U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-02809/94-001(DRSS)

Docket No. 030-02809

License No. 34-10921-03

Category G Priority 2

Licensee: Bethesda Hospital
619 Oak Street
Cincinnati, OH 45206

Inspection Conducted: December 15, 1993 and January 27-28, 1994

Inspectors: W. P. Reichhold — 17 March 1994
W. P. Reichhold
Radiation Specialist — Date

W. J. Slawinski — 3-17-94
W. J. Slawinski
Senior Radiation Specialist — Date

Reviewed By: B. J. Holt — 3/16/94
B. J. Holt, Chief
Nuclear Materials Inspection
Section 1 — Date

Approved By: Roy J. Caniano — 3/16/94
Roy J. Caniano, Chief
Nuclear Materials Safety Branch — Date

Inspection Summary

Inspection during the period December 15, 1993 and January 27-28, 1994, (Report No. 030-02809/94-001(DRSS))

Areas Inspected: This was an announced special inspection conducted in response to a licensee reported incident and potential misadministration involving a dislodged cesium-137 sealed source used in a brachytherapy treatment. The inspection also included a review of the licensee's organizational structure; facilities and equipment; training for nurses; Quality Management Program (QMP) for conventional brachytherapy; and activities associated with the High Dose Rate (HDR) remote afterloading brachytherapy device.

Results: Of the areas inspected, seven apparent violations were identified and consist of failure to:

1. Maintain control of licensed material (Section 6).

2. Maintain radiation levels in unrestricted areas within regulatory limits (Section 6).

3. Instruct nurses caring for brachytherapy patients (Section 6).

4. Provide annual retraining of nurses caring for brachytherapy patients (Section 6).

5. Sign and date an orally revised written directive (Section 6).

6. Include all required information on a written directive (Section 7).

7. Check a survey meter for proper operation prior to use (Section 8).

In addition to the apparent violations, two unresolved issues related to the dislodged source incident were identified. These pertain to the classification of the incident and the adequacy of the licensee's written directive.

DETAILS

1. Persons Contacted

*William Groneman, Senior Vice President
*John Dickey, Vice President
+John Liebold, M.D., Radiation Safety Officer
*Michael Gabannesch, Safety and Health Coordinator
*Margaret Wierenga, Manager of Risk Management
*Kevin Harlan, Director of Radiology and Oncology
*Ronald Droege, Ph.D., Medical Physicist
*Lois Vorhees, Supervisor, Imaging Services
*Robert Galley, Supervisor Imaging Services
*Renita Heeger, R.T, Director of Radiology
Jay Shree Desai, Dosimetrist
Ken Murdock, M.D., Radiation Oncologist
*Joyce Schack, R.N., Manager
Diane Irby, R.N., Staff Nurse
Marylin Strunk, R.N., Staff Nurse
Ethel Winn, R.N., Staff Nurse

+ Denotes telephone contact only.
* Denotes attendance at exit meeting on January 28, 1994.

2. Purpose and Scope of Inspection

This was an announced special inspection conducted to review the circumstances associated with a licensee reported incident involving a nominal 37 millicurie (1.4 GBq) cesium-137 sealed source that was dislodged from its applicator during a brachytherapy treatment. The inspection also included a review of the licensee's QMP and HDR remote afterloading brachytherapy activities. This inspection was limited to the activities conducted at the licensee's Bethesda Oak hospital.

3. Licensed Program and Inspection History

Bethesda Hospital is authorized, pursuant to NRC License No. 34-10921-03, to use radioactive material at Bethesda Oak Hospital in Cincinnati, Ohio and Bethesda North Hospital in Montgomery, Ohio for diagnostic and therapeutic medical procedures as described in 10 CFR 35.100 - 35.400 (excluding generators and aerosols for diagnostic studies) and for in vitro studies pursuant to 10 CFR 31.11.

Bethesda Oak Hospital uses byproduct material for conventional brachytherapy and for HDR treatments utilizing an iridium-192 sealed source in a Nucletron Corporation Micro Selectron HDR remote afterloading brachytherapy unit. Conventional brachytherapy is performed four or five times per year. The HDR unit is used each week to treat patients. Four physician users perform the majority of brachytherapy treatments.

Activities authorized under Bethesda Hospital's NRC license were inspected by the NRC on May 13, 1990 and February 11, 1993. Onsite inspections were conducted at both hospitals. Included in the 1993 inspection was a review of two reported diagnostic misadministrations that occurred on July 27, 1991 and December 18, 1991 at Bethesda North Hospital. No violations were identified during the May 1990 and February 1993 inspections.

4. Organization and Program Oversight

The Senior Vice President at Bethesda Oak Hospital is responsible for the management oversight of NRC licensed activities at that facility. The Radiation Safety Officer (RSO) is responsible for the radiation safety programs at both Bethesda Oak and Bethesda North hospitals; however, the RSO maintains an office only at Bethesda North Hospital and does not regularly frequent the Oak Street facility. To ensure proper implementation of licensed activities in radiation therapy at Bethesda Oak, the RSO has delegated direct radiation safety oversight responsibilities to the Medical Physicist. Similarly, the Director of Radiology and Oncology has been delegated the responsibility for daily oversight of activities in the radiology and oncology departments at Bethesda Oak Hospital. These individuals report on the status of the radiation safety program at the licensee's quarterly radiation safety meetings. These meetings are chaired by the RSO.

5. Incident Summary

On December 8, 1993, a patient was implanted with four cesium-137 sources to treat a tumor in the nasopharynx area and diseased tissue in the nasal area. This implant was the fourth in a series of brachytherapy treatments for the patient, preceded by three treatments with iridium-192 in an HDR remote afterloading brachytherapy device. The total activity of the cesium-137 sources implanted was 36 mg radium equivalent, approximately 90 millicuries (3.3 GBq), with three sources containing 20 millicuries (0.7 GBq) each and one source containing 30 millicuries (1.1 GBq). The cesium-137 sources and three spacers were loaded into a plastic insert tube. The arrangement was held in place by a plastic rod (plunger) taped to the insert tube. The insert tube was then placed into an endo-trachael (ET) tube which had been sutured to the patient's nose. Tape was used to secure the insert tube to the ET tube. The licensee's written directive specified a dose of 2,000 rads (cGy) at approximately 1.2 centimeters or 24 hours. The treatment plan developed for the source loading indicated a dose rate of 80 cGy/hr at 1.2 cm. The licensee reported that this dose rate was to a point nearly 1.2 cm lateral to the most distal source (30 millicuries).

