Yale New Haven Hospital
1826
20 York Street, New Haven, CT 06504

Radiological Physics - WWW 204

Licensee No.: 06-00819-03
Docket No.: 030-01244

January 4, 1992

Keith Brown, Ph.D.
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406

Report of Source Loss and Recovery

Dear Mr. Brown:

At 2:30 PM on December 2, 1992, Yale-New Haven Hospital (YNHH) discovered that a 35 mCi Cesium-137 (Cs-137) encapsulated source was missing. An immediate search was conducted by the Radiation Safety Officer (RSO) to locate the missing source. The source was recovered at approximately 4:45 PM the same day. The source was found in a washing machine located in a laundry service which is contracted by the Hospital. A leak test was performed of the source and the wash water was sampled for evidence of contamination. These tests showed no evidence of source rupture. The source was intended to be used for a gynecological brachytherapy treatment. It appears that the source was never placed into the applicator as intended. Consequently, a therapeutic misadministration also occurred which is documented in a separate report dated December 22, 1992 and sent to Region I. The RSO conducted an immediate investigation of this incident and a description of the believed scenario follows.

A. Chronological Description of Events

Monday, November 31, 1992

A brachytherapy patient was fitted with a Fletcher-Suit Delclos (FSD) applicator and tandem (Exhibit 1) scheduled to be loaded with one 24 mCi and three 35 mCi Cs-137 tubes (Exhibits 2 & 3). The FSD and tandem are afterloading devices which are placed into the patient in the operating room and later the radioactive sources are placed into the devices in the patient's room. The plan of treatment was to place a 35 mCi source into each of the FSD applicator ovoids and the other two sources were to be placed into the tandem with the 35 mCi source at the tip followed by a spacer and then the 24 mCi source.

Before noon, a therapeutic dosimetrist removed the sources from the inventory and placed the sources into the afterloading source carriers. The source carriers were then placed in a shielded transport container and brought to the patient's room by the dosimetrist.

ENCLOSURE (3)

At 12:00 PM, in the patient's room, a therapeutic radiology resident physician placed the sources into the patient with the assistance of the dosimetrist. After investigation, we believe during this process one of the 35 mCi sources intended for a FSD ovoid became dislodged from the source carrier and fell into the bed and rolled under the patient. Neither the resident or the dosimetrist noticed this event. The knurled screw caps which seal the sources into the FSD and tandem were attached and the resident and dosimetrist exited the room.

At some time after the loading, estimated to be approximately 15 minutes, a nurse entered the patient's room and changed the bedpad which is placed under the patient's posterior. The bedpad is used to prevent the bed linen from becoming soiled and is changed whenever it becomes contaminated with bodily fluids. The nurses use a technique to change the bedpad to keep the patient in a prone position. They have the patient roll to one side and roll the bedpad up like a rug to the back of the patient. They then have the patient roll to the other side and continue to roll the rest of the bedpad up. We believe the source was on the bedpad and was rolled up during this process. The nurse did not notice the source in the bedpad during this process and exited the room with the bedpad and placed it in a laundry hamper located in the hallway (Exhibit 4) outside the patient's room.

All gynecologic brachytherapy patients are placed in one of six shielded rooms located at the end of a corridor on the 9th floor of the Memorial Building designated as 9-5. The nursing station is located at the other end of the corridor. We believe that the source in the bedpad remained in the hamper in the hallway from November 30, 1992 at 12:15 PM until the morning of December 2, 1992, a period of approximately 42 hours. We believe that this hamper stayed in the hallway because it is at the far end and fills up more slowly than other hampers closer to the nursing station.

The RSO was on 9-5 at the time of the loading. He was preparing a room across the hall for an Iodine-131 (I-131) therapy scheduled for that afternoon. He performed a radiation survey (Exhibit 5) of the Cs-137 patient at 2:00 PM. Radiation levels were measured with a Keithley 36150 ion chamber survey meter (Cs-137 calibrated on 10-Sep-92) at 1 meter from the patient, and in the adjacent rooms and hallway and were within normal levels. He again performed a survey a 4:30 PM of the hallway and adjacent room of the I-131 patient. These measurements also were within normal limits.

Tuesday, December 1, 1992

The next day at 4:00 PM, the resident who originally loaded the sources went to the patient's room to remove the sources. He unscrewed the knurled caps of the applicators and attempted to remove the afterloading carrier from the tandem. Upon removing the tandem carrier, the long plastic spacer separated from the rest of the assembly which is usually fixed with a small piece of tape. He then used a set of long forceps kept with the transport shield to remove the tandem carrier. He visually confirmed that both sources were present in the tandem carrier during this process.

He then unloaded the two ovoids and placed the source carriers into the transport shield. He did not notice at this time that one of the ovoid applicators was missing a source. He then performed a geiger (GM) counter survey of the patient and room using an Eberline E-530 with a HP-270 energy compensated probe (Cs-137 calibrated on 25-Nov-92). He then proceeded to remove the packing and the non-radioactive portion of the FSD and tandem.

While removing the rest of the apparatus, he noted that a Penrose drain which is usually tied around the FSD and tandem to hold them together, was missing. Because of these two unusual circumstances he carefully conducted a second GM survey of the patient and the room. He wrapped the non-radioactive portion of the applicators in a blue absorbent plastic pad and placed it with the transport shield outside the room. He then conducted a third GM survey of the unloaded applicators, patient, bed, trash receptacles and room. After documenting the negative survey result in the survey log and the patient chart, he transported the shielded sources to the source storage room. He left the sources in the transport shield and placed the non-radioactive FSD and tandem in a basin of water to soak overnight.

The RSO went to 9-5 shortly after the unloading process was completed to perform a radiation survey of a Palladium-103 (Pd-103) patient in the room immediately adjacent to the Cs-137 patient room. The survey was performed at 5:00 PM and measurements in the hallway and in the adjacent Cs-137 patient's room were less than 0.1 mR/hr.

Wednesday, December 2, 1992

At some time during the early morning, th .amper which contained the source was transported possibly by a nurse, to the soiled utility room on 9-5. A building services employee then dumped the hampers into a laundry chute which travels from the top of the building to the basement. The laundry chute drops the linen into plastic utility trucks located in an enclosed area. The utility trucks are then transported to the loading docks and placed on a delivery truck which is used to transport the laundry to the linen service. The source most likely left the hospital on the laundry truck which departed from the dock at 7:30 AM (Exhibits 6 & 7). The laundry truck went directly to the linen service with no intermediate stops. Drive time is approximately 15 minutes.

Later that day, the dosimetrist who witnessed the loading, went to the source storage room to clean the Cs-137 sources and applicators and to return the sources to the active inventory. She removed one of the sources from an ovoid source carrier and then went to unload the second one. When she went to remove the second ovoid source she noticed that the source was missing. She put down the source carrier and began to search the transport shield and source storage room for the missing source. During this process she neglected to note whether the left or the right source was missing. After her initial search failed to locate the missing source, she immediately notified the RSO and the resident who loaded and removed the sources at 2:30 PM.

The RSO and resident responded immediately and went to the source storage room. The RSO resurveyed the storage room and was unsuccessful in locating the missing source. The RSO and the resident then went to 9-5 and resurveyed the patient's room without success. A survey of the hallways, exam room, soiled utility room, and other areas was negative.

The RSO and resident then went to the basement and surveyed the laundry chute, medical waste area, regular waste area and the loading docks. The RSO also interviewed the medical waste personnel to see if the Ludlum Model 177 alarming rate meter with a 44-3 scintillation probe, used to survey the waste for radioactivity, had gone off recently for unexplained reasons. The personnel reported that they had noted nothing unusual during the day. This meter is

also located near to the regular waste compactor and is sensitive enough to alarm if a 35 mCi Cs-137 source entered the normal waste stream.

Since the waste alarm had not gone off, the RSO concluded that the source may have escaped the hospital through the soiled laundry. The RSO and the resident then contacted the materials management office to find out the location and phone number of the laundry service. A call was placed to the laundry service and arrangements were made to conduct a survey of their facilities. The RSO then went to his laboratory to get an appropriate lead shield and tongs (Exhibit 8) in case the source was found offsite. At this time, the resident informed the patient's attending physician of the situation. He retrieved his car, picked up the RSO and they proceeded to the laundry service.

The RSO and the resident arrived at the laundry service at approximately 4:30 PM. The day shift at the laundry service had left for the day, but plant management personnel were present and escorted the RSO and resident through the plant. The RSO suggested that they follow the route of the soiled linen through the washing process, starting at the unloading dock. The RSO surveyed the loading dock, elevator, soiled laundry sorting area, and the entire second floor processing area without success. They then proceeded to the first floor where the washing machines are loaded through chutes from the second floor processing area. Two rows of four industrial sized washing machines were located in the northwest corner of the first floor. The RSO surveyed the washing machines and found a source of radiation emanating from the last machine in the north west corner of the first floor. The source of highest exposure was found to be located at the drain valve of the washing machine.

A plant engineer assisted the RSO by placing a screen in the open floor drain system to prevent the source from escaping when the valve was released. The engineer then quickly opened and shut the valve to release the source. After the initial rush of water subsided, the RSO located the source directly under the valve in the floor drain. The RSO then picked up the source with the tongs and placed it temporarily behind a concrete footing of the washing machine and instructed everyone to stand back from the source. He also instructed the resident to retrieve the lead shield from his car.

The RSO quickly examined the source to determine if the source was visibly damaged and checked the source serial number to verify that it was the missing source. The source appeared intact but the RSO retrieved a water sample from the washer to test for contamination. The source was placed in the lead shield by the RSO and he informed the laundry management that the incident would be reported to the Nuclear Regulatory Commission.

The RSO and resident transported the shielded source to the car. The RSO surveyed the shield and measured a maximum dose rate of 1.0 mR/hr at one foot from the shielded source and 15 mR/hr at contact with a Ludlum Model 3 survey meter with a pancake GM Probe (Cs-137 calibrated on 25-Nov-92). They then left the laundry service at approximately 5:00 PM and proceeded directly back to the hospital.

The RSO took the shielded source to his laboratory and performed a wipe test of the source (Exhibit 9) at 5:25 PM. A 5 ml aliquot of the wash water was also tested for contamination. The samples were counted with a Picker Spectroscaler 4 with a 2" X 2" NaI(Tl) crystal which was calibrated for Cs-137 with a count standard source. Both the water sample and the source wipe test counts were

less than the Minimum Detectable Activity of the system. The MDA of the system at 4.66 standard deviations was determined to be 1.33 x 10^{-4} uCi (295 dpm).

After determining that there was no apparent leakage from the source, the RSO secured the source in his laboratory. At 6:10 PM, the RSO reported the incident to Rudy Karsch of the NRC Operations Center. The resident informed the attending physician and the Director of Therapeutic Radiology about the incident and that the source had been recovered. The RSO informed them that there was no apparent leakage from the source.

Thursday, December 3, 1992

The next morning the RSO informed hospital management, the Chairman of the Radiation Safety Committee, and the Director of Radiological Physics about the incident. He also discussed the incident with Jenny Johansen of NRC Region I.

