U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-14033/85001(DRSS)

Docket No. 030-14033

License No. 34-00855-07 Category G Priority III

Licensee: Jewish Hospital
3200 Burnet Avenue
Cincinnati, Ohio 45229

Inspection Conducted: July 15, 1985

Inspector: S. R. Lasuk S. R. Lasuk 8-6-85
Date

Reviewed By: D. J. Sreniawski, Chief D J Sreniawski 8/8/85
Nuclear Materials Safety Date
Section 2

Approved By: W. L. Axelson, Chief W. L. Axelson for 8-12-85
Nuclear Materials Safety Date
and Safeguards Branch

Inspection Summary

Inspection on July 15, 1985 (Report No. 030-14033/85001(DRSS))
Areas Inspected: This was an announced special inspection conducted to review the circumstances surrounding a reported unintended exposure of a brachytherapy patient to radiation following the removal of an implant on April 29, 1985.
Results: One violation (overpossession of Group VI sources - Section 7) was identified. No apparent violations were identified in regard to the exposure incident.

DETAILS

1. Persons Contacted

*Paul A. Feller, Ph.D., Director, Physics Services and Radiation Safety Officer
Archie Fine, M.D., Authorized User

*Denotes individual present at exit interview on July 15, 1985.

2. Purpose of Inspection

This was a special inspection to review the circumstances surrounding an exposure of a brachytherapy patient to radiation from a cesium-137 sealed source which was found in her bed following the removal of an implant on April 29, 1985.

This incident was reported to the NRC-Region III office by telephone on April 30, 1985, and was documented in the licensee's followup report dated May 3, 1985 (copy attached).

3. Organization

Warren Falberg, Chief Executive Officer
Michael Coler, Senior Vice President, Administration
Patricia Schoenung, Administrative Director, Oncology
Harry Horwitz, M.D., Medical Director, Radiation Therapy

At the time of this incident, thirteen physicians were listed on the latest license amendment (No. 7, issued April 24, 1985) as being authorized to use Group VI (brachytherapy) sealed sources. However, only four of the 13 M.D.'s are most likely to perform brachytherapy procedures (Drs. Fine, Levy, Horwitz, and Murdock); 3 M.D.'s do 1-2 implants per year, four have done no implants for over a year, and two are no longer with the hospital.

The licensee has averaged six implants per month over the past couple of years.

The services of two physicists, Dr. Feller and Mr. Kent Krugh, were available to the Oncology Department.

4. Licensed Program and Inspection History

License No. 34-00855-07 was issued on April 4, 1979 to the Jewish Hospital Association, Department of Radiology, for possession and use of Group VI sealed sources only, with a total possession limit of one curie. The license is currently being reviewed for renewal and, at the time of the incident, authorized Groups I-VI, xenon-133, gadolinium-153, and other materials for in-vitro studies.

This license was inspected by the NRC twice since it was issued, on May 12, 1981 and June 14, 1984; one violation was identified in 1981 and two violations in 1984.

5. Radiological Protection Procedures

The licensee' letter dated October 16, 1981, which is referenced in License Condition No. 16, includes a section entitled, "Use of Brachytherapy Sources (Ra 226, Cs 137)." In item 4, under Responsibility of Radiotherapist, it states, "When sources are removed from patient, the radiation therapist or designate shall personally see that a source count and a radiation survey are performed on the patient before discharge. The radiation therapist shall also personally see that the sources are returned to designated safe storage area (the technologist may assist therapist by receiving sources and returning sources immediately to safe storage area)."

6. Review of Incident

Cesium-137 brachytherapy sources were used to treat a 56 year old female inpatient for Adenocarcinoma of Endometrium. The six cesium-137 sources, totaling approximately 224 millicuries (89.6 mg. Ra. eq.), were implanted at 6:00 p.m. on April 26, 1985 by one of the authorized radiotherapists. The implant, which was to deliver an average dose of 5,000 rads to the treatment area within the uterine wall, was scheduled for removal during the morning of April 29, 1985.

The radiotherapist removed the implant shortly after 8:00 a.m. on April 29 and placed the material in a lead container (which was brought into the patient's room earlier by a physicist, along with a survey meter). He failed to notice that one of the sources dropped out of its hinged bucket holder and into the patient's bed. The radiotherapist left the room and the physicist came in shortly thereafter to perform the required radiation survey and to account for all the sources. When he obtained a higher than expected radiation reading near the patient, the physicist checked the lead container and saw that one source was missing. The physicist and another radiotherapist subsequently removed the source from the bed and placed it in the lead container.