During the course of the treatment, the authorized user verbally changed the treatment time from 24 hours to 23 1/4 hours. Observation of the insert tube at 23 1/4 hours post implant revealed that the plunger and one spacer was gone and one of the 20 millicurie (0.7 GBq)

sources was missing. The two remaining 20 millicurie (0.7 GBq) sources had migrated several centimeters from their originally loaded position. The 30 millicurie (1.1 GBq) source, however, remained in its original position. After an extensive search by the licensee, the missing source was found by the medical physicist inside a trash dumpster near the hospital's loading dock approximately 1.5 hours after the explanation procedure. After wipe tests confirmed the source was not leaking, the source was returned to storage. The plunger and spacer were found in the trash can near the patient's bed.

On December 10, the licensee reported the incident to the NRC Operations Center as a possible misadministration. The licensee informed the referring physician of the possible misadministration on December 10, 1993. Both the authorized user and the referring physician concluded that telling the patient of the incident would worsen the anxiety of the patient who was already depressed by the existing medical problems. Accordingly, the patient was not informed. Subsequent to this decision, the licensee concluded that a misadministration did not occur since the dose delivered to the prescribed point was within 20% of the intended dose. The patient's relatives or guardians were not informed of the incident.

The NRC has requested one of its medical consultants, Judith Stitt, M.D., to evaluate the medical aspects of this incident. The consultant's report will be forwarded to the licensee and the referring physician when it becomes available.

6. Event Evaluation

The licensee's written directive for this treatment was a combination of two documents, the "Sealed Source Request Form" (Attachment 2) and the treatment plan (Attachment 3). The written directive indicated that the authorized user prescribed 2,000 rads (cGy) at 1.2 centimeters or 24 hours. The inspection disclosed that the authorized user marked a simulator film to indicate the location of the prescribed dose. According to the authorized user, the 2,000 rad (cGy) dose was prescribed to a point located nearly 1.2 centimeters lateral to the 30 millicurie (1.1 GBq) cesium-137 source.

The written directive appears to provide conflicting information since a 24 hour treatment time at 80 cGy/hr (the dose rate at 1.2 cm from the 30 millicurie source) gives a dose of 1920 rads (cGy), not 2000 rads (cGy). The inspection confirmed that the authorized user initially intended to have the sources implanted for a 24 hour period. The 80 cGy/hr contour indicated on the treatment plan was used as an approximation for both location and dose. The licensee later calculated the exact dose rate at 1.2 cm lateral to the 30 millicurie (1.1 GBq) source to be 73.1 rads/hr (cGy/hr). On the basis of this calculation, the total dose prescribed for a 24 hour treatment period is 1753 rads (cGy).

On December 9, 1993, the day following the implant procedure, the authorized user contacted the medical physicist and gave verbal orders to change the total treatment time from 24 hours to 23 1/4 hours. The medical physicist noted this change on the patient's treatment plan (see Attachment 3), but the authorized user did not sign or date the revision to the written directive. The footnote to 10 CFR 35.32(a)(1) allows oral revisions only under special circumstances where a delay in the order would jeopardize the patent's health. In this case, the revision apparently was made to coincide with the authorized user's arrival at the hospital. According to the authorized user, he arrived early to see how well the patient was tolerating the treatment. The authorized user stated that he may have left the implant in for the intended 24 hour period, had there not been a problem with the implant apparatus. Neither NRC regulations or the licensee's QMP address verbal changes to written directives when there is no emergency that would jeopardize the patient's health. Nevertheless, revisions to a written directive must be documented and the revised directive must be signed and dated by the authorized user.

Failure to have the authorized user sign and date a revised written directive is an apparent violation of 10 CFR 35.32.

The licensee requested clarification on the requirements pertaining to revising written directives in a letter dated February 2, 1994. This matter has been discussed with the licensee and a written response will be provided in a separate correspondence.

Further review of the written directive indicated the treatment site is noted as a general anatomical site (such as nasopharynx) rather than a specific treatment volume (such as the treatment contours shown on the treatment plan). A review of the licensee's other written directives for brachytherapy also indicated the treatment site as a general anatomical area (such as vaginal or bronchial) rather than a specific treatment volume as indicated on the treatment plan. The NRC is reviewing this issue to determine the specificity required when documenting the treatment site on the written directive. Consequently, this matter is currently unresolved.

During the inspection the authorized user clarified the intent of the treatment plan, indicating that the focus of the treatment was to the nasopharynx at a point 1.2 cm lateral to the 30 millicurie (1.1 GBq) cesium source. However, the authorized user also intended to irradiate the nasal mucosa volume because of lingering disease in that area. The authorized user had no specific dose planned for the nasal mucosa volume, provided it received a dose less than that given to the nasal pharynx.

The NRC inspectors requested the licensee evaluate the likely dose to the prescribed treatment point and to the remaining treatment area (nasal mucosa) in consideration of the dislodged and migrated sources. The 30 millicurie source (1.1 GBq) did not migrate out of its intended position. The licensee assumed that three of the four implanted sources moved when the patient sat up to eat breakfast on December 9, 1994, approximately 16 hours after implantation of the sources. Breakfast was the first meal taken by the patient and it is plausible that the dislodged source was discarded in the dumpster with food waste. This appears to be a reasonable assumption since no materials were removed from the patient's room other than the food trays and the contents of an emesis basin. The medical physicist determined that the dose to the point 1.2 centimeters lateral to the 30 millicurie (1.1 GBq) cesium-137 source for a 23 1/4 hour treatment period to be 1619 rads (cGy), a difference of approximately 8% from the prescribed dose of 1753 rads (cGy) at the same location for a 24 hour period. The medical physicist determined that the most noted difference in the prescribed dose versus the actual dose occurred in the middle of the implant where it is assumed no source resided for a period of approximately 8 hours. In that area, he determined a maximum underdose of approximately 27% (See Attachment 5). The NRC is reviewing these details to determine if a misadministration occurred. Consequently, this matter is currently unresolved.

The inspectors' review of this incident disclosed three main factors that contributed to the temporary loss of the cesium-137 source. These are outlined below:

(1) This was first time the licensee's oncology staff used the ET and insert tube apparatus for performing a nasopharynx implant. The oncology staff, including the authorized user, did not adequately evaluate the implant apparatus to assure all potential safety problems were considered. The ET tube, for example, was opened at both ends and the insert tube containing the cesium-137 sources was only taped to the ET tube. If the tape holding the insert tube had failed, the insert tube containing the cesium-137 sources may have slipped through the ET tube and lodged at other locations in or near the patient's throat. Licensees were alerted to the potential problems associated with use of open-ended catheters in brachytherapy procedures in NRC Information Notice 92-10.