At approximately 2:00 PM, Keith Brown and Kathleen Dolce of NRC Region I arrived and conducted an investigation of the incident. The RSO escorted them through the facility to identify the route the source took through the facility and arranged for them to meet hospital personnel involved with the incident.

The patient who was involved in the incident was seen in the clinic during the day by the attending and resident physicians. They informed her at that time of the incident and discussed the impact of the episode on her case. The patient's referring physician was also informed of the incident.

Friday, December 4, 1992

The RSO and the NRC inspectors continued their review of the incident. Various nursing and materials management personnel were interviewed to determine exposure times and distances. The RSO made arrangements with the laundry service to visit the plant. The RSO and the inspectors traveled to the laundry and met with plant management. They were then given a tour of the plant following the route of the source through the building. They witnessed how the workers sorted the laundry and moved it through the plant. The washing machine where the source was found was identified.

The RSO and the NRC inspectors returned to the hospital. The inspectors then had an exit interview with the Hospital's Assistant Vice President, the Director of Radiological Physics, and the RSO. During this meeting, a number of actions to prevent recurrence were identified and discussed. It was agreed that five actions would be taken immediately. Those actions were:

1. All therapeutic radiology residents will be reinstructed to visually confirm that sources are present in the applicators during the patient loading process and to visually track the sources into the FSD or other afterloading device.

2. Dosimetrists will be instructed to visually observe the patient loading process to confirm the applicators are correctly loaded and placed into the patient.

3. A linen hamper will be placed in each brachytherapy room so linen will not be allowed out of the room until it is surveyed during the unloading process.

4. Soiled linen which cannot be left in the room will be GM surveyed by nursing personnel before being placed into the normal linen hampers for washing.

5. All therapy residents will be instructed to visually reconfirm correct source placement upon removal and to inventory afterloaded sources promptly after removal.

The RSO met with the Head Nurse of the 9-5 floor later that day and discussed the incident. He informed her that linen should not be removed from the rooms of brachytherapy patients unless it has been surveyed. They agreed that linen hampers should be kept in each brachytherapy patient's room to collect the bedpads as they are changed during the treatment. Bedpads or other laundry which becomes badly soiled before the end of treatment and before the final survey should be surveyed by nursing personnel before being allowed into the normal laundry. The head nurse said she would review this information with all floor nursing personnel at the next staff meeting. Since there were two more brachytherapy patients on the floor that day, the RSO also informed the patient's nurses at that time of these requirements and demonstrated how to perform a survey of the linen.

The RSO also met with the Chief Dosimetrist, the involved resident and dosimetrist and reviewed the identified actions they were responsible for. The RSO also insisted that the dosimetrists should clean and return afterloaded sources to the active inventory at the beginning of the next work day and not leave that duty until the afternoon.

The resident dictated his account of the incident (Exhibit 10 & 11) and summarized the change in the patient's dosimetry as a result of the missing source.

Monday, December 7, 1992

The attending physician dictated a note (Exhibit 12 & 13) describing the patient exam and the clinical implications of the missing source.

Tuesday, December 8, 1992

Ms. Jenny Johansen of the NRC Region I office contacted Mr. Norman Roth, Assistant Vice President by phone. She reviewed the immediate actions which were identified and notified him that a Confirmatory Action Letter would be mailed to confirm these actions.

Wednesday, December 9, 1992

The attending physician dictated a follow up note (Exhibit 14) describing the absence of any skin reaction at this time.

Thursday, December 10, 1992

The NRC's Confirmatory Action Letter No. 1-92-017 was received by the Assistant Vice President.

Monday, December 14, 1992

The scheduled quarterly Radiation Safety Committee was held and the incident was discussed. Actions taken to prevent recurrence were described.

Thursday, December 17,1992

The monthly therapeutic radiology brachytherapy conference was held. The RSO presented the incident and described the actions needed to prevent recurrence. Particular attention was given to the responsibilities of the residents and dosimetrists to ensure proper placement and recovery of sources. The RSO also discussed the Omnitron incident during this meeting and described changes in the GammaMed program as a result.

Friday, December 18, 1992

The RSO described the misadministration and source loss incident at a meeting of the radiation therapy department quality improvement and safety committee meeting. The Omnitron incident and its implications was also discussed.

Monday, December 21, 1992

The patient called her attending physician to report that she was experiencing some pain along her thigh and that there was darkened spot on her leg. She was seen in the clinic that day and a 4 X 20 mm area of hyperpigmentation was observed (Exhibit 15) along her posterior right thigh. No ulceration was evident and the patient was scheduled for further follow-up in January.

B. Analysis of Events Contributing to the Loss of the Source

The primary cause of this incident was the resident's failure to visually track the source into the FSD applicator. Since YNHH is a teaching hospital, the residents who perform the applications are in training. They are instructed initially by the RSO. The involved resident received his initial training by the RSO on July 12, 1991. After their initial training they are supervised by the second year residents and rotate through the different sections of the department during their first year. During this period they observe and practice the various techniques involved for the safe use of radiation sources and their applications for therapy. As they gain experience, during their second year they become responsible for the implantation and removal of after-loaded brachytherapy sources. The resident in question performed four source removals during his first year, between November 27, 1991 and May 1, 1992, and performed ten more between October 2 and December 1, 1992.

The resident training includes an emphasis on the importance of verifying the proper placement of sources and applicators for patient treatments. It also discusses the need to keep occupational exposures As Low As Reasonably Achievable (ALARA). The resident knew that he should perform the source application quickly to minimize occupational exposure. In this effort however, he evidently did not fully track the source into the FSD applicator and into the patient. The resident and the rest of the staff now fully appreciate these dual requirements and that ALARA does not take priority over proper placement

of the sources. The RSO demonstrated during the brachytherapy staff meeting on December 17 how the sources should be visually tracked from the transport shield and into the applicator. He also demonstrated that it need not increase ALARA exposure times.

Partially because residents are under training, YNHH dosimetrists who are on permanent staff attend almost all source loadings. They have performed the dosimetry calculations for the patient and are responsible for the removal of the appropriate sources from the inventory. They place the sources in the afterloading applicators and transport the sources to the patient's room. They assist the resident by handing them the applicators during the loading process. Since they have more experience, they observe the loading and represent a resource for the resident to ensure proper source placement. In this case, the dosimetrist did not observe the loss of the source. The RSO has instructed the dosimetry staff to also visually track the source from the transport shield into the patient to ensure proper source placement in the future.

On December 9, 1992, another dosimetrist reported to the RSO that she observed that at least one of the FSD applicators seemed to hold the source loosely, allowing the source to flip out of the holding cup relatively easily. Usually the source fits the applicator snugly requiring a purposeful effort to remove them from the cup. The RSO tested the fit of all applicators with the lost source. Of the sixteen available applicators, one right and one left, were found where the source fit was relatively loose. Those applicators were removed from the active inventory and will be adjusted or replaced.

A secondary cause of this incident was the removal of the bedpad from the patient's room and its placement in the laundry hamper in the hallway. On pages 3 and 4 of the YNHH's Nursing Procedure Number R-1, Items 1, 7 and 15 (Exhibits 16, 17, 18, 19 & 20) state the following:

1. Bed Linen will not be changed during interstitial therapy unless it becomes soiled...

7. During nursing care procedures, the nurse must check all materials used by the patient (linen, bedpans, emesis basins, etc.) for radioactive sources which may have become dislodged.

15. The patient's room is to be monitored after all sources have been removed. Everything used by the patient (except dishes) must be saved and monitored before disposal.

In this case the nurse removed the bedpad from the room without checking for dislodged sources. This is partially due to a change of hospital materials use which took place a year ago. In the past, disposable bedpads were used throughout the hospital. Soiled bedpads were disposed in the medical waste receptacles within the room. Materials management personnel are not allowed to enter patient's rooms to empty these receptacles until the treatment is concluded and a survey has been performed. In an effort to reduce solid waste volume and conserve the environment, the hospital changed to the use of reusable linen bedpads. The RSO did not appreciate the implications of this change until this incident. This change in policy resulted in the movement of

bedpads to the laundry hampers without appropriate survey. The RSO informed nursing personnel and management the day after discovery of the incident that all linen and trash must remain in the room until surveyed prior to disposal as required by the written nursing procedures. The RSO will revise nursing training and written procedures to emphasize this requirement.

Another item of concern, was the resident's failure to identify the missing source during the removal of the sources from the patient. During the brachytherapy meeting on December 17, the RSO instructed the therapeutic radiology staff to visually inventory sources during removal to verify their correct placement and complete recovery. Future resident training will emphasize both visual inventory as well as radiation survey techniques. Both are required and are not substitutes for each other.

The dosimetrist who was responsible for cleaning and returning the sources to the active inventory had an opportunity to possibly identify the missing source before it had left the hospital. Had she gone to the storage room on Wednesday morning instead of leaving the duty until the afternoon she might have identified the missing source in time to catch it at the loading dock. The RSO discussed this issue with the chief dosimetrist to ensure that return of the sources to the active inventory is given priority on the morning of the next work day after removal.

The RSO and the Director of Radiological Physics have discussed the possibility of future placement of alarming rate meters at strategic control points to prevent inadvertent loss of sources. Since the floor where most of the placements are performed is due to be moved to a new building this summer, this option will be evaluated further as an additional control measure. The movement to the new facility will also entail the movement of the source storage room from the second floor to the patient floor where they will be used. This may allow a future change in procedures to allow the resident to remove the sources from the applicators and clean them immediately after removal. They can then be returned to the safe so a complete inventory of all Cs-137 sources could be performed soon after removal.

C: Dosimetry Estimates for Involved Personnel
(Worst Case Analysis)

Note: 8 hour shift = 480 minutes

1. Nurse Who Removed Source from the Room

a. Whole Body Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
30	5	2.13	11
100	15	0.192	3
300	60	0.0213	1
500	400	0.00767	4
		Total Estimated Whole Body Exposure:	18 mR

b. Hand Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
5	2	76.6	153
10	5	19.2	96
30	10	2.13	21
	Total Estimated Hand Exposure:		270 mR

2. Other Floor Nurses
(Assumed present for two 8 hour shifts)

a. Whole Body Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
100	30	0.192	6
300	120	0.0213	3
500	810	0.00767	6
	Total Estimated Whole Body Exposure:		15 mR

3. Patient Adjacent to Laundry Hamper
(Assumed 42 hour exposure)

a. Whole Body Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
400	2520	0.0120	30
	Total Estimated Whole Body Exposure:		30 mR

4. Hospital Materials Handling Personnel

a. Whole Body Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
30	5	2.13	11
100	15	0.192	3
300	30	0.0213	1
500	60	0.00767	1
	Total Estimated Whole Body Exposure:		16 mR

5. Laundry Service Driver

a. Whole Body Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
30	5	2.13	11
100	15	0.192	3
300	30	0.0213	1
500	60	0.00767	1
		Total Estimated Whole Body Exposure:	16 mR

6. Laundry Service Handling Personnel

a. Whole Body Exposure

Estimated Distance from Src. cm	Estimated Time min	Exposure Rate mR/min	Estimated Exposure mR
30	5	2.13	11
100	15	0.192	3
300	30	0.0213	1
500	430	0.00767	3
		Total Estimated Whole Body Exposure:	18 mR

D: Actions Taken to Prevent Recurrence

Yale-New Haven Hospital took the following actions immediately after the initial analysis of the incident. These actions were implemented by the RSO on Friday, December 4, 1992, immediately after the conclusion of the NRC onsite inspection. They were also formally presented to the hospital management, Radiation Safety Committee, Therapeutic Radiology Quality Improvement and Safety Committee, therapy staff and nursing staff in the following weeks:

In order to prevent a recurrence of this incident, the following steps were taken immediately:

1. All therapeutic radiology residents were reinstructed to visually confirm that sources are present in the applicators during the patient loading process and to visually track the sources into the FSD or other afterloading device.