Based on the location of the source (35.8 millicuries) when it was retrieved and, an estimated time of 35 to 40 minutes that it could have been in contact with the patient, the licensee estimated (using their treatment planning computer) a maximum dose of 450 to 500 rads to a small area of the patient's skin in the buttock/perineum region.

The patient was checked two days after this incident and there were no visible effects in the exposed area.

The RSO has discussed this matter with the physicians named in Section 3 of this report, one of which was the treating radiotherapist, and with the physicist. Since they consider this a highly unusual and unexpected occurrence, no changes in their procedures are being considered at this

time. However, a copy of Dr. Feller's attached report was forwarded to these individual's to remind them of the normal (unwritten) procedure at this hospital regarding the removal of implants. That is, if a radiotherapist is going to work alone, he/she is responsible for all activities, including the radiation surveys and source accountability.

Dr. Fine, who has been associated with this hospital for 50 years and does about 50% of the implants, stated that he never heard of such an incident occurring in the past. He added that the patient had a total hysterectomy within 72 hours after removal of the implant.

No apparent violation of NRC requirements was identified as a result of the incident. However, Dr. Feller was advised to have the information in his report forwarded to all physicians who may be involved in brachytherapy procedures under this license.

7. Material Inventory and Leak Tests

The licensee's Brachytherapy Source Inventory records dated March 12, 1985 and June 7, 1985, show that they possessed, on each of those dates, 70 cesium-137 sources with a combined activity of 1,923.8 millicuries. This is a violation of License Item 8.E., which shows that the maximum amount the licensee may possess at any one time is 1 curie total for all byproduct material sources listed in Group VI of Schedule A, Section 35.100 of 10 CFR 35.

The licensee submitted a timely renewal application for this license; however, licensing action was not completed as yet. The application requested authorization for 3 curies of Group VI sources. Therefore, Dr. Feller contacted the Chief of the Region III Licensing Section during the inspection to discuss the overpossession and necessary corrective action. He was informed that the renewal amendment would be issued as soon as possible, which will correct this violation.

All of the above brachytherapy sources were leak tested on March 21, 1985. The results showed no removable activity above the 0.005 microcurie limit.

8. Exit Interview

The inspector met with Dr. Feller during the late afternoon of July 15, 1985, to review the findings of this inspection. The one apparent violation was discussed plus the probability that no response to this item will be required since the licensee had already submitted an application calling for a higher Group VI possession limit.

During a discussion of the skin dose due to the incident and the probable dose to the surface of the uterine wall due to the implant, Dr. Feller said he would perform a computer calculation of the latter dose and send the results to the inspector.

Dr. Feller voiced his displeasure, once again, regarding Region III's reaction to this incident, especially the onsite inspection, which has caused him to spend more time than he believes is warranted on this relatively minor matter. He believes this reaction has a negative effect on licensees in regard to the reporting of incidents.

9. Subsequent Correspondence

In a followup letter dated July 19, 1985, Dr. Feller submitted the computer calculation results, the steps he has taken to avoid a repetition of the incident, and comments on Region III's reaction to the incident. A copy of his letter has been added as an attachment to this report.

Attachments:
A. Incident Report, P. A. Feller to D. J. Sreniawski, May 3, 1985
B. Letter, P. A. Feller to D. J. Sreniawski, July 19, 1985

May 3,. 1985

Mr. Donald J. Sreniawski
Office of Inspection and Enforcement
Region III
U.S. Nuclear Regulatory Commission
799 Roosevelt Road
Glen Ellyn, Illinois 60137

SUBJECT: Unintended Exposure of a Brachytherapy Patient to Radiation

LICENSEE: The Jewish Hospital

LICENSE: #34-00855-07

Dear Mr. Sreniawski:

In accordance with 10CFR20.405 and as a result of conversations with John Madera and Bill Axelson of NRC Region III, I am reporting an unintended exposure of a brachytherapy patient to radiation from a Cs-137 tube source (activity = 14 mg. Ra. eq., 35.8 mCi; total length = 2.0 cm.; active length = 1.5 cm.; diameter 0.3 cm.).

The patient was completing a 62-hour gynecological implant consisting of 6 Cs-137 tube sources having a combined activity of 89.6 mg. Ra. eq. The implant was designed to deliver an average dose of 5000 rads to a depth of 1.5 cm. in the uterine wall. Following our usual procedures, a representative of the Radiation Safety Office was to meet the radiation therapist in the patient's room at 8 A.M. on April 29, 1985 to remove the implant.