(2) The cesium-137 sources were held in place by a "plunger" that was taped to the insert tube. The medical physicist stated that he wrapped tape around the "plunger" and insert tube two or three times as he usually did for vaginal implants. A few wraps of tape around a insert tube is sufficient for vaginal implants because the insert tube is inserted into an applicator that can be sealed at the end. In this case, however, the tape around the insert tube did not hold and the "plunger," spacer, and a cesium-137

source fell out of the insert tube. After this incident, the medical physicist admitted that to secure the "plunger," he should have taped over the end of the "plunger" and then wrapped tape around the circumference of the insert tube and "plunger."

To prevent similar problems in the future, Bethesda issued a memo to the authorized users requiring that they meet with the medical physicist and the nursing staff to discuss the details and any special safety issues at least one day before an "atypical" implant is performed (see Attachment 1).

(3) Two of the nurses assigned to the patient had not received radiation safety training for brachytherapy patients. Neither were they shown the "normal" appearance of the implant apparatus, which would have enabled them to recognize aberrations or other problems. A third nurse assigned to the patient had received the initial radiation safety training, but had not received the annual refresher training.

10 CFR 35.410 requires the licensee to provide radiation safety instruction to all personnel caring for the patient undergoing implant therapy. The instruction must describe, among other things, the size and appearance of the brachytherapy sources and safe handling and shielding instructions in case of a dislodged source.

Failure of the licensee to provide radiation safety instruction to nurses caring for a brachytherapy patient is an apparent violation of 10 CFR 35.410.

License application dated March 25, 1991, (referenced in License Condition 22A) states that the model program described in Appendix A of NRC Regulatory Guide 10.8, Revision 2, will be followed for training personnel. Appendix A requires, in part, that personnel will be instructed before assuming duties with or in the vicinity of radioactive materials and during annual refresher training.

Failure to annually retrain nurses caring for brachytherapy patients is an apparent violation of License Condition 22.

Subsequent to the incident, the licensee made available to the individual responsible for nursing assignments, a listing of nurses who had had the required radiation safety training. The licensee has also conducted annual retraining of all pertinent nursing staff and will require the authorized user to discuss the physical and medical aspects of an implant with the attending nurse immediately after the placement of the implant. The attending nurse is required to communicate the content of these discussions, especially the appearance of the applicator, to the next shift.

Inspector interviews with one of the nurses who attended to the patient initially after source implantation disclosed that the implant apparatus was intact at 11:00 pm on December 8, 1993. Using the licensee's assumptions based on a worst case scenario, the "plunger" was dislodged from the insert tube some time after 11:00 pm on December 8, 1993 and the 20 millicurie (0.7 GBq) cesium-137 source fell out of the implant apparatus about 9:00 am on December 9, 1993, during the patient's breakfast. The cesium-137 source was "lost" from about 9:00 am on December 9, 1993 to 6:00 pm that evening when it was found in the hospital's trash dumpster.

10 CFR 20.207(b) requires that licensed material in an unrestricted area and not in storage be under constant surveillance and immediate control of the licensee.

Failure to maintain control of the 20 millicurie (0.7 GBq) cesium-137 source is an apparent violation of 10 CFR 20.207(b).

If the nurses caring for the implant patient had been properly trained, they may have discovered that the "plunger" had fallen out of the implant apparatus and this discovery may have prevented the temporary loss of the cesium-137 source. To prevent similar problems in the future, the licensee has developed a list of nurses who have received radiation safety training, and only trained nurses will be assigned to care for brachytherapy patients.

All of the nurses who cared for the implant patient were issued whole body film badges. The nurses' film badges were immediately returned for processing and minimal doses were reported. During a telephone conversation with the medical physicist on February 15, 1994, it was learned that he received extremity doses of 50 and 60 millirem (0.5-0.6 mSv) and a minimal whole body dose. Since the medical physicist spent approximately 30 minutes retrieving the source from the trash dumpster, it is unlikely that any other person received a dose greater than he.

The dose rate from the 20 millicurie (0.7 GBq) source was about 6.5 mr/hr (about 2 micro C/kg/hr) at 1 meter. Since it is assumed that the source was uncontrolled in an unrestricted area from approximately 9:00 am to 6:00 pm on December 9, 1993, the dose rates in unrestricted areas exceeded regulatory limits. 10 CFR 20.105 requires that no licensee allow the creation of radiation levels in unrestricted areas so that an individual who was continuously present in the area could receive a dose in excess of 2 millirems in any one hour or 100 millirem in any seven consecutive days.

Exceeding the allowable radiation levels in an unrestricted area is an apparent violation of 10 CFR 20.105.

Four apparent violations of NRC regulatory requirements were identified.

7. Quality Management Program Review

The inspectors reviewed all conventional brachytherapy files (8 files) from the date the licensee's QMP was implemented on January 13, 1992 to December 8, 1993.

The results of the review indicated that Bethesda followed its QMP, with the exception of several paperwork problems. For example, on January 13, 1992, October 27, 1993, and December 12, 1993, authorized users initialed rather than signed the written directives. The written directives prepared on July 14, 1992, and August 5, 1992, were not dated by the authorized user when these directives were signed. On April 10, 1992, the written directive for a brachytherapy case indicated the time when the sources were to be explanted, rather than the total dose or total treatment time.

10 CFR 35.32(a)(1) requires, in part, that the licensee establish and maintain a written quality management program which must include written policies and procedures to meet the objective that, prior to the administration, a written directive is prepared for any brachytherapy radiation dose. 10 CFR 35.2 defines a written directive as an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, and includes, prior to completion of a brachytherapy procedure, the radioisotope, treatment site, and total source strength and exposure time or total dose. Item 1 in the licensee's quality management program for HDR and other brachytherapy treatments dated January 13, 1991, states, in part, that an authorized user (physician) must sign and date a written directive prior to treatment.

Failure of the authorized users to sign, date, and include the total dose or exposure time on the written directive is an apparent violation of 10 CFR 35.32(a)(1).

Bethesda performed audits of its QMP in December 1992 and December 1993, but the medical physicist admitted that the review did not include a detailed audit of the dates and signatures of the authorized users.

The dosimetrist was interviewed concerning QMP training and methods of identifying the patients. The dosimetrist recalled receiving training on the QMP when it was implemented in January 1992. The dosimetrist explained that she identified patients by more than one method, such as asking the patient's name, checking the identification wrist band, social security number, or patient's picture. The dosimetrist also explained that she asked the authorized user to clarify a written directive when she did not understand it.

One apparent violation of NRC regulatory requirements was identified.

8. Other Areas Inspected

A routine inspection of the licensee's Nucletron Micro Selectron-HDR remote afterloading brachytherapy device was also performed. The areas inspected included a selective review of training, QMP implementation, facilities, equipment, HDR operation, maintenance, instrument calibration, operational and emergency procedures, radiation protection, and waste disposal. The review of this area identified one violation for failure to check the operability of survey instrumentation on a daily basis with a check source.