2. Dosimetrists were instructed to visually observe the patient loading process to confirm the applicators are correctly loaded and placed into the patient.

3. Linen hampers are now placed in each brachytherapy room so linen will not be allowed out of the room until it is surveyed during the unloading process.

4. Soiled linen which cannot be left in the room is being surveyed by nursing personnel before being placed into the normal linen hampers for washing.

5. All therapy residents were instructed to visually reconfirm correct source placement upon removal and to inventory afterloaded sources promptly after removal.

These actions will be integrated and stressed during future training sessions and this and other incidents will be used to illustrate their importance in maintaining patient, staff and public safety. Current written procedures will be updated to stress their importance.

In addition to the immediate steps taken, YNHH will evaluate the use of alarming ratemeters as a possible second line of defense to prevent the loss of sources due to human error. The current treatment floor and source storage room will be consolidated this summer when YNHH opens a new building. Patient treatment rooms and the source storage rooms will then be located on one floor, considerably reducing the movement of sources through the hospital. At this time residents may be required to physically remove sources from the after-loading applicators and clean and return them to the active inventory promptly after removal.

If there are any further questions concerning this incident please contact Michael J. Bohan, Radiation Safety Officer at (203) 785-2950.

Sincerely,

Norman G. Roth
Asst. Vice President

Michael J. Bohan
Health Physicist/RSO

cc: All Staff Dosimetrists
All Staff Residents
All Staff Attendings
All Radiation Safety Committee Members
Stephen Bencivengo, Associate Administrator, Therapeutic Radiology
Robert Lange, Ph.D., Chairman, Radiation Safety Committee
Ravinder Nath, Ph.D., Director, Radiological Physics
Kevin Nowak, Regional Manager, Laundry Service
Norman Roth, Assistant Vice President, Administration
Stuart Warner, Asst. Counsel, Medicolegal Affairs

Attachments (20)

Figure 1

3M Fletcher-Suit-Delclos Applica

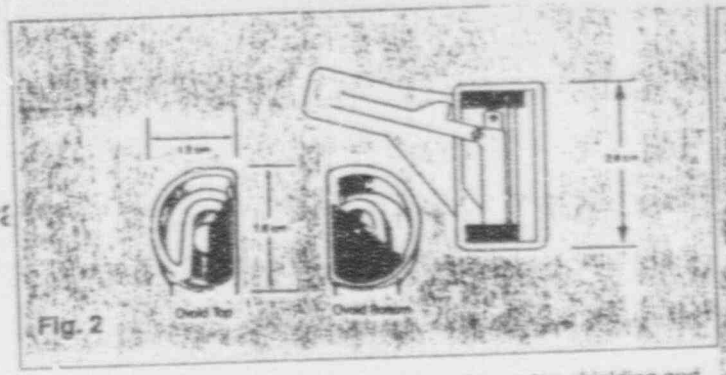


Figure 2 depicts the positioning of the internal tungsten shielding and source carrier alignment in the ovoid heads.

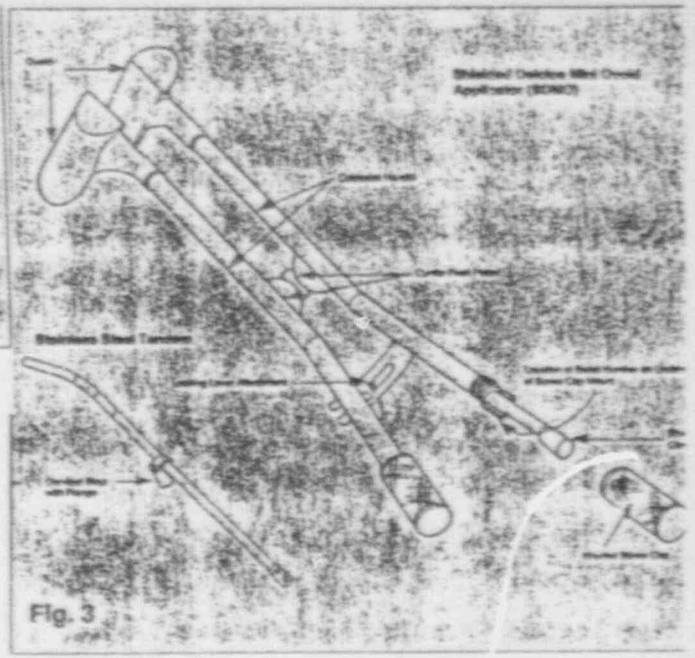
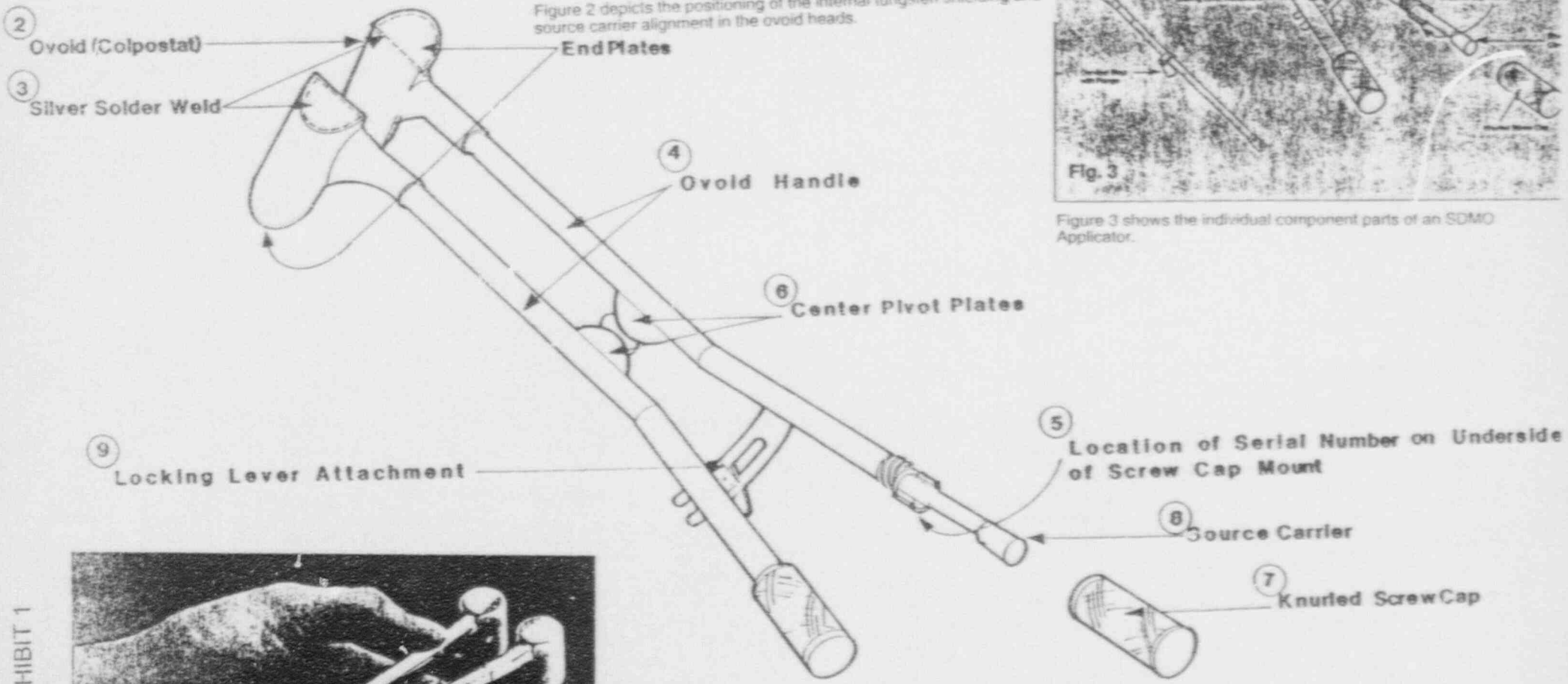


Figure 3 shows the individual component parts of an SDMO Applicator.



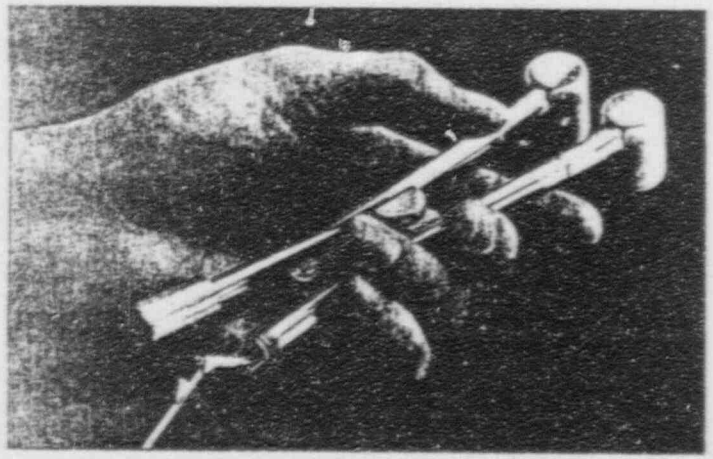


EXHIBIT 1

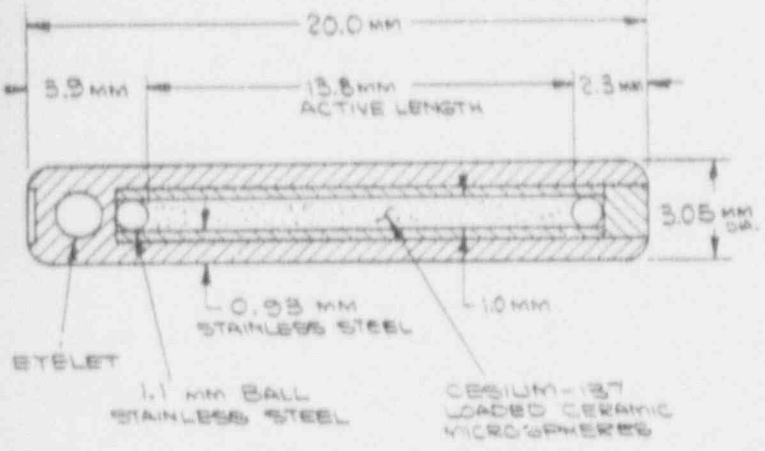
EXHIBIT 2

3M Cesium-137 Tube Sources

Series 6500, 6520

Description

3M Cesium-137 tube sources consist of two stainless steel capsules – an outer casing and an inner core containing cesium-labeled ceramic microspheres packed along the active length. Each tube source is nickel-plated, engraved with the nominal activity and serial number, and color-coded on the eyelet end according to nominal activity.



