returned to Radiation Safety for disposal except for reusable high activity ^{125}I seeds (40 mCi), which are to be stored in Radiation ONcology's shielded safe. These will be returned when the activity is below 10 mCi each.

7. All operators and technologists handling ^{125}I seeds will wear finger badges.

I-125 Seeds
No. 6702

Description

I-125 Seeds 6702 consist of a welded titanium capsule containing Iodine-125 adsorbed on anion exchange resin spheres.



Physical Characteristics

Iodine-125 has a half-life of 60.2 days and decays by electron capture with the emission of characteristic photons and Auger electrons. The electrons are absorbed by the titanium wall of the I-125 Seed. The principal photon emissions are 27.4 and 35.5 keV x-rays and a 35.5 keV gamma.

To correct for the physical decay of Iodine-125, the decay factors at selected days after the assay date are shown in the table below.

Decay Chart Iodine-125, Half Life 60.2 Days

Days	Decay Factor	Days	Decay Factor
0	1.000	36	0.661
2	0.977	38	0.646
4	0.955	40	0.631
6	0.933	42	0.617
8	0.912	44	0.603
10	0.891	46	0.589
12	0.871	48	0.575
14	0.851	50	0.562
16	0.832	52	0.550
18	0.813	54	0.537
20	0.794	56	0.525
22	0.776	58	0.513
24	0.759	60	0.501
26	0.741	62	0.490
28	0.724	64	0.479
30	0.708	66	0.468
32	0.692	68	0.457
34	0.676	70	0.447

Radiation Protection

The half value thickness of lead for Iodine-125 is 0.025 mm. Thus, a 0.25 mm lead sheet will provide > 99% reduction in exposure.

Actions

I-125 Seeds emit 27.4 and 35.5 keV x-rays and a 35.5 keV gamma. The clinical efficacy of the sources derives solely from the interaction of these ionizing radiations with the tissue being treated.

Dose distribution around each individual seed is not isotropic. This anisotropy should be included in dose distribution calculations.

Titanium encapsulation assures good tissue compatibility and results in a total self-absorption of approximately 16%.

Indications

I-125 Seeds are indicated for interstitial treatment of tumors which have the following characteristics: unresectable, localized, and moderate radiosensitivity.

I-125 Seeds may be used for selected radiation applications as removable implants.

I-125 Seeds are indicated to treat residual tumors following completion of a course of external radiation therapy. In addition, recurrent tumors may be implanted with I-125 Seeds.

Contraindications

As with other brachytherapy sources, treatment of tumors in generally poor condition (eg, ulcerated) is not recommended with

Warnings

The I-125 Seed titanium capsule has excellent corrosion resistance, but it is attacked by concentrated hydrochloric acid. I-125 Seeds have been designed not to be used in a concentrated HCl environment.

Precautions

Preparation for Use/Sterilization

I-125 Seeds are radioactive and appropriate precautions must be taken when handling these sources. All steps of the implantation procedure should be planned in advance to minimize radiation exposure to personnel, consistent with published exposure limits.

Personnel monitoring is required for individuals working with I-12 Seeds. A film badge or TLD dosimeter worn on the body and, for handling, a ring badge will provide adequate detection.

I-125 Seeds are provided in a glass vial which should be maintained in a lead vial container for storage. When transporting seeds within the hospital premises, an appropriate carrier with adequate shielding should be used.

All manipulations involving I-125 Seeds should be carried out behind shielding of such size and thickness as will adequately shield the operator. DIRECT CONTACT WITH THE SOURCES SHOULD BE AVOIDED. In addition, I-125 Seeds should be handled only with forceps, with as much distance as practical between sources and the operator. I-125 SEEDS SHOULD NOT BE PICKED UP WITH THE HANDS.

I-125 Seeds are NOT sterile when shipped and as such must be sterilized with steam (autoclave) or ethylene oxide (EO) before implantation. Regardless of the method selected, I-125 Seeds should be placed in an adequately shielded container prior to placement in the sterilization chamber. Manipulation of the seeds prior to or following sterilization should be carried out behind shielding of such size and thickness as will adequately shield the operator. In addition, I-125 Seeds should be handled only with forceps, with as much distance as practical between sources and the operator. Autoclaves should be equipped with traps or other means to prevent seed loss through the drain hole.

I-125 Seeds have been designed to withstand normal autoclave temperature and pressure variations from 121° C at 15 psi to 138° C at 35 psi. I-125 SEEDS ARE NOT INTENDED TO BE STERILIZED USING DRY HEAT AND SHOULD NOT BE SUBJECTED TO TEMPERATURES AND PRESSURES IN EXCESS OF THESE LIMITS (138° C and 35 psi).