The licensee uses a Victoreen 471 (Serial 1202) ion chamber to perform final surveys of the patient after the HDR treatment is completed. The medical physicist checks the ion chamber for proper operation quarterly rather than daily as required by 10 CFR 35.51(c). During the inspection, the medical physicist committed to performing daily operational checks of the ion chamber.

Failure to check each survey instrument for proper operation with a dedicated check source each day of use is an apparent violation of 10 CFR 35.51(c).

One apparent violation of NRC regulatory requirements was identified.

9. Exit Meeting

An exit meeting was held on January 28, 1994, with the individuals listed in Section 1 of this report. The inspectors summarized the inspection findings which included a review of the incident and its root causes and the apparent violations. The inspectors also explained the NRC's enforcement options. During a telephone discussion on February 15, 1994, the medical physicist indicated that no proprietary information had been given to the inspectors.

Attachments:
1. Licensee Incident Report
2. Sealed Source Request Form
3. Treatment Plan
4. Sketch of Insert Tube and Sealed Sources
5. Reconfigured Treatment Plans

Bethesda ATTACHMENT 1

December 22, 1993

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
799 Roosevelt Road
Glen Ellyn, IL 60137

RE: LICENSE #34 10921 03

Gentlemen:

On December 9, 1993 an incident occurred in which a Cs-137 source was lost and subsequently recovered. Attached is a description of the events and circumstances.

In the event that this incident might be classified as a misadministration, we reported the incident by phone the following day and are now filing this report. However, as we more carefully examine the definition of misadministration and the circumstances of this incident, we doubt that a misadministration occurred. We cite four reasons:

1. Part of a Multiple Treatment Regimen.

   This patient had received 7440 cGy to this site by external beam radiation from March to June 1992. When the tumor recurred, a series of three HDR treatments to the nasopharynx were planned beginning in May 1993. The progress notes recorded in the patient's chart at that time, make it clear that a fourth or even a fifth treatment might be required after completion of the first three. The possibility of additional treatments is repeatedly mentioned in subsequent progress notes. Accordingly, we view this fourth brachytherapy treatment to the nasopharynx as part of a regimen in which 3100 cGy was delivered in the first three treatments, 1750 cGy was prescribed for the fourth, and a fifth treatment remains a possibility.

   It should be noted that even if all four sources had fallen out at breakfast 9:00am on December 9, the dose delivered in the fourth treatment would be reduced 600 cGy (34%) compared to the prescribed 1750. But this amounts to only 12% of the 3100 + 1750 = 4850 planned for the four treatment regimen. If taken as part of a multi-treatment regimen, it would appear that there was no misadministration, especially since only one source fell out.

2. Prescription Point

We believe the dose actually delivered in the fourth treatment was within 8% of the dose prescribed for that treatment. So, even if the fourth treatment is not viewed as part of a multi-treatment regimen, the dose error would be less than the 20% which constitutes a misadministration.

The treatment plan developed for this source loading revealed a dose rate of 80 cGy/hr at a point nearly 1.2cm lateral to the most distal source. This was the calculation point identified by the physician on the simulation film. The physician wrote "2000 cGy at 1.2cm or 24 hours".

This written directive seems inconsistent. A 24 hour treatment at 80 cGy/hr suggests 80 x 24 = 1920 cGy, not 2000 cGy. But it was clear from the physician's discussion with the physicist when the directive was written, that the intent was to leave the implant in 24 hours. The 80 cGy/hr contour was being used as an approximation, for both location and dose.

Accordingly, to evaluate the possibility of a misadministration, the dose has been calculated for a 24 hour implant at a point 1.2 cm lateral to the most distal source. The dose rate at exactly 1.2 cm is found to be 73.1 cGy/hr (see TECHNICAL NOTES). So the dose specified by a 24 hour implant becomes 73.1 x 24 = 1750 cGy.

The following day, the physician called to say that he wanted to remove the implant early, at 4:30pm instead of 5:15pm. Accordingly, we reported a "revised prescription" of 23.25 hours in our early discussions with the NRC. We also recorded this verbal order in the patient's chart, since this was clearly the intent of the physician. But since a "written revision" signed by the physician was not obtained prior to the removal of the implant, the NRC may not consider this revision valid. Accordingly, for consideration of a misadministration, we have computed the dose error relative to the originally prescribed 24 hour treatment of 1750 rad. The early removal at 4:30 is considered an "error," inspite of being directed by the prescribing physician and recorded as such.

The calculations described in the TECHNICAL NOTES shows that the dose to the prescription point is reduced at most 8% with the loss of the proximal source at 9:00am, and the subsequent redistribution of the remaining three sources at that time. This is the only dose calculation point described in the written directive. Since the error in the delivered dose to this point is less than 20%, this does not seem to be a misadministration.

3. Premature Source Removal.

The definition of misadministration states that a temporary implant not removed upon completion of the procedure constitutes a misadministration. But the definition says nothing about a source inadvertently removed too early, perhaps because of the opportunity to provide subsequent treatment to compensate for the early removal. We are considering such supplemental treatment and could easily deliver it if judged appropriate. Accordingly early removal, whether by accident or intent, does not seem to constitute a misadministration.

4. Source Migration

The definition of misadministration states that sources of a permanent implant are permitted to migrate in an unplanned fashion. But there are no limits specified for the unplanned movement of a temporary implant. This migration, by itself, does not seem to constitute a misadministration. If the migration caused the wrong anatomical site to be treated, a misadministration might result. But in this case, the planned source placement extended from the prescription point to a point 2 cm from the tip of the nose. As sources migrated proximally, they left both the target volume and the body. No other tissues were treated as a result of the source migration.

We are determine that nothing like this should happen again, so regardless of the NRC's classification of this incident we are taking the corrective action described in the attached report. Please advise us regarding the issue of misadministration.

Sincerely,

Ronald T. Droege

Ronald T. Droege, Ph.D.
Physicist

cc John Leibold, M.D. (RSO)
John Dickey, V.P.
Kenneth Murdock, M.D.
Pearl Compaan, M.D.

Attachment

INCIDENT REPORT EVENTS AND CIRCUMSTANCES
Bethesda Oak Hospital
December 9, 1993

Prescribing Physician: Kenneth Murdock, M.D.

Description of the Event.

12 noon to 4 pm, December 8: In surgery the patient had an endo-tracheal (ET) tube inserted through the nose into the nasal cavity and suctured in place. Subsequent to recovery the patient had both CT and X ray simulation exams to plan the treatment for the nasopharynx. Four Cs-137 sources were prescribed, having nominal activities of 15, 10, 10, 10 mgRaEq with actual decayed activities of 12, 8, 8, 8 mgRaEq.