Physical Characteristics

Cesium-137 has a half-life of 30.0 years and decays with the emission of a monoenergetic gamma ray of 622 keV.

To correct for the physical decay of cesium-137, the decay factors at selected years after the assay date are shown in the table below.

Decay Chart for Cesium-137, Half-Life 30.0 Years

Years	Decay factor	Years	Decay factor
0.0	1.00	5.5	.88
0.5	.99	6.0	.87
1.0	.98	6.5	.86
1.5	.97	7.0	.85
2.0	.95	7.5	.84
.5	.94	8.0	.83
3.0	.93	8.5	.82
3.5	.92	9.0	.81
4.0	.91	9.5	.80
4.5	.90	10.0	.79
5.0	.89		

Radiation Protection

The half-value layer in lead for cesium-137 is 6 mm.

Actions

3M Cesium-137 tube sources emit a gamma ray of 662 keV. The clinical efficacy of the sources is a result of interaction of this ionizing radiation with the tissues being treated.

Indications

3M Cesium-137 tube sources, when placed into appropriate afterloaded or pre-loaded applicators, are indicated for intracavitary radiation treatment of gynecological cancer, in addition to cancers located in or about other body cavities.[1]

3M Cesium-137 tube sources may be used in conjunction with other treatment modalities.

The use of 3M Cesium-137 sources for any indication should be prescribed by a qualified practitioner.

Precautions

Preparation for Use

3M Cesium-137 tube sources are radioactive and appropriate precautions must be taken when handling these sources. All steps of the use procedure should be planned in advance to minimize radiation exposure to personnel consistent with published exposure limits.[2]

Personnel monitoring is required for individuals working with cesium-137 sources. A film badge or TLD dosimeter worn on the body and, for handling, a ring dosimeter will provide adequate detection.

3M Cesium-137 tube sources must be stored in a protective lead safe or vault of such thickness as is necessary to reduce exposure rates to permissible levels[3]. When transporting sources within the hospital premises, an appropriate carrier with adequate shielding should be used.

All manipulations involving 3M Cesium-137 tube sources 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. The preparation of applicators incorporating tube sources should be carried out behind a protective L-block, constructed of lead. In addition, 3M Cesium-137 tube sources should be handled only with forceps, with as much distance as practical between sources and the operator. 3M CESIUM-137 TUBE SOURCES SHOULD NEVER BE TOUCHED WITH THE HANDS.

Radiation detection equipment should be available whenever 3M Cesium-137 tube sources are being handled.

Application to Patient

3M Cesium-137 tube sources should be used only by individuals who are qualified by training and experience in the safe use and handling of radionuclides and whose experience and training have been approved by the appropriate government agency authorized to license the use of radionuclides.

All practical physical protection should be provided during the application procedure. When the use of protective barriers is not practical, operators must rely on distance and speed to minimize radiation exposure.[3] Persons should not remain closer than necessary to the radioactive material, either before or after its introduction into the patient.

The correct fitting of an unloaded applicator to the anatomy of the patient should be verified prior to the insertion of 3M Cesium-137 tube sources, to assure that the prescribed radiation dose is delivered to the patient. In addition, careful planning of the geometrical arrangement of the sources will reduce radiation exposure to personnel during the loading procedure by avoiding hesitation and changes.

Treatment of Patient

All patients should be informed of the nature of treatment with 3M Cesium-137 tube sources and the expected period of time during which radiation precautions will be necessary. Patients, their close associates, and associated medical personnel should be instructed in the necessary radiation safety procedures required for someone who is being treated with cesium-137. Guidelines for necessary precautions have been established by the National Council on Radiation Protection and Measurements and are detailed in NCRP Reports.[2, 3, 4, 5, 6]

The bed, cubicle, or room of the hospital patient should be marked with a sign or tag indicating the presence of brachytherapy sources. In addition, the patient's chart should indicate the number and nature of the sources, the total amount of activity, and time and date of application and anticipated removal.

The extent to which a patient with 3M Cesium-137 tube sources must be segregated depends upon the total activity used, its location in the patient, how long it is to be there, and to what exposure other persons near him are subject. Consideration must be given to the proximity of patients in adjoining rooms, since normal wall construction may have little value in shielding gamma radiation.

EXHIBIT 3

A patient being treated with 3M Cesium-137 tube sources should be restricted to his room. The patient must not be allowed to leave the hospital until the sources have been removed. During the course of treatment, the patient should carry a wristband or suitable identification which provides information regarding the radioactive nature of the treatment.

During the course of treatment with 3M Cesium-137 tube sources, bandages and dressings should be changed only by individuals trained in radiation safety techniques. Dressings must not be discarded until they have been checked for the presence of sources and found to contain none. Bed baths should be omitted while the sources are in place. Nursing care necessary for the patient's well-being should be preplanned and delivered quickly to minimize time spent at the bedside.

If a source becomes loose or falls out, it should be picked up with forceps and placed in a shielded container in the patient's room. The physician and radiation protection supervisor should be notified of such an event as soon as possible after its occurrence.

Removal/Accountability

When 3M Cesium-137 tube sources are removed from a patient, the same radiation safety procedures used for insertion should be observed. All linens, dressings, clothing, and equipment should be kept within the cubicle or room where the removal takes place until all sources are accounted for. Appropriate detectors and a shielded carrier should be available in the room where source removal takes place.

After the removal procedure, it should be determined that all 3M Cesium-137 tube sources have been removed. This may be accomplished by surveying the patient with an appropriate radiation detector.

Following their removal from a patient, 3M Cesium-137 tube sources must be returned to an individual designated as the source custodian for cleaning, inventory, and storage in a controlled area.

Cleaning/Sterilization/Storage

3M Cesium-137 tube sources should be cleaned following their removal from the patient and before being returned to a storage safe. While cleaning or sterilizing sources, adequate precaution should be taken to avoid radiation exposure to the staff, damage to sources, and loss of sources.

Cleaning of 3M Cesium-137 tube sources may be accomplished by rinsing or soaking the sources in water or, if dried fluids are present, in a hydrogen peroxide: water (1:1) solution. An ultrasonic bath may also be used. Following cleaning, 3M Cesium-137 tube sources should be air-dried or rinsed in alcohol.

Abrasive substances (e.g. metal cleaners, polishes) must not be used to clean 3M Cesium-137 tube sources. In addition, sources should not be allowed to contact mercury or mercury-containing solutions, or any other toxic or biologically hazardous materials.

3M Cesium-137 tube sources may be sterilized with steam (autoclave), dry heat, or ethylene oxide (EO). Regardless of the method selected, the sources should be placed in an adequately shielded container prior to placement in the sterilization chamber. Manipulation of the sources prior to or following sterilization should be carried out behind shielding of such size and thickness as will adequately shield the operator. In addition, 3M Cesium-137 tube sources should be handled only with forceps. Autoclaves should be equipped with traps or other means to prevent source loss through the drain hole.

3M Cesium-137 tube sources withstand normal sterilization conditions of temperature and pressure. 3M Cesium-137 tube sources retain their integrity at temperatures of 800° C for 60 minutes.

34-7018-3844-2

Leak Testing

3M Cesium-137 tube sources are leak tested prior to shipment and the results provided on shipping certification papers that accompany each shipment.

3M Cesium-137 tube sources must be leak tested periodically by the user according to requirements described in 10 CFR 35.14. The U.S. Nuclear Regulatory Commission has specified a three-year leak test interval for 3M Cesium-137 tube sources, series 6500 (formerly model 6D6C).

Adverse Reactions

No adverse reactions involving 3M Cesium-137 tube sources have been reported.

Dosage and Administration

The total activity of 3M Cesium-137 tube sources required for any given treatment depends upon several factors, among which are tumor type and size, anatomical geometry, and previous radiation history to the tumor site. The treatment plan for a particular patient, including the number and strength of sources and the length of treatment time, should be prescribed by a qualified physician. 3M Cesium-137 tube sources decay at a rate of approximately 2% per year, and, as a result, treatment times should be adjusted periodically.

How Supplied

3M Cesium-137 tube sources are available as standard size tubes, series 6500 (20 mm long × 3.1 mm diameter, 14 mm active length). Each source contains cesium-137 in amounts listed below, by product number. Short tubes, series 6520 (16 mm long × 3.1 mm diameter, 10 mm active length), are available upon special request, in activities from 5 to 25 mg Ra equivalents.

Series 6500

Model	mg Ra equivalent
6500	5
6501	10
6502	15
6503	20
6504	25
6505	30
6506	35
6507	40

Each 3M Cesium-137 tube source is nickel-plated and engraved with the nominal activity in milligrams radium equivalent and serial number.

3M Cesium-137 tube sources are packaged in a lead pig which is labeled to indicate the isotope, amount of activity, and calibration date, as well as precautionary regulatory statements pertaining to licensing of the product.

Licensing

3M Cesium-137 tube sources are licensed by the U.S. Nuclear Regulatory Commission for distribution to persons licensed pursuant to §§ 35.14 and 35.100 Group VI of 10 CFR Part 35 or under equivalent licenses of Agreement States.