A radiation physicist arrived at the patient's room at 7:55 A.M. with survey meter and other appropriate instruments. The radiation therapist was temporarily detained at another site, and after approximately 15 minutes the physicist left the patient's room for a short time. The radiation therapist arrived at approximately 8:20. He proceeded to remove the sources and the afterloading source containers from the patient and placed them in the lead pig. Having completed the removal of the implant, the therapist exited the patient room in order to enter a physician's note into the patient's chart. Approximately 10 minutes later the physicist returned and performed a radiation survey of the patient and obtained initial readings of approximately 10 to 25 mR per hour near her pelvic region. He then took the lead pig containing the sources out of the room and examined the source containers. He discovered that one of the bucket holders for the colpostats was empty. He returned to the patient's room and informed her that one of the sources was apparently somewhere in her bed. He pulled back the blanket and sheet to see if the source was readily visible, but it was not. By this time the radiation therapist had left the floor and the Department. The physicist paged a second therapist for assistance (he felt that a physician should be present during any further search of the patient's bed linens or bed clothes). The patient was subsequently rolled onto her right side, at which time

the source was visible on the bed near the buttock/perineum region. The source was retrieved with a long-handled forceps and placed in the lead pig. The patient was surveyed again, this time yielding a background reading. The procedure was completed at approximately 8:55 A.M. Thus, the maximum time that the source could have been in the bed under the patient was 35 to 40 minutes.

The treatment planning computer at The Jewish Hospital was used to obtain an estimate of radiation dose to the patient from this source. On the attached sheet are plotted isodose lines in rads around a tube source of Cs-137 having a source strength of 14 mg. Ra. eq. and left in place for 40 minutes. Conservatively assuming that the source touched the same point on the patient's skin for the entire 40 minutes, I estimate a maximum skin dose to the surface of between 450 and 500 rads. As seen from the isodose curves, the dose rapidly decreases to 75 or 80 rads at 1 cm. from the source. The dose is reduced to approximately 5 rads at 4 cm., and 1 rad at just over 8 cm. from the source. An 8 cm. distance from the position at which the source was found would extend inferiorly to approximately mid-thigh and superiorly to the approximate position of the prescribed implant. The dose at this point is a negligible percentage of the prescribed dose. It is doubtful a skin dose of 450 to 500 rads will cause perceptible erythema to the skin surface. However, the patient is scheduled to be in the hospital for several more days, and the radiation therapist will check the patient for any observable reaction during that period.

The radiation therapist who performed the implant and the therapist who assisted in the source retrieval each wrote an explanation of the incident in the patient's chart. In addition, the referring physician was informed by telephone on April 30, 1985.

From the time that the incident was reported to me, I questioned whether the situation warranted notification of the NRC. Regulation 10CFR20.403 specifies dose action levels which relate to the whole body, the skin of the whole body, or extremities. While a skin dose of 450 to 500 rads may have occurred, this dose was confined to an area of one or two square centimeters. Furthermore, only tissues within a radius of 4 cm. from the source received a dose greater than 5 rads, and at this location the exposed volume consists primarily of fatty tissue. In addition, proper radiation safety procedures were followed within a reasonable amount of time, enabling us to locate the source before any serious complications could arise. Nevertheless, since the requirements are nebulous for this situation, I called the Region III office on April 29 for an interpretation, and was asked to file a written report.

Although proper procedures were followed in accordance with our license, nevertheless, all personnel involved in the incident realize we can make some improvements in our routines. It is normal procedure at The Jewish Hospital that either (a) a radiation therapist personally removes the sources, performs the radiation safety survey and returns the sources to the brachytherapy room; or (b) a trained member of the radiation safety staff accompanies the radiation therapist to the patient's room, performs the radiation survey immediately after source removal and subsequently takes charge of the radiation sources, returning them to the brachytherapy safe. The radiation therapists will be reminded that if a representative of the radiation safety office is not present at the scheduled time of a source removal, the therapist should either (a) remove the sources and perform the radiation survey immediately themselves, or (b) contact the radiation safety office and wait for a representative to arrive before removing the sources. Radiation safety personnel will be instructed to leave word at the nursing station as to how they can be contacted if they leave the patient area before the radiation therapist arrives. In addition, the therapist suggested a bit of sticky wax on the colpostat bucket

would help prevent the source from falling out of the bucket during removal from the colpostat. This idea will be investigated as well.