I-125 Seeds should be autoclaved in bulk or individually in appropriate containers of autoclave-compatible materials. These materials include stainless steel, glass, nylon, and teflon. I-125 Seeds may also be autoclaved in selected accessories to commercially-available implant tools. Among these accessories are the stainless steel cartridge of the Mick applicator and gun, and nylon and teflon tubing used as seed holders with Henschke and Scott applicators. When in doubt about the chemical nature of these seed holders, either sterilize the materials with ethylene oxide or autoclave a sample of the materials containing dummy seeds before attempting to load with radioactive seeds. DO NOT AUTOCLAVE I-125 SEEDS IN PLASTIC TUBING OR OTHER PLASTIC CONTAINERS.

Although I-125 Seeds have a high structural integrity, it is possible through rough handling, high temperatures or crushing, that a seed could leak or be ruptured. If such a rare occurrence does happen, the area should be closed off, the seeds packaged into a sealed container and the area decontaminated. Decontamination can be confirmed by taking "wipe" samples of the immediate area. Personnel movement should be controlled to avoid spread of any radioactive contamination. Whenever a source is damaged, personnel working in the area should undergo a thyroid scan to assure that they have not been contaminated by contact, ingestion or inhalation of Iodine-125.

Medical Products Division/3M

TCAAP
New Brighton, Minnesota 55112

3M

Certification	KM54963	70-4.9
Iodine-125 Sealed Sources For Medical Uses		1 Sep.1983

Consignee: UNIV CINCINNATI MED. CTR RADIOISOTOPE LAB

Address: 234 GOODMAN ST CINCINNATI, OH 45267

The following radioactive sources are certified by Minnesota Mining and Manufacturing Company (3M) to have been subjected to the tests described below and to have been given the results listed.

Model Number	6702					
Lot Number	IS-819					
Quantity	10					
Activity Range (mCi)*	38.0-40.0					
Total Activity (mCi)*	390.0					
Assay Date	8-13-84					

All seeds have passed a leak test showing <0.005 μCi of removable ^{125}Iodine activity. No other certification is to be implied.

* By "mCi" we mean "apparent activity in millicuries", which is descriptive of output activity only and not the total quantity of I-125 contained within the titanium capsule of the Seed.

For accounting purposes, the quantity of I-125 contained in Model 6702 or Model 6711 Seeds is about 1.2 or 1.6 respectively multiplied by the stated apparent activity in millicuries.

Read the reverse side of this form for information about Seed construction, method of calibration and definition of "apparent activity in millicuries".

Sharon J. Drew

Quality Control

9 August 1984

Date

Wilmes - Hug -

The following procedure is furnished by Phillip H. Gutin, M.D.,* for informational purposes:

The Coaxial Afterloading Catheter can be used for implantion of radioactive sources into brain tumors. The outer catheter is generally placed to a tumor target through a burr hole or twist drill hole using a stylet guided by computed-tomography directed sterrotaxy. The catheter passes through the silicone base before entering the brain.

When the catheter is at the target, the silicone base is pushed down to the skin or to the skull. It can then be sutured in position, or, in the case of the skull, it can be glued to the bone with biological adhesive. Then, the outer catheter is glued to the base with biological adhesive. The stylet is removed and replaced with the inner catheter containing the radioactive sources. The inner catheter is secured to the outer catheter with a drop of biological adhesive.

HOW SUPPLIED

Each catheter is provided individually wrapped in a NONSTERILE condition, and consists of an external catheter with suturing flange and two telescoping internal catheters. All catheters must be cleaned and sterilized per the instructions below.

*Phillip H. Gutin, M.D.
University of California
Hospitals
505 Parnassus
Department of Neurosurgery
OR8M423
San Francisco, 94143

Special order devices are supplied either sterile or nonsterile as indicated on the product label. Nonsterile products, if intended for implantation or an aseptic application, must be cleaned and sterilized prior to use; if your product is nonsterile, the cleaning and sterilization procedures given below have been found effective and are provided as a guide.

STERILIZATION

This product is recommended for single use only. It is recommended that each institution establish the efficacy of its sterilization procedure by a method which includes the sterilization of an intentionally contaminated product.

Do not sterilize in the packaging system supplied.

The following cleaning and sterilization techniques have been found effective and are provided as a guide:

Remove the Heyer-Schulte Coaxial Afterloading Catheter from its package in a clean environment using gloved hands. Lint, fingerprints, talc and other surface contaminants can cause foreign body reactions. Utmost caution should be taken to avoid contaminants.