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

References

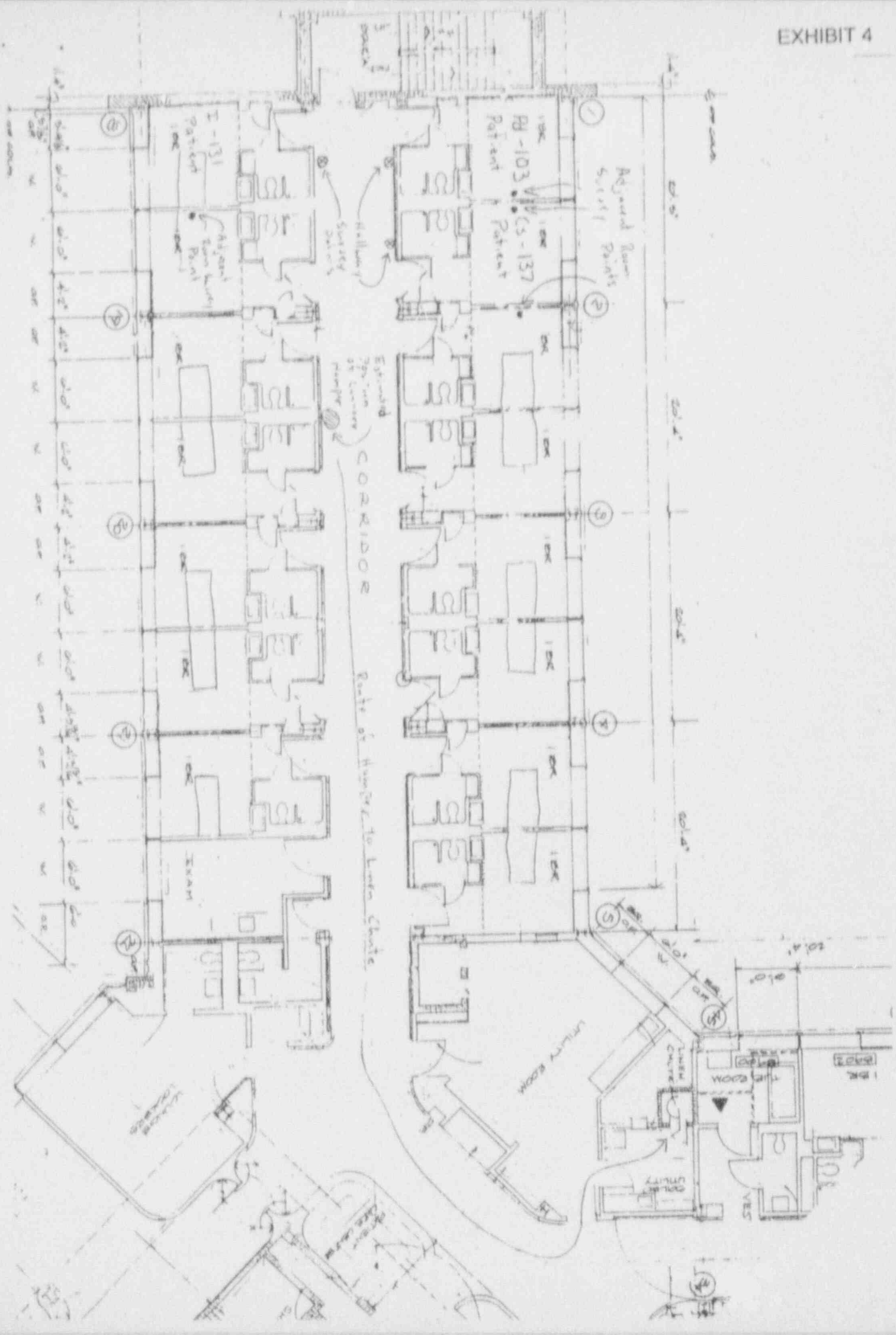
1. Fletcher, GH, M.D., ed. *Textbook of Radiotherapy*. Lea & Febiger, Philadelphia, Pennsylvania, 1973.
2. NCRP Report No. 37, NCRP Publications, P.O. Box 30175, Washington DC 20014
3. NCRP Report No. 40, NCRP Publications, P.O. Box 30175, Washington DC 20014
4. NCRP Report No. 41, NCRP Publications, P.O. Box 30175, Washington DC 20014
5. NCRP Report No. 48, NCRP Publications, P.O. Box 30175, Washington DC 20014
6. NCRP Report No. 49, NCRP Publications, P.O. Box 30175, Washington DC 20014

7-80

Medical Products Division/3M
225-5S 3M Center
St. Paul, MN 55144

3M

EXHIBIT 4



CORRIDOR
Route of Hamper to Linen Chute
I-131 Patient
EXAM
UTILITY ROOM

YALE-NEW HAVEN HOSPITAL --- BRACHYTHERAPY IMPLANT SURVEY LOG

INSTRUMENT CODES:
K1 - KIETHLEY 36100 #149870 L1 - LUDLUM MODEL 3 #511164 E1 - EBERLINE E-120 #789
K2 - KIETHLEY 36150 #39129 L2 - LUDLUM MODEL 3 #731191

INITIAL SURVEY --- ALL EXPOSURE MEASUREMENTS IN mR/HR														REMOVAL SURVEY				
PATIENT NAME	ISO-TOPE	ACTI-VITY	ROOM NO.	1 METER	DOORWAY UNSHLD	DOORWAY SHLD.	ADJACENT ROOMS		HALLWAY	TIME	DATE	SURV. INIT.	SURV. METER	RESULT	TIME	DATE	SURVEYOR	SURV. METER
5 Room Diagram	137 CS	165 mg Rs Eq	9-520	19.7	4.6	0.7	9-515 0.4	9-522 0.4	0.8	[illegible]	27 Nov 92	MB	K2	(-)	8:[illegible]	4/Dec 92	CW	L-1
9-524 / 9-523 / 9-522 / 9-521 / 9-520 / 9-519 / 9-518 / 9-517 (NURSING STATION)	137 CS	51.4 mg Eq	9-521	16.0	5.0	1.0	9-523 0.3	9-519 0.5	1.0	2:00 PM	30 Nov 92	MB	K2	(-)	4 pm	1/4/1	LW	E-1
	131 I	100.1 mCi	9-524	19.0	0.5	NA	9-522 0.4	NA	0.3	4:30 PM	30 Nov 92	MB	K2	Room Secured by RSO	8:30 AM	4 Dec 92	MB RSO	Ludlum model 3-2 Eberline
	103 Pd	58.35 mCi	9-523	1.0	NA	NA	9-521 0.0	NA	0.0	5:00 PM	1 Dec 92	MB	K2	Permanent Implant	N/A	N/A	MB RSO	n/a
	137 CS	78.27 mg Eq	9-523	22.5	8.3	1.3	9-521 1.9 [illegible]	NA	0.5	5:10 PM	4 Dec 92	MB	K2	(-)	8:00 am	12/4/92	MCJS	E-1
	125 I	299 mCi	9-521	6.0	1.5	NA	9-523 NA	9-515 0.0	0.0	7:45 PM	4 Dec 92	MB	K2	(-)	9:45 AM	7 Dec 92	MB RSO	L-1
	131 I	46.1 mC	9-523	8.1	0.2	NA	9-521 0.2	NA	0.1	5:00 PM	7 Dec 92	MB	K2	Room Secured by RSO	6:45 PM	9 Dec 92	MB RSO	Ludlum model 3-2 Eberline

EXHIBIT 5

EXHIBIT 6

DRIVER'S DAILY LOG

(ONE CALENDAR DAY - 24 HOURS)

ORIGINAL - File each day at home terminal.
DUPLICATE - Driver retains in his possession for eight days.

RECAP

1 (MTH) 30 (DAY) 92 (YEAR) 102 (TOTAL MILEAGE TODAY)

I certify that these entries are true and correct. 3932/TEX242/6645 (VEHICLE NUMBERS - (SHOW EACH UNIT)

102 (TOTAL MILES DRIVING TODAY)

(DRIVER'S SIGNATURE IN FULL)

(NAME OF CARRIER OR CARRIERS)

None (NAME OF CO-DRIVER)

St Louis Mo. (MAIN OFFICE ADDRESS)

Milford Ct. (HOME TERMINAL ADDRESS)

MID-NIGHT 1 2 3 4 5 6 7 8 9 10 11 NOON 1 2 3 4 5 6 7 8 9 10 11 MID-NIGHT

TOTAL HOURS

OFF DUTY — 1.6
SLEEPER BERTH — 0
DRIVING — 3.5
ON DUTY (NOT DRIVING) — 4.5
REMARKS — 24

Milford Ct. New Haven Ct. Milford Ct. New Haven Ct. Stratford Ct. Milford Ct.

Document, manifest number, or name of shipper and commodity

Time and enter name of place you reported and where released from work and when each change of duty occurred. Explain excess hours.

FROM: Milford Ct. (STARTING POINT OR PLACE) TO: New Haven Ct. (DESTINATION OR TURN AROUND POINT OR PLACE)

USE TIME STANDARD AT HOME TERMINAL

RECAP

30 DAY TOTAL

3.5 DRIVING HRS TODAY TOTAL LINE 3

0 DRIVING VIOLATION TODAY

8 ON DUTY HRS TODAY TOTAL LINES 3 & 4

70 HR/8 DAY DRIVERS

A. TOTAL HRS ON DUTY LAST 7 DAYS INCL TODAY

B. TOTAL HRS AVAILABLE TOMORROW (70 HRS MINUS A)

C. TOTAL HRS. ON DUTY LAST 8 DAYS, INCL TODAY

60 HR/7 DAY DRIVERS

A 31.5 TOTAL HRS ON DUTY LAST 7 DAYS INCL TODAY

B 28.5 TOTAL HRS AVAILABLE TOMORROW (60 HRS MINUS A)

C 4.0 TOTAL HRS ON DUTY LAST 7 DAYS INCL TODAY

EXHIBIT 7

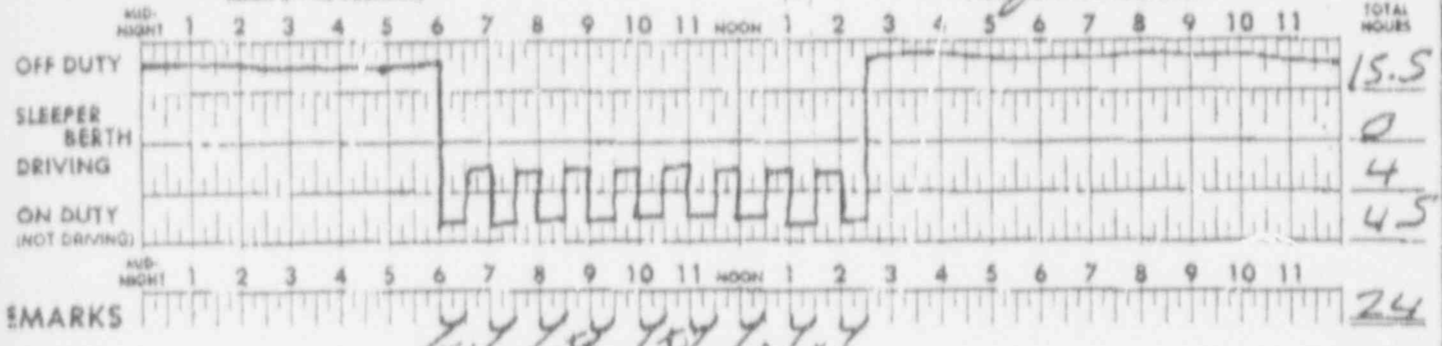
12 / 1 / 92 (MONTH) (DAY) (YEAR) — 70 (TOTAL MILEAGE TODAY)

I certify these entries are true and correct. — 3932/EX242/E45 VEHICLE NUMBERS (SHOW EACH UNIT)

70 (TOTAL MILES DRIVING TODAY) — (DRIVER'S SIGNATURE IN FULL)

(NAME OF CARRIER OR CARRIERS) — None (NAME OF CO-DRIVER)

St Louis Mo (MAIN OFFICE ADDRESS) — Milford Ct. (HOME TERMINAL ADDRESS)



	TOTAL HOURS
OFF DUTY	15.5
SLEEPER BERTH	0
DRIVING	4
ON DUTY (NOT DRIVING)	4.5
	24

REMARKS: Milford Ct. / New Haven Ct. / Milford Ct. / Bridgeport Ct. / New Haven Ct. / West Haven Ct. / Milford Ct. / Milford Hospital / Milford plant

...the time... enter... when and where each change of duty occurred. Explain excess hours.