4:30 pm, December 8: The physicist loaded the prescribed four Cs-137 sources (2.1 cm long) with three spacers into a plastic "insert" tube 26 cm long. They were held at the distal end of the insert tube by a 16 cm "pusher." A piece of tape was placed over the end of the insert to hold the pusher and the sources in the insert. Sources were transported to the floor at 5:00 pm.

5:15 pm, December 8: The prescribing physician placed the insert into the ET tube, with 6 cm of the insert's taped end extending beyond the proximal end of the ET tube. Tape was used to secure the insert to the ET tube. Post implant surveys showed the exposure rate at bedside (0.5 meters) to be 50 mR/hr, and at the foot of the bed (2 meters) to be 8 mR/hr, consistent with expectations for this four source implant.

4:00 pm, December 9. The physician called to say he was on his way to the hospital, and he wanted to take the implant out at 4:30. The dosimetrist and physician arrived at the patient room at 4:30 pm to remove the insert. The dosimetrist noticed that the pusher was not present. A source count revealed that one of the four sources was missing. A survey of the room, trash, toilet, and other areas on the patient floor failed to detect the missing source. The pusher and one of the spacers was found in the patient's trash can, evidence that trash had not been emptied in accordance with safety instructions.

4:30 to 5:15 pm, December 9. Nursing personel were interviewed. The physicist was called at home (4:45 pm). An attempt was made to call the RSO, but he was unable to be reached. Since only food trays had left the room, security was notified to restrict access to the hospital dumpster. Since a nurse reported the patient spit up into an emesis basin which had been rinsed in the patient's bathroom, maintenance personnel were notified that access to the sanitation system might be required.

5:15 to 6:00 pm, December 9. A second search of the room and floor was conducted by the physicist while the dosimetrist returned the other three Cs-137 sources to storage. The search proceeded to the cafeteria and then to the trash dumpster at the loading dock. At 6 pm, a radiation reading indicated the source to be present about 2.5 feet from the end of the dumpster. A lead pig, gloves and additional survey meters were obtained while security restricted access to the area.

6:35 pm, December 9. The source was isolated from the trash loaded in the storage pig, and returned to storage at 6:45 pm.

December 10. The invesigation continued and management was briefed. The NRC was notified.

December 13. A Wipe test revealed no removable contamination on the source retrieved from the trash dumpster.

Why the Event Occurred - Improvements to Prevent Recurence.

1. Planning. This was the first implant of its kind at our institution. Previously, Cs-137 "tube" sources had always been used in gynological implants where the sources were double sealed. In addition to the tape at the end of the insert, the insert for GYN implants is placed in a metal "tandem" sealed with a threaded end cap. This was the first time a plastic insert with Cs-137 tube sources was placed in anything but a metal tandem with end cap In hindsight, the small piece of tape at the end of the insert should have been supplemented with additional tape.

Corrective Action. For any atypicaly implant the prescribing physician must meet with the physicist and nursing stall at least one day prior to the implant to discuss details of the implant and any special safety issues. An atypical implant is defined as:

1. First use of an applicator.
2. First use of an applicator in a non standard placement, or with sources not previously used with that applicator.

2. Food Trays. We previously restricted food trays only for certain types of implants. We had not restricted tray removal for Cs-137 implants because source escape and subsequent deposition on a food tray was considered virtually impossible for a GYN implant. But for this first non-GYN implant with Cs-137, the very real possiblilty of source escape to a food tray was not recognized.

Corrective Action. Regardless of the type of implant food trays will not be permitted to leave the patient's room until they have been surveyed by the physicist or dosimetrist. In most instances "isolation" trays which use disposable materials will be used. These will be emptied into trash bags in the patient's room, to be removed daily only by the physicist or dosimetrist.

3. Nursing Instruction. This patient was heavily sedated, and did not have full control over movements which might have dislodged either the applicator or the sources Had periodic monitoring of the implant's integrity been performed, it is likely the dislodged pusher and expelled source could have been detected earlier.

Corrective Action. We now require that the physician discuss the physical and medical aspects of the implant with the attending nurse immediatly after placement of the the implant. The attending nurse is required to communicate the content of these discussions especially the appearance of the applicator, to the next shift. Special instructions such as monitoring frequency must be specified in writing by the physician.

4. Nurse Assignment. We perviously performed all implants on 6 South, a nursing unit with numerous trained nurses Six months ago, we moved this

service to 1-West. The mixture of trained and untrained nurses lead to a misassignment of nursing personnel. The first nurse who attended the patient from 5:15 pm to 11:30 pm was a trained nurse originally from 6-South. Interviews with this nurse, conducted by both Bethesda and the NRC, demonstrated the adequacy of this training. But the two nurses assigned to the patient overnight and the following morning, were not originally from 6-South, and had received no recent training.

Corrective Action. The list of recently trained nurses will be made available to the resource nurse responsible for nursing assignments. Before a nurse is assigned to a brachytherapy patient, the resource nurse must verify that the nurse's name appears on the list.

Effect on the Patient.

At the distal end of the implant the dose reduction is so minimal as to be inconsequential. Lateral to the more proximal portions of the implant, the dose reduction is greater depending on the assumed source migration. But considering the previous radiation to this site, and the potential for compensatory additional radiation, the effect at the more proximal portions is minimal. Normal adjacent tissues received no extra dose since source migration out of the target volume resulted in migration out of the body.

The refering physician was notified December 10. Both he and the prescribing physician felt that telling the patient of this incident would only worsen the anxiety of this patient already depressed by her multiple medical problems, and would have no bearing on her ultimate prognosis. Accordingly, they decided not to inform the patient.

Personnel and Public Exposures.

The exposure rate at 1 meter from the dislodged 8 mgRaEq source is 6.6 mR/hr. The physicist spent about 30 minutes at a average 0.5 meters from the source during the search through the dumpster. The resulting whole body exposure is estimated to be less than 20 mR Hand exposure resulting from the search (20 minutes at 0.5 meters, 10 min at 10 cm, 5 sec at 1 cm) is estimated to be about 200 mR. Both body and finger badges were worn, so better estimates will be available after the badges are processed.

The person who collected food trays is likely to have spent less time than the physicist in close proximity to the source. So that person's exposure is expected to be no greater than the physisict's.

The person who cleared food scraps from the trays in the cafeteria, is estimated to have stood about 0.5 meters from the source once it was inadvertantly scraped into the trash can. If the source entered the can when it was nearly empty, and the can required one full hour of scraping trays to become full, it is estimated that the most this worker would receive is twice the physicist's exposure, i.e., less than 40 mR whole body exposure.

The film badges for the attending nurses were returned for analysis immediately after the incident. All readings were below the 10 mR threshold for a film badge reading.