The Jewish Hospital's policies and procedures for radiation safety in brachytherapy procedures are quite thorough. In this case those procedures were carried out properly, in accord with our license requirements and in such a manner as to prevent any significant exposure to patient or personnel. Nevertheless, the reminders mentioned above will be distributed in order that we reduce unnecessary exposures to the lowest possible levels.

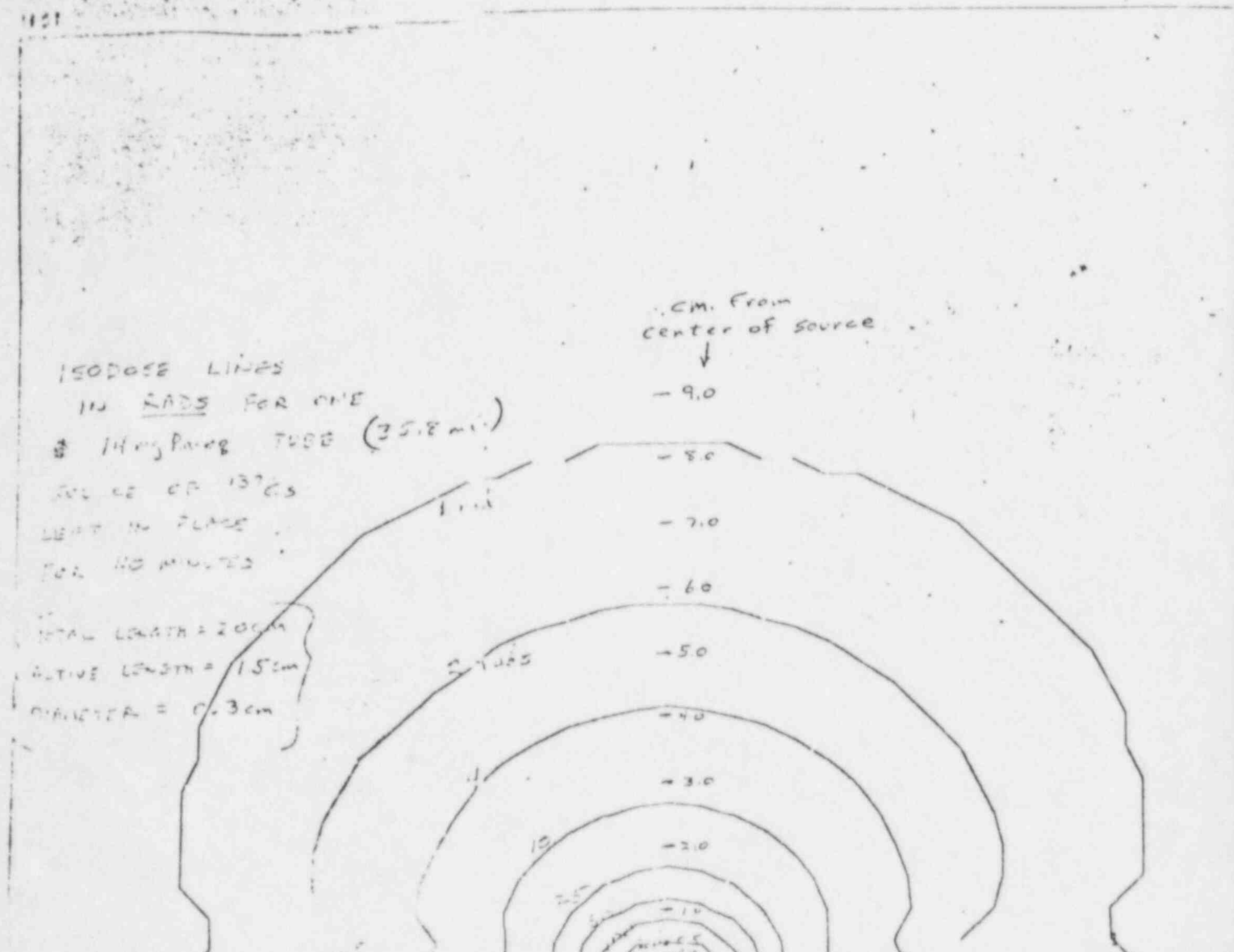
If I can answer any questions you have regarding this report, please call me at 513-569-2285.

Yours truly,

Paul A. Feller

Paul A. Feller, Ph.D., Director - Physics Services
Radiation Safety Officer

PAF/sk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