FROM: Milford Ct. (STARTING POINT OR PLACE) TO: Bridgeport Ct. (DESTINATION OR TURN AROUND POINT OR PLACE)

USE TIME STANDARD AT HOME TERMINAL

RECAP: 1 DAY NO. — 4 DRIVING HRS. TODAY TOTAL LINE 3 — 0 DRIVING VIOLATION TODAY — 8.5 ON DUTY HRS. TODAY TOTAL LINES 3 & 4

70 HR/8 DAY DRIVERS: A. TOTAL HRS. ON DUTY LAST 7 DAYS, INCL. TODAY — B. TOTAL HRS. AVAILABLE TOMORROW 70 HRS. MINUS A — C. TOTAL HRS. ON DUTY LAST 8 DAYS, INCL. TODAY

60 HR/7 DAY DRIVERS: A. 32 TOTAL HRS. ON DUTY LAST 6 DAYS, INCL. TODAY — B. 28 TOTAL HRS. AVAILABLE TOMORROW 60 HRS. MINUS A — C. 40 TOTAL HRS. ON DUTY LAST 7 DAYS, INCL. TODAY

DRIVER'S DAILY LOG

(ONE CALENDAR DAY - 24 HOURS)

ORIGINAL - File each day at home terminal
DUPLICATE - Driver retains in his possession for eight days

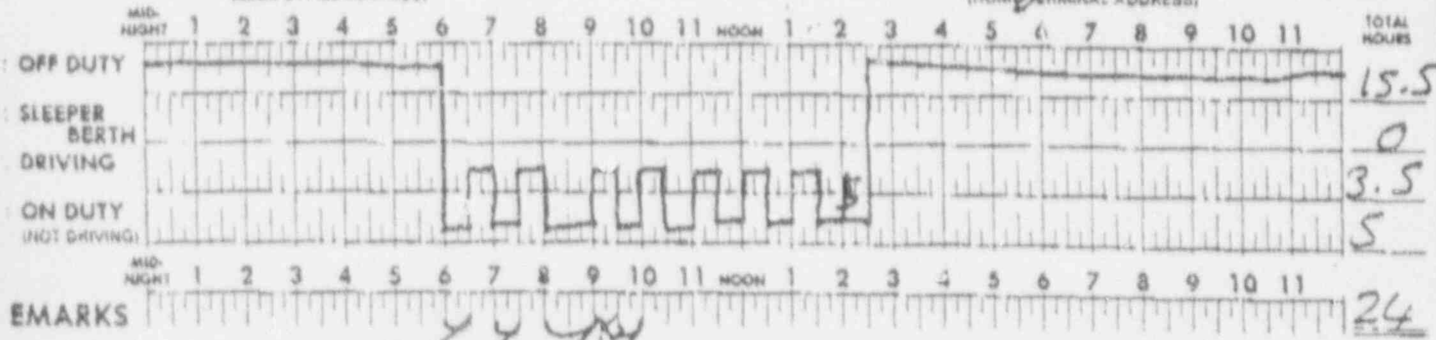
12 / 2 / 92 (MONTH) (DAY) (YEAR) — (TOTAL MILEAGE TODAY)

I certify these entries are true and correct. — 3932/E45/ VEHICLE NUMBERS - (SHOW EACH UNIT)

(TOTAL MILES DRIVING TODAY) — (DRIVER'S SIGNATURE IN FULL)

(NAME OF CARRIER OR CARRIERS) — None (NAME OF CO-DRIVER)

St Louis Mo. (MAIN OFFICE ADDRESS) — Milford Ct. (HOME TERMINAL ADDRESS)



	TOTAL HOURS
OFF DUTY	15.5
SLEEPER BERTH	0
DRIVING	3.5
ON DUTY (NOT DRIVING)	5
	24

REMARKS: Milford Ct. / New Haven Ct. / Milford Ct. / Bridgeport Ct.

...going document... enter... the time and enter... released from work and when and where each change of duty occurred. Explain excess hours.

FROM: Milford Ct. (STARTING POINT OR PLACE) TO: New Haven Ct. (DESTINATION OR TURN AROUND POINT OR PLACE)

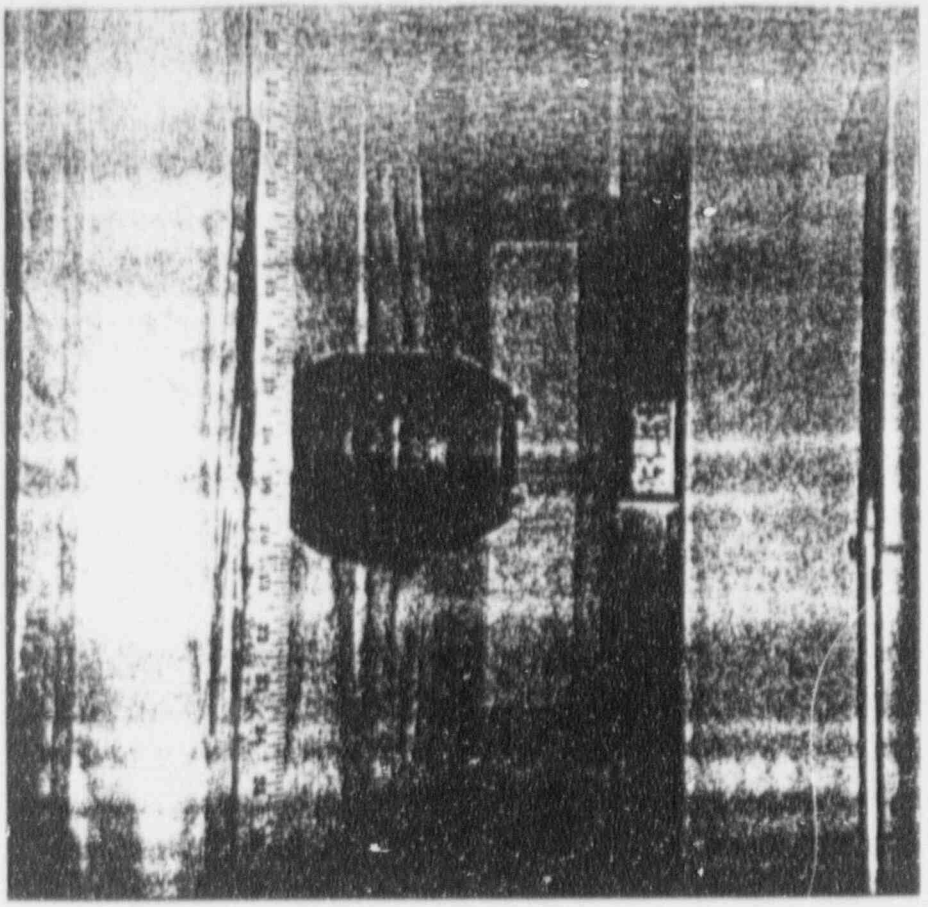
USE TIME STANDARD AT HOME TERMINAL

RECAP: 2 DAY NO. — 3.5 DRIVING HRS. TODAY TOTAL LINE 3 — 0 DRIVING VIOLATION TODAY — 8.5 ON DUTY HRS. TODAY TOTAL LINES 3 & 4

70 HR/8 DAY DRIVERS: A. TOTAL HRS. ON DUTY LAST 7 DAYS, INCL. TODAY — B. TOTAL HRS. AVAILABLE TOMORROW 70 HRS. MINUS A — C. TOTAL HRS. ON DUTY LAST 8 DAYS, INCL. TODAY

60 HR/7 DAY DRIVERS: A. 41.5 TOTAL HRS. ON DUTY LAST 6 DAYS, INCL. TODAY — B. 18.5 TOTAL HRS. AVAILABLE TOMORROW 60 HRS. MINUS A — C. 41.5 TOTAL HRS. ON DUTY LAST 7 DAYS, INCL. TODAY

EXHIBIT 8



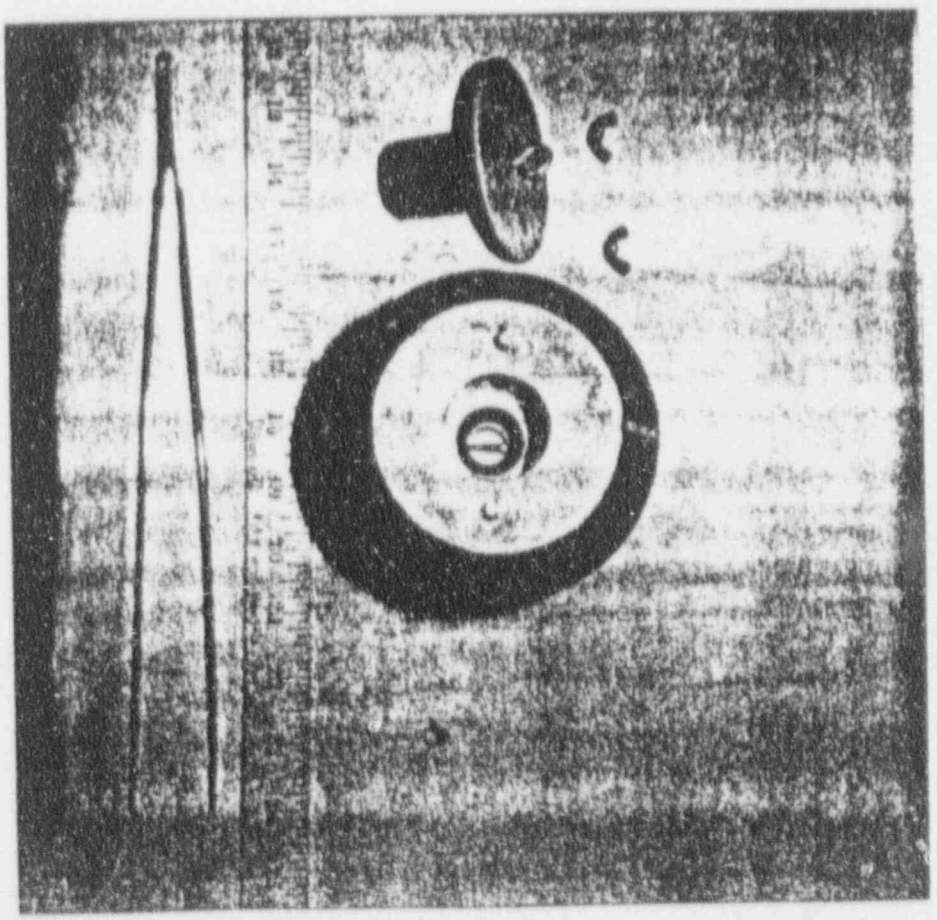


EXHIBIT 9

Yale-New Haven Hospital Cs-137 Leak Test of Lost Source Date: 02-Dec-92

Instrument: Picker Spectroscaler 4, Model No. 628436, Ser. No. 19747
2 X 2 NaI Well, Model No. B641018, Ser. No. E827
HV Set: 253 MeV Range: 1.0 LL: 425 UL: 600
(750 Volts)

Standard: 1.070 uCi @ 15-Aug-69 23.30 Years of Decay
Cs-137 0.625 uCi @ 02-Dec-92 30.00 Year - Half Life

Calibration:

Count No.	1	2	3	Ave.	St. Dev.		MDA @ 4.66 St. Dev.
Std.:	121763			121783	0		
Bkg.:	31	32	30	31	6	*Note	1.33E-04 uCi

Calibration: 194932 cpm/uCi @ 8.8% Efficiency

Source Leak Test Results:

Source Group	Org. Act. (uCi)	Count Number 1	2	3	Ave.	Net (dpm)	(uCi)	% NRC Std.
Tube Source #04505	35.04	24	20	26	23	-87	-3.93E-05	<MDA
Wash Water Sample	N/A	22	[illegible]	32	27	-46	-2.05E-05	<MDA

*Note: The square root of the average background was used to calculate the standard deviation because the actual backgroud counts agreed within +/- 1 cpm.