TECNICAL NOTES

1. Localization "Error."

The NRC should take note of the rapid fall off of dose with distance in brachytherapy implants. The dose rate at exactly 12 mm lateral to the distal source of this implant was 73 cGy/hr. When both the source position and calculation points are entered by touching these locations with a sonic digitizer, localization errors of +/- 0.5 mm are typical. These errors are clinically inconsequential and common to all treatment planning hardware. The result of a 0.5 mm digitization "error" for this implant is a dose increase to 78 Gy/hr at 11.5 mm. This accounts for the approximate nature of the written directive. It was based on a treatment plan in which source entry was performed using a sonic digitizer. The 80 Gy/hr was recognized to be approximate, but sufficently close to the prescription point to permit the implant duration to be determined to be 24 hours.

2. Redistribution.

All evidence suggests that the source left the patient's room via a food tray. The patient refused a tray the evening of December 8, and the evening shift nurse reported the implant intact at about 11:00 pm. The first meal was served approximately 9:00 am December 9, so in a worst case senerio, it is assumed that the source was dislodged at that time.

The most distal souce is assumed to have stayed in place for the duration of the treatment. Due to a slight kink near the end of the plastic insert, the dosimetrist found it difficult to dislodge the source from this position in the insert when she returned the soures to storage.

The positions of the other two sources from 9:00 am till the 4:30 pm explant time can only be estimated. But the dosimetrist upon entering the patient's room, noticed the tip of the insert tube to be grey (the color of a source) instead of white (the color of the pusher). When the patient lay back for removal of the insert, the source slid distally out of sight. In a worst case senerio, we have assumed that one of the two "movable" sources resided at the end of the insert tube, outside the nose from 9 am till 4:30 pm. The other source is assumed to have resided, on average, 4 cm from its original position, 2 cm inside the nose.

The first 15.75 hours of the treatment, with the sources in the original positions, produce a dose to the prescription point of 15.75 hr x 73 cGy/hr = 1150 cGy. When the sources were redistributed as described above, the dose rate dropped to 62.4 cGy/hr. So the final 7.5 hours of the implant produced a dose of 62.4 x 7.5 = 470 cGy. The total dose to the prescription point is therefore estimated to be 1620 cGy, a reduction of 130 cGy from the prescribed 1750 (24 hr x 73 cGy/hr = 1750). This is an error of less than 8% relative to the dose prescribed for 24 hours. We argue that the 24 hour time period is the critical element of the "2000 cGy at 1.2 cm or 24 hours" written directive. However, even if 2000 cGy is considered to be the prescribed dose, the 1620 cGy actually delivered to the prescription point is within 19% of 2000 cGy. So, even by that measure, and ignoring the other three treatments of the regimen, there would appear to be no misadministration.

ATTACHMENT 2

ITEM #1: SEALED SOURCE REQUEST FORM

Request Received: Date_____ By_____

Insertion Scheduled: yes or no

Date 12/8/93 Time_____

Patient_____

~~Diagnosis~~ Nasopharynx

Type of Instruments Requested:

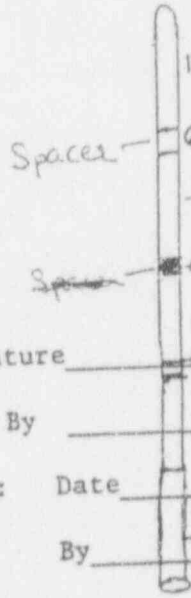
Fletcher_____ Del Clos_____ Simons_____

Del Clos Dome_____ Needles_____

Type of Sources required:

192 Ir_____ 137 Cs ✓ 125 I_____ Other_____

Loading:



Physician's Signature KM

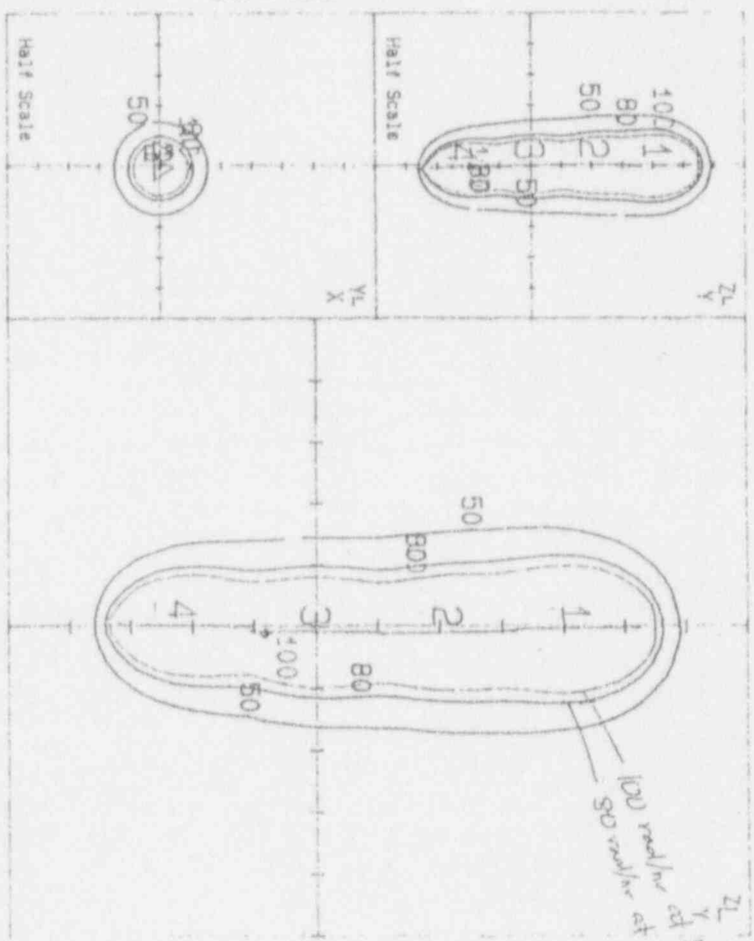
Sources Prepared By RD.

Returned to Safe: Date_____ Time_____

By_____

ATTACHMENT 3

SLICE NO. 1 OFFSET 0.0



Isodoses
100
80
50

OK/
Deliver 2000 cGy at ~1.2 cm in 24 hr.