Use an alcohol (ethyl or isopropyl) swab to remove oily surface contaminants.

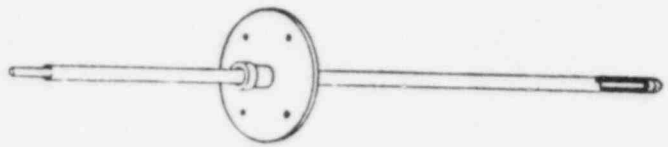
Hand wash soiled silicone devices for a maximum of 15 minutes in a solution of mild surgical soap or a one percent anionic detergent. If it is necessary to use a brush, only

SPECIFICATIONS (All Dimensions are Nominal)

Catalog Number	Description	Tip	Suture Collar Diameter	Catheter Length: Inner	Outer
GR80035-01	Coaxial Afterloading Catheter	Clear	2 cm	16.5 cm	15 cm
-02		Radiopaque	2 cm	16.5 cm	15 cm
-03		Radiopaque	1 cm	23.5 cm	22 cm
-04		Radiopaque	2 cm	23.5 cm	22 cm

Special Order Devices are Manufactured & Distributed by:

AMERICAN HEYER-SCHULTE
Division of
American Hospital Supply Corporation
600 Pine Avenue
Goleta CA 93117
Telephone (805) 967-3451



Manufactured and Distributed by:

AMERICAN HEYER-SCHULTE
Division of
American Hospital Supply Corporation
600 Pine Avenue
Goleta CA 93117
Telephone (805) 967-3451

Functional failure of the catheter system due to separation of its component parts can result in serious complications. Catheters may migrate into other areas causing serious harm to the patient.

Infection is a common and serious complication of a catheter system and is most frequently caused by skin contaminants. Septicemia, which occurs most frequently in debilitated infants, can result from infections anywhere in the body and may develop with few or no symptoms. It may occur as a result of a wound infection. In the event of an infection, removal of the catheter system is indicated in addition to the appropriate chemotherapy.

RETURNED GOODS POLICY

U.S. Customers

Authorization must be received from American Hoyer-Schulte, Division of American Hospital Supply Corporation, prior to the return of merchandise. Merchandise returned must have all manufacturer's seals intact and be received within 60 days of date of invoice to be eligible for credit or replacement. Returned products may be subject to restocking charges.

International Customers

Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

PRODUCT INFORMATION DISCLOSURE

American Hoyer-Schulte has exercised reasonable care in the choice of materials and manufacture of this product. American Hoyer-Schulte excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. American Hoyer-Schulte shall not be liable for any incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. American Hoyer-Schulte neither assumes nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

PRODUCT ORDER INFORMATION

U.S. Customers - Catalog Products

To order directly in the U.S.A., please contact American V. Mueller, exclusive United States distributor for all American Hoyer-Schulte products with distribution centers in Irvine and Hayward CA; Orlando FL; Norcross GA; McGaw Park IL; Bedford MA; Romulus MI; Minneapolis MN; Maryland Heights MO; Edison NJ; Columbus OH; Richardson and Woodland TX.

U.S. Customers - Special Products

For information on special order devices, please contact the Customer Service Department of American Hoyer-Schulte, 600 Pine Avenue, Goleta CA 93117. Toll-free telephone (800) 235-5731.

International Customers - Catalog Products

For product information or to order directly, contact your local American Hoyer-Schulte distributor or the American V. Mueller International Customer Service Department at 1500 Waukegan Road, McGaw Park IL 60085 USA. Telephone (312) 473-1500, Telex (TWX) 910 210-195.

In Canada, contact AHS/Medical Specialties, Division of McGaw Supply Ltd., 2390 Argentia Road, Mississauga, Ontario, Canada L5N 3P1. Telephone (416) 821-9891.

International Customers - Special Products

For information on special order devices, please contact the Customer Service Department at American Hoyer-Schulte, 600 Pine Avenue, Goleta CA 93117 USA. Telephone (805) 967-3451, Telex (TWX) 910 334-1165.

Caution: Federal law restricts this device to sale by or on the order of a physician.