Leak Test Performed By:

Michael J. Bohan
Health Physicist/R.S.O.

137LTEST.WK1

EXHIBIT 10

YALE-NEW HAVEN HOSPITAL
AMBULATORY SERVICES
HISTORY AND
PROGRESS NOTES

(If handwritten, record name, unit no., and birth date)

DATE	Problem No.	
12/4/92		Removal note: At 4 pm on 12/1/92 Cs-137 sources were removed, as was the Fletcher-Suit device. Patient tolerated the placement well, and the total placement time was 28 hrs allowing for a total of 1439 mg hrs. Of note, upon removal of the tandem source, the long plastic spacer was withdrawn from the tandem, but did not come out in toto with the clear sleeve and sources. The distal end of the sleeve was seen protruding from the tandem, which was removed using long forceps and the two cesium sources were grossly visualized and placed into the pig without difficulty. The two culpostat applicators were then removed without difficulty and placed into the pig. At that juncture, a patient and room survey were conducted with the Geiger counter, which was negative. The packing was then removed, followed by removal of the Fletcher-Suit device without difficulty. The patient and room (including the bathroom and trash can) were then again surveyed and were negative. The Fletcher-Suit was surveyed as well and it was negative for radioactivity. Because of the irregularity noted in the tandem spacer becoming dislodged from the remainder of the source holder, a third survey of the patient, bed, trash and room was then done which was negative. After chart work was completed, the lead pig and Fletcher-Suit device were taken to the "radium room" and the Fletcher-Suit device was placed into a metal basin in the sink which contained fresh water. The patient tolerated the unloading procedure well, and our plan is for parametrial boost.
		mp Lynn Wilson, M.D. for Kenneth Roberts, M.D.
12/4/92		Missing source note: At approx. 2:30 pm on 12/2 I received a call from Anita Dodson and she stated that one of the 15 mg Cs-137 culpostat sources was missing. I immediately met her at the radium room, and the Fletcher-Suit applicator and source holders were examined and demonstrated that the source was not present. Apparently it was not clear whether the right or left culpostat source was the one that was missing. We immediately alerted Mike Bohan, the radiation safety officer, who joined us at the radium room and at that point we were not able to locate the source within the room, and Mike Bohan and myself then surveyed the laundry areas in the basement of the MU, and the trash areas. There was no evidence of the source in these areas, and the patient's room was also surveyed which was negative. At that point we suspected that the source might be outside the institution, as we could not account for its loss and thought that it might possibly be at the laundry plant or garbage endpoint in Bridgeport. We proceeded immediately to the laundromat, which was several miles from the hospital, and began to survey the plant beginning at the loading dock where trucks brought laundry into the building. The survey was entirely

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EXHIBIT 11

2/4/92 (cont'd)

negative until we reached the point of the washers, at which time we began to note increased activity on the Geiger counter and localized increased activity at a drain in one of the washers. We had a representative of the laundry plant with us, and informed her that we had likely found the source. An engineer released the water valve from this washer after we had set up a screen system to capture the source in the water drainage system, and within several seconds after opening the valve we identified the source both by Geiger counter and direct visualization. The source was recovered using long forceps and placed into a lead pig. A water sample was also obtained, and after the source was placed into the pig there was no increased level of radioactivity remaining. Michael Bohan tested the source and apparently there had been no rupture and no leakage. From the time of realizing the source was missing to the time of recovery, approx. 2½ hrs had elapsed. The NRC was then contacted by Michael Bohan.

Dosimetry: As doumented in the note of 11/30/92 would be the presumed totals for an Implant which had all sources included for the entire 28 hrs. Assuming that the left culpostat source was not utilized at all for the treatment, the following matrix represents the individual treatment doses and totals. These doses, assuming the worst case scenario which would be that the left culpostat was without a 15 mg Cs-137 source for the entire treatment were also reviewed by Dre. Richard Peschel and Barry Kacinski and were thought to be acceptable in the patient's treatment.

Planned Rx

	Rt A	Lt A	R	B
EBRT	3960	3960	3960	3960
T&O #1	2440	2280	892	656
T&O #2	1568	1848	694	580
Total	7968	8088	5546	5196

Worst Case Analysis

	Rt A	Lt A	Rt B	Lt B	R	B
EBRT	3960	3960	3960	3960	3960	3960
T&O #1	2440	2280	480	480	892	656
T&O #2	1439	1235	252	168	504	420
Total	7839	7475	4692	4608	5356	5036

Lynn Wilson, M.D. for
Kenneth Roberts, M.D.

mp
cc: Dr. J. Chambers
D:12/4
T:12/7

EXHIBIT 12

YALE-NEW HAVEN HOSPITAL
AMBULATORY SERVICES
HISTORY AND
PROGRESS NOTES

(If handwritten, record name, unit no., and birth date)

DATE	Problem No	
12/7/92		Dr. Wilson's notes of 12/4/92 nicely document the events that transpired on 12/2, when it was discovered that a 15 mg Ra eq Cs-137 source was missing. The exact cause of this mishap is somewhat unclear, but our best guess is that during the loading procedure the source fell out of the culpostat applicator and onto the bed sheets. This is clearly a serious problem and we were gratified that the missing source was found. The following day on 12/3/92, we had the patient come to the clinic and informed her of this unfortunate situation. The alternative explanation for what happened would be some tampering with the culpostats by the patient or another person. This was denied by the patient and I have no reason to doubt Ms. Pt's Name veracity. Mrs. Pt, Name described that during the course of her implant the nurses removed some bed pads several times underneath her pelvis as is part of the usual nursing routine, considering the expected problems with vaginal discharge with these procedures. We suspect that the missing cesium source was rolled up in some of these beddings which were subsequently sent to the laundry. In terms of the treatment of the patient's cancer, the worst case would be that one of the culpostats was not loaded for the entire duration of her second T&O insertion of 11/30-12/1/92. Dosimetric calculations indicate that the total minimum dose to point A would be 7475 cGy. Given that the patient's primary disease was limited to her cervix, this would actually be considered adequate treatment. It is relevant to note that the patterns of care study from the ACR recommend that total doses to the paracentral dose point (which is similar to the classical definition of point A) should be from 7000-8500 cGy for non-bulky stage IB disease. I do not believe that any alteration in our treatments is required as a result of the misplaced culpostat cesium source. I have reviewed the dosimetry with Dr. Peschel in our dept., who is in agreement with this assessment. I have also reviewed this situation carefully with the patient, indicating that the probability of a central pelvic recurrence should not be appreciably altered because of a source not being loaded in one of her culpostats for the second ICRT. Mrs. Pt's Name is quite intelligent and demonstrated an excellent understanding of this situation. She already is aware that there is an appreciable risk of recurrent disease with her tumor having metastasized to lymph nodes. I have indicated to the patient that if she desired we could arrange for a second opinion regarding her treatments. We plan to proceed with a pelvic side wall boost for three additional fractions. No further dose to the central pelvis, either by teletherapy or brachytherapy, is felt to be warranted.

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EXHIBIT 13

	Problem No	
/7/92 (cont'd)		
		With the possibility that a cesium source was lying next to the patient's skin for an undefined period of time, she was examined and no skin changes such as focal erythema were noted. The patient will let us know if any rash or ulcers over the skin develop.
		Dr. Wilson and I have conveyed our apologies to the patient for her being subjected to an improper administration of RT. Fortunately for all concerned, no apparent harm has been done. We take this situation very seriously. The Nuclear Regulatory Commission has been informed of this problem in a timely fashion and they will no doubt be conducting a thorough investigation. Drs. Peter Schwartz and Joseph Chambers in the gyn oncology division have also been notified. Mrs. Pt Name knows that we will be available to answer any further questions or concerns that she or her family may have. I will be seeing the patient again next week as she completes her course of RT.
		Kenneth Roberts, M.D.
		mp cc: ~~Dr. J. Chambers~~, Carter, Ethe D:12/10 T:12/10

EXHIBIT 14

YALE-NEW HAVEN HOSPITAL
AMBULATORY SERVICES
HISTORY AND
PROGRESS NOTES

(If handwritten, record name, unit no., and birth date)

DATE	Problem No.	
12/9/92		Patient has now completed her course of RT today. She has just completed her pelvic sidewall boost and is not having any appreciable difficulty. There have been no problems with any skin reaction vis a vis the misplaced cesium source from her last brachytherapy several weeks ago. Overall, she is clinically stable. We will have her return to our clinic in one month for routine FU. Confidential Patient Information
		Kenneth Roberts, M.D.
		mp
		cc: Drs. Chambers, Bartlett, Kische
		D:12/9
		T:12/10

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EXHIBIT 15

YALE-NEW HAVEN HOSPITAL
AMBULATORY SERVICES
HISTORY AND
PROGRESS NOTES

(If handwritten, record name, unit no., and birth date)

DATE	Problem No.	
12/9/92		Patient has now completed her course of RT today. She has just completed her pelvic sidewall boost and is not having any appreciable difficulty. There have been no problems with any skin reaction vis a vis the misplaced cesium source from her last brachytherapy several weeks ago. Overall, she is clinically stable. We will have her return to our clinic in one month for routine FU. Confidential Patient Information
		Kenneth Roberts, M.D.
		mp
		cc: Drs. Chambers, Bartlett, Kische
		D:12/9
		T:12/10
12/21/92		The patient called today complaining of some pain along her posterior right thigh. In this area the patients' mother had noted a blackened area, raising concern that this was related to the malplaced Cesium source. I had the patient come into the clinic, and on examination there is a area of hyperpigmentation which is linear, measuring approximately 4 x 20 mm. The dermis itself is intact without any ulceration. The patient notes that along the lesion there is mild tenderness, and on examination there is no associated mass. This undoubtedly is related to the Cesium source lying up against the skin. With no ulceration or soft tissue necrosis at this stage, we would hope and expect to see no significant complications from this episode of localized irradiation of the skin. A photograph has been taken to document this skin lesion. The patient knows to get in touch with me if there should be any further problems.
		Confidential Patient Information
		The patient will be returning for further follow-up in January.
		cm
		Kenneth B. Roberts, M.D.
		cc:Dr. J. Chambers
		D:12/30/92
		T:1/4/93

F680 (Rev. 5/81)

Procedure For Nursing Care of Patients Containing Radioactive Sources For Therapy

PURPOSE:

1. To utilize skills necessary for the care of patients containing radioactive sources for therapy in order to provide comfort and security for the patient.
2. To provide safety for all who have contact with the patient.