ORIGINAL WRITTEN DIRECTIVE

ORAL REVISION

Prescription revised to remove sources at 4:30 pm (23 1/4 hr) instead of 24 hr. Verbal order 12-9-93

TITLE	TYPE	UNIT	SSD	100%	WIDE	LONG	GNTRY	COLLM	STRT-STOP	X	Y	Z	WDG	BAR	WEIGHT	TAR
	IMP. TUBE	CS-137			ANGLES		0	0	0	0.0	0.0	0.0	TIME:			1.0 HOURS

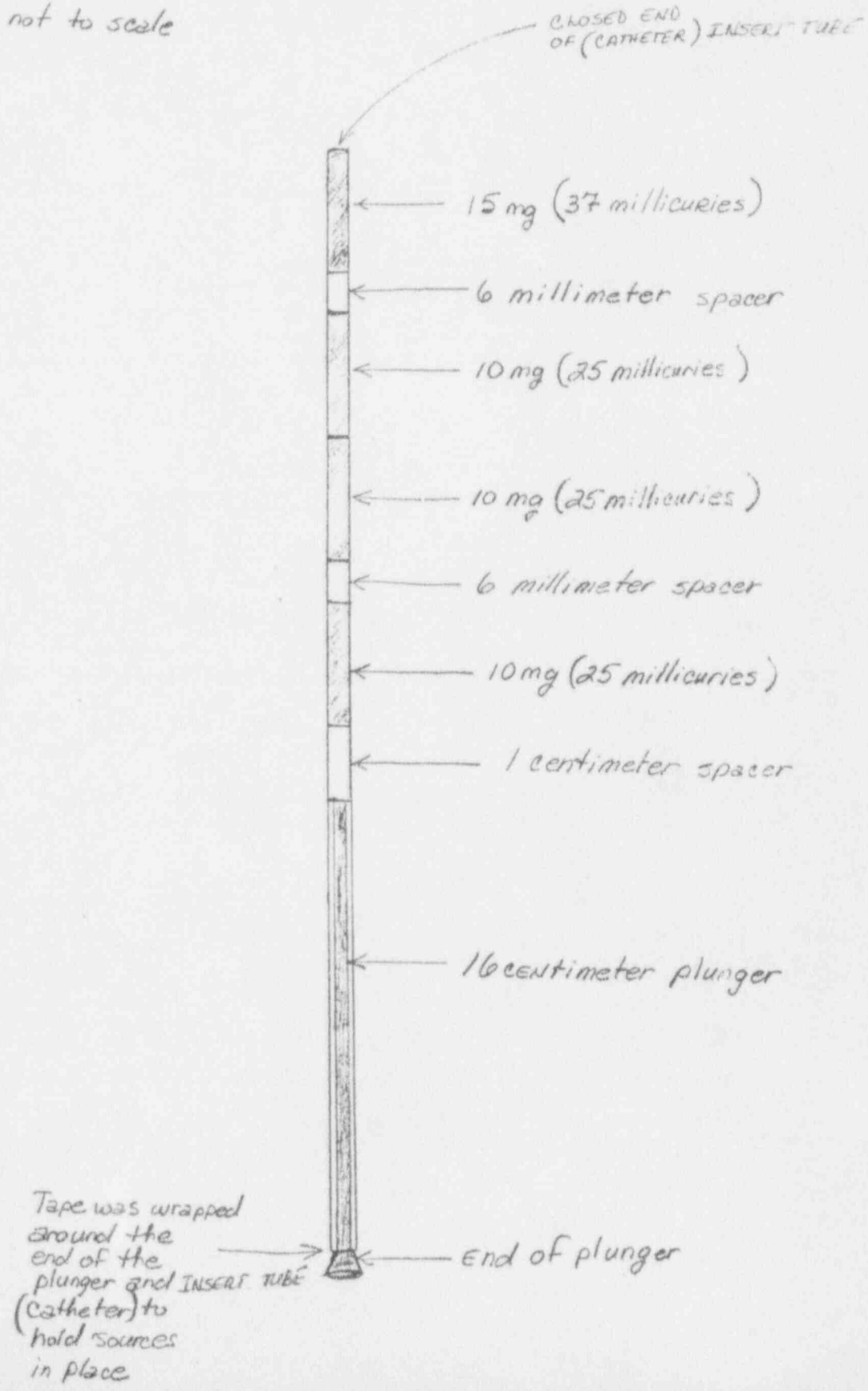
x: 20000 80000 %) at X= 0.1 Y= -0.8 100%= 100

ATTACHMENT 4

ALL SOURCES WERE CESIUM-137

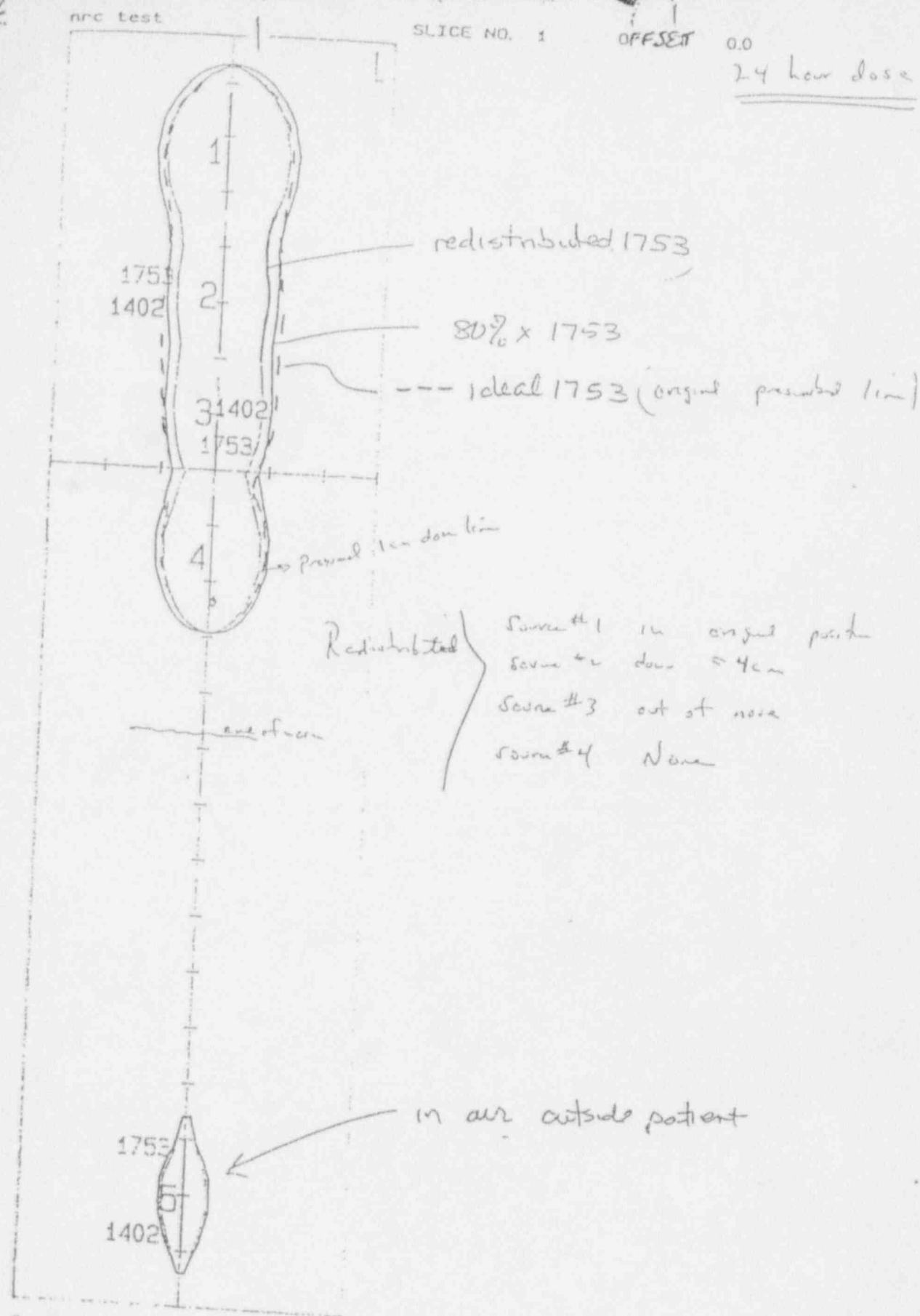
ALL SOURCE STRENGTHS ARE NOMINAL ACTIVITIES