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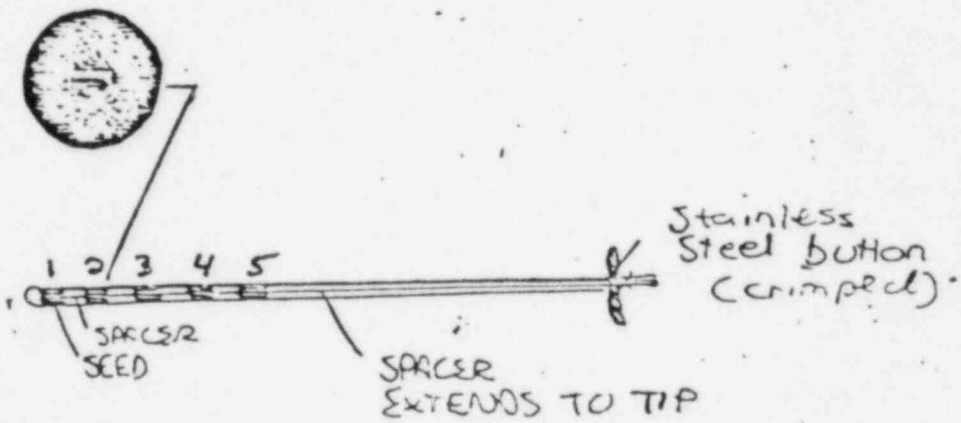
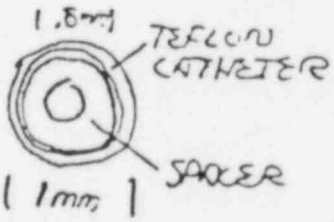


9 & 10 Dood pig



APPROXIMATELY ACTUAL SIZE

MiniMonitor 125

Contamination Monitor

Measures low-level ^{131}I surface contamination quickly and accurately

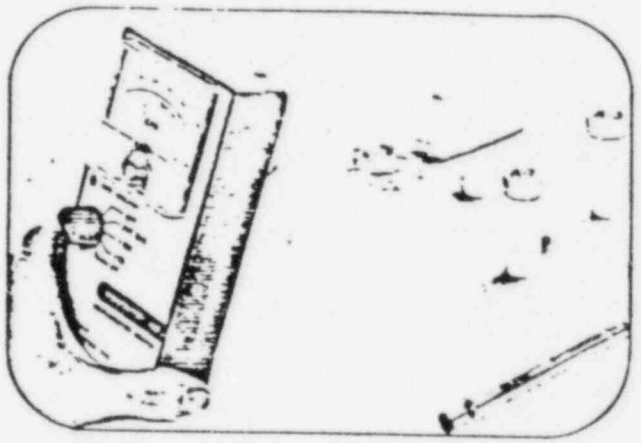
- **High sensitivity (lower detection limit — 0.002 μCi).**
- **Three ranges (0-500, 5K and 50K cpm).**
- **Large-area, screened detector permits contact surface measurements.**

For the first time, a compact, sensitive monitor is available for the detection of ^{125}I surface contamination levels as low as 0.002 μCi.

A large-area, thin-window GM detector, recessed in a conical housing on the back of the instrument, permits direct-contact measurements of surfaces. The maximum amount of removable contamination allowed* (0.005 μCi) is well within the detector limits of the unit. All surfaces as well as hands, clothing, shoes, etc., may be routinely monitored by using this hand-held instrument.

Lightweight (22 ounces) and portable, the monitor operates on 4 alkaline "AA" cells. All controls are conveniently located on the instrument's face. An LED indicator flashes with each incident radiation pulse. The LED also indicates that the unit is "on."

MiniMonitor 125 may be used as a convenient, general-response survey meter for radiation detection in the laboratory. The 3-range selector switch permits rapid changing of survey ranges. Radiation levels are read on a large 2½" meter. The monitor includes a plastic contamination shield for protecting the detector housing and a license-free radioactive source for checking the instrument's overall operation.



Detector: Halogen-quenched GM pancake tube, 1.2" diam.
Readout: 2½" analog meter, marked 0 to 500.
Ranges: 0-500, 0-5,000, 0-50,000 cpm.
Accuracy: ±10% of full scale.
Controls: Off, Battery Test, x100, x10, x1 ranges – all on one switch.
Time Constants: 10 secs (x1); 2 secs (x10); 0.3 secs (x100).
Batteries: Four "AA" alkaline cells (500-hour life).
Operating Temperature: –20°C to +55°C (–4°F to +130°F).
Temperature Dependence: ±15% over noted temperature range.
Construction: All solid state electronics. High-impact plastic case.
Accessories Supplied: Plastic contamination shield. License-free check source.
Size: 6" high x 3¼" wide x 2" thick. **Weight:** 22 ounces.

05-572 MiniMonitor 125 Contamination Monitor $325.00

* Per NRC or Agreement State regulations.