NOTES:

1. There are many radioisotopes used in radiotherapy. Each radioisotopic source has it's own individual characteristics which will dictate the techniques needed to control radiation exposure. The general guidelines below, outline information pertinent to all radiotherapy patients. Individual sources are grouped into special categories with specific guidelines.
2. These guidelines are from the recommendations of the National Council on Radiation Protection (NCRP) and comply with the requirements of the Nuclear Regulatory Commission (NRC). Further information can be found in NCRP Report numbers 37, 40 and 48. NRC requirements can be found in Title 10 of the Code of Federal Regulations parts 19, 20 and 35
3. If an emergency should arise, or if there are any questions concerning radiation safety, contact the Radiation Safety Officer (RSO) at X-2950. During evenings, nights, weekends or holidays contact security X-2500 and ask for the RSO's home phone number.

GENERAL GUIDELINES:

1. Radiation therapy involves the use of sealed or unsealed sources of radioactive materials. Sealed sources prevent the radioactive material from being dispersed. Radioactive contamination cannot occur unless the therapy source is ruptured. Only external radiation protection procedures are required for patients containing sealed sources. Unsealed sources of radioactive materials allow radioactivity to circulate through the patients bloodstream. The possibility of contamination does exist with these patients. In addition to external radiation protection methods, unsealed sources require isolation and contamination control procedures.

   A. EXTERNAL RADIATION PROTECTION PROCEDURES
   Protection of nursing personnel can be easily attained by controlling the factors of TIME, DISTANCE and SHIELDING.

   TIME: This is the most important factor used to reduce radiation exposure. Limit the time in the vicinity of the patient to the essential duties required for adequate care. Do not linger needlessly near the patient.

   DISTANCE: The distance between the implant site and nursing personnel should be maximized when possible. Radiation intensity drops rapidly as distance increases; e.g. radiation intensity at three feet is only 10% of the level at one foot.

   SHIELDING: This is the least effective protective device to offer

the nurse. Shielding is often so cumbersome that the increased time needed to accomplish nursing duties outweigh the benefits of shielding. Shielding is used only when time and distance factors cannot be reasonably controled.

B. CONTAMINATION CONTROL PROCEDURES

Contamination control is accomplished by following isolation procedures similar to those used for infectous dieases. Gloves and protective clothing should be worn by nurses while caring for the patient. These materials should be placed in the proper receptacles when leaving the room. Extra caution should be exercised when handling bodily fluids. Care should be taken to limit the potential for spills. Patient meals should be delivered on disposable trays and plates. All bed linens and wastes should be kept for disposal by the RSO. After leaving the room, hands should be thoroughly washed with mild soap and warm water.

PRELIMINARY PRECAUTIONS

1. Generally, a single room is necessary for any patients undergoing radioisotope therapy. Patients receiving Iodine-125 therapy may be placed in a multiple bed room if external radiation levels are acceptable under the direction of the RSO.
2. A "Limit Visitors" sign should be placed on the door. The RSO will specify visitor time and distance requirements if indicated on the patient's door and chart.
3. The RSO or his designee will perform a radiation safety survey of each patient undergoing therapy. This survey will include measurement of dose rates at various locations and to insure all documentation is properly posted on the patient's door and chart.
4. The patient will wear a wrist band indicating that he or she is undergoing treatment with radioactive materials. This wrist band should be discarded once temporary implant sources are removed or upon release for internal dose and permanent implant patients.
5. The following information will be noted on a form supplied by the Department of Therapeutic Radiology, Physics Section:
   a. Date and time inserted
   b. Area inserted
   c. Radioisotope being used
   d. Type of sources (needles, seeds, liquid, etc.)
   e. Number of sources
   f. Strength of each source
   g. Date and time to be removed
   h. Radiation dose rate at 1 meter (1 foot for Iodine-125 patients)
6. Copies of this form will be kept:
   a. In the patient's chart (white copy)
   b. In the patient's Kardex (blue copy)*
   c. On the patient's door (yellow copy)*
   d. By the RSO (cardboard copy)

   * Discard after source is removed or after patient is released.
7. A lead storage cart will be placed in the patient's room for the removal of sources.
8. Portable radiation shields will be placed in the patient's room if deemed necessary by the RSO.
9. The physician must indicate the extent of movement allowed the patient in order for the nurse to plan her nursing care.

NURSING PROCEDURES:

The following nursing care procedures are recommended when indicated, based on the time, distance and shielding factors previously discussed, and are consistent with adequate nursing care.

1. Bed linen will not be changed during interstital therapy unless it becomes soiled. Change the bed before the implantation of the source and immediately after the source is removed. If the patient is allowed out of the bed, have him sit on the opposite side of the room if it is necessary to change the bed.
2. Baths - No bed baths will be given during interstital therapy. Wash the patient before implantation and immediately after source removal. If the patient is allowed to move, and is able to move, he should be permitted to wash himself.
3. Back rubs - No back rubs will be given unless the patient is uncomfortable and the back rubs are ordered spefically by the physician.
4. Vital signs and medications - Vital signs will be taken and medications given as ordered by the physician.
5. Feeding - Patients should feed themselves whenever they are able. Use routine procedure for disposal of dishes unless the patient is under isolation precautions. Carry out tube feedings as quickly and efficiently as possible.
6. Emergency care of patient - (Seizures, coronary occlusion, etc.) This should be carried out quickly and without fear of being exposed to radiation.
   a. Contact the appropriate emergency personnel - (Code 5 team)
   b. Call resident to remove radiation sources.
   c. Contact the therapeutic radiologist immediately.
7. During nursing care procedures, the nurse must check all materials used by the patient (linen, bedpans, emesis basins, etc.) for radioactive sources which may have become dislodged.
8. If possible, the nurse will inspect the source to make certain that the source appears to be in its proper position.
9. Explain to the patient that nursing care may be limited during the treatment; reassure the patient that you are present and will check on their needs frequently.
10. Regular visiting hours may be observed.
    a. Visitors should be instructed to stay by the doorway, 4-7 feet away from the patient except for a brief moment for greetings.
    b. No pregnant women or no one under the age of 18 are allowed to visit during the therapy.
11. Maids and porters should not be allowed in the room while the source is present. The room should be cleaned before insertion of the source and only after the room is checked for lost sources upon removal.
12. The patient and room must be monitored with a geiger counter after source removal to ensure all radioactive material is removed before discharge. (Except for permanent Iodine-125 implants)
    NOTE: The physician and the nurse with him at the time the radioactive source is removed from the patient are responsible for the monitoring of the patient, the room, and the return of the radioactive material to the Radium Room.
13. If a radioactive source becomes dislodged or displaced. call the

resident and the therapeutic radiologist immediately.

14. Never pick up a radioactive source with your hands. Use a Kelly clamp or sponge forcep for this purpose. Gently pick up the source and place it in the lead storage cart.
15. The patient's room is to be monitored after all sources have been removed. Everything used by the patient (except dishes) must be saved and monitored before disposal.
16. This survey must be documented in the patient survey log by the nurse.
17. If a patient containing radioactive material expires, notify the therapeutic radiologist and the RSO in addition to other necessary personnel.

SPECIFIC CHARACTERISTICS OF INDIVIDUAL ISOTOPES:

Iodine-125

a. Administration - Multiple seeds (approximately 5 mm X 0.4 mm each) implanted directly into tumor individually. Occasionally may be incorporated into suture material or catheters. Usually implanted permanently, except for brain tumors.
b. Radiation emission - low energy gamma, requires minimal shielding measures, radiation doses outside of patient are very low. Use time and distance to limit external radiation exposure.
c. Isolation - Not required because of low radiation levels.
d. Contamination precautions - not required because sources are sealed.
e. Prostate implants - Collect all urine and save Foley catheter for inspection by RSO to prevent loss of passed seeds.
f. Head and neck implants - save wound dressings for inspection by RSO.
g. Brain implants - Have patient wear helmet shield during nursing care or when visited by family or friends.
h. Source loss - recover seeds with forceps, place in container, label and isolate. Notify RSO for proper disposal.

Iodine-131

a. Administration - Orally, by capsule or through a straw.
b. Radiation emission - medium energy gamma, shielding normally not attempted because of contamination problems. Time and distance principles used for external radiation protection.
c. Isolation required - disposable food service, isolation gowns and gloves for nurses are indicated, save wastes and linens in plastic isolation bags for monitoring and disposal by RSO. Advise patient to limit personal belongings and to wear hospital gowns when in isolation.
d. Contamination precautions - Handle bodily fluids with care, especially urine (the primary route for excretion of iodine). Before administration, cover bathroom floor, bed matress, pillow, chairs, and table with blue diapers, plastic bags, or folded sheets to facilitate decontamination after patient release. Take blood or urine samples before administration of iodine, if needed. Notify RSO if blood samples are ordered after administration.
e. Room cannot be released to next patient until decontaminated by RSO.

Phosphorous-32

a. Administration - Light green colored, liquid colloid infused into pleural or peritoneal cavity usually by saline drip.

b. Radiation emission - Beta emitter, most radiation absorbed within patient's body, very low external radiation levels.
c. No isolation required
d. Contamination precautions - Wear gloves when changing dressings over wound site. Save linen and dressings in plastic bags for inspection by RSO.

Iridium-192

a. Adminirtration - Small seeds (approximately 3 mm X 0.25 mm each) incorporated into wires or catheters.
b. Radiation emission - High energy gammas, shielding is difficult because of highly penetrating gamma radiation. Utilize time and distance techniques to minimize exposure.
c. Isolation required - Limit visitation to RSO recommendations posted on patient's door or chart.
d. Contamination precautions not required - sealed sources do not permit escape of radioactivity unless damaged.

Cesium-137 or Radium-226

a. Administration - Needles (variable dimensions) or tubes (approximately 10 mm X 2 mm) incorporated into plaques or holders for primarily intercavitary applications.
b. Radiation emission - High energy gammas, shielding is difficult because of highly penetrating gamma radiation. Utilize time and distance techniques to minimize exposure.
c. Isolation required - Limit visitation to RSO recommendations posted on patient's door or chart.
d. Contamination precautions not required - sealed sources do not permit escape of radioactivity unless damaged.

Americium-241

a. Administration - Large tubes (20 mm or 40 mm X 10 mm) or tandem incorporated into plaques or holders for intercavitary applications.
b. Radiation emission - Low energy gamma, patient can be easily shielded by placing a diagnostic x-ray type leaded apron over the implant area. Time and distance constraints can be relaxed when shielding is in place.
c. No isolation required - except pregnant women and children less than 18 years of age.
d. Contamination precautions not required - sealed sources do not permit escape of radioactivity unless damaged.