DRAWING IS NOT TO SCALE



ATTACHMENT 5

Reconfigured treatment plans - assuming loss of one source (4) and repositioning of sources # 2 and 3.


nrc test
SLICE NO. 1
OFFSET 0.0
24 hour dose
1
redistributed 1753
1753
1402
2
80% x 1753
--- ideal 1753 (original prescribed line)
3
1402
1753
4
Prescribed 1cm dose line
Redistributed
Source #1 in original position
Source #2 down 4cm
Source #3 out of room
Source #4 None
end of room
in air outside patient
1753
5
1402
Scale = 1.00 : 1
12:42 16-DEC-93
PLANNER

	Ideal (24 hr)	First 15.75 hr	Next 7.5 hr	Total 15.75 + Next 7.5	Change from Ideal
Prescript 1.2cm	1753 rad *	1151 rad	468 rad	1619 rad	-8%
Middle row	1874	1230	85	1315	-30%
Proximal row	1640	1076	431	1507	-8%
Prescription (Planned 1/2 mm)	1868 (+6.5%)	1226	503	1729	-7%

* Prescribed 1750 at 1.2 cm (24 hr) exactly

Dec 16, 1993

[redacted] (Summary Cs-137)

Ideal implant, left for 24 hr would have resulted in 1753 rad at 1.2cm from sources. The prescription change (verbal order) to 23¼ hr would result in 1700 rad.

But due to the dislodged source, it is estimated that only 1619 rad was actually delivered to this point, 5% lower than revised prescription. Along the full length of the implant the dose reduction (at 1cm from the sources) was comparable, except where no source was assumed to reside (-30%). But in consideration of other earlier fractions via HDR, (3100 rad), the 5% reduction at "middle" (1874 → 1315 rad) is only $\frac{55}{3100}$ = 1.6%

Patient Dosimetry

Note total mg·hr

Prescribed 8+8+8+12 for 24 hr = 864 mg·hr
Revised to 23¼ hr → 837 mg·hr

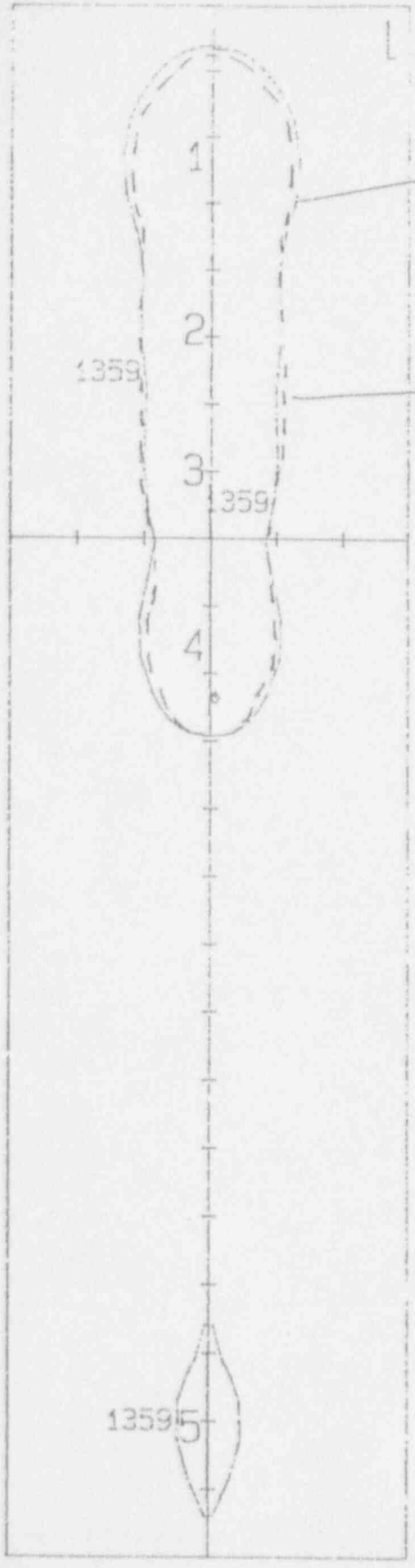
Delivered (8+8+8+12)(15¾ hr)
+ (8+8+12)(7½ hr) = ~~777~~ 717 mg·hr

Delivered is ~~10%~~ 17% below original prescribed
~~14%~~ 14% below revised prescription

Since dose varies ≈ 1/r from a line source at r = 1 cm, a ≈15% reduction corresponds to a ≈1½ mm shift in the treatment contour from 10 mm to 15 mm from the sources. This assumes a "uniform" loss of activity. If some sources "stay put" – no shift at those locations, but ≈3 mm shift where source "lost".

23.25 hour dose

nrc test SLICE NO. 1 OFFSET 0.0



actual 80% (——) 80% × 1699 = 1359
is "outside" ideal everywhere except for a short length near the middle of the implant

ideal (- - - -) 1699 at 1.2 cm

Scale = 1.00 : 1 13:09 27-JAN-94 PLANNER _____ APPR

	Ideal 23¼ hr	actual 1st 15.75hr	actual last 7.5hr	Total Actual 23¼hr	Actual − Ideal ×100%
Prescription Point (1.2cm)	1699	1151	468	1619	−5%
Middle of Implant (1.2cm)	1489	1008	83	1091	−27%

Ideal implant, 23¼ hours, would result in 1699 rad. But due to dislodged source & subsequent redistribution, the prescription point received 1619, a 5% reduction.

By comparison, near the middle of the implant, the dose would have been 1489 if the ideal implant had remained intact. But a 27% reduction resulted due to the source dislodged.