July 19, 1985

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

RE: FOLLOWUP OF THE MAY 3, 1985 REPORT
LICENSEE: THE JEWISH HOSPITAL
LICENSE #: 344-00855-07

Dear Mr. Sreniawski:

After our telephone conversation of July 10, 1985, and after spending the entire afternoon of July 15 with NRC inspector Stanely Lasuk, I am writing this followup letter (1) to reiterate my argument that this may not have been a reportable incident and (2) to dismiss the notion that this incident can be classified as a therapeutic misadministration.

My phone calls of April 29 and 30, 1985, and my May 3, 1985 report occurred because of the possible but questionable applicability of 10 CFR 20.403 (a)(1). In my letter of May 3, I stated that a skin dose of 450 to 500 rads may have occurred but that the dose was confined to an area of 1 or 2 square cms in the patient's buttock region. I questioned whether a report was necessary because skin exposures to this small area and in this region are simply not covered in 10 CFR 20.403. First it is a skin exposure, but not to the skin of the whole body. Thus, the limit of 150 rems to the skin of the whole body is not applicable in this case. Second, it was not a penetrating or internal exposure to the feet, ankles, hands or forearms so the limit of 375 rems to those areas is not applicable. There appears to be no regulation for skin exposure to a limited area. A reasonable interpretation might be to compare the ratio of limits to skin of whole body vs. whole body and apply that ratio to the penetrating limit for the specific areas of the body. The limit for the skin of the whole body (150 rems) is 6 times the limit for the internal dose to the whole body (25 rems). Thus, the limit dose to a small area of skin could be interpreted to be 6 times the 375-rem limit for penetrating radiation to a limited area, or 2,250 rem. This is why from the beginning I questioned the applicability of 10 CFR 20.403, and this is why I called the Region III office for an interpretation.

Both you and Mr. Lasuk indicated to me that this occurrence was being investigated as a misadministration as defined in 10 CFR 35.41 (f). It is invalid to compare my calculation for maximum skin dose (500 rads) to the stated prescribed dose at 1.5 cm. depth in the uterine wall (5000 rads), and conclude that the incident qualifies as a misadministration. Because of the unusual treatment geometries involved in brachytherapy, physicians can prescribe treatment doses to patients in several different ways. Since the radioactive sources are placed inside the patient and are surrounded very closely by the tissues to be treated, the tissues that lie adjacent to the sources receive a relatively very high dose rate. The dose rate falls off very rapidly as the distance from the sources increases (somewhat more slowly than the inverse square law would pre-

The Jewish Hospital of Cincinnati
3200 Burnet Avenue / Cincinnati, Ohio 45229 / Telephone: 513/569-2000

ATTACHMENT B

dict since we are dealing with an active volume as opposed to a point source). Some physicians will prescribe an average dose to the surface of the uterine wall while others will prescribe an average dose to depths of 0.5, 1.0, 1.5, or 2.0 cms from the surface of the uterine wall. A third method described in text books and used by many physicians, is to prescribe a treatment in terms of milligram - hours (mg-hr). This is simply the total activity inserted into the patient (in mg. radium equivalents) multiplied by the time (in hours) that the sources are left in the patient. In attempting to determine criteria for misadministrations in brachytherapy, the least ambiguous and most valid determination is made by comparing mg-hr of treatment. In this case, the prescribed treatment consisted of 6 sources of Cs-137 having a total activity of 89.6 mg. Ra.eq., and left in place for 62.3 hours, resulting in a treatment of 5,582 mg-hr. The source which fell into the patient's bed had an activity of 15 mg. Ra.eq. (as opposed to 14 mg. as stated in the May 3 report) and was in contact with the patient for a maximum of 40 minutes (2/3 hr), resulting in an additional 10 mg-hr. This is less than 0.2% of the total treatment in mg.-hr. Dose comparisons in rads are somewhat more questionable due to the different geometries of the two situations. Nevertheless one can compare the dose at 1.5 cm. from the single source to the dose given at 1.5 cm into the uterine wall. Another possibility is to compare the surface (skin) dose from the single source to the average dose given to the surface of the uterine cavity (I have attached a computer calculation of this latter dose; the other figures were submitted previously). The results of these three comparisons are listed here:

	Single Source	Given During Treatment	Ratio
Dose in mg.-hr	10	5582	0.0018
Dose at 1.5 cm (rads)	40	5096	0.0078
Dose at surface (rads)	500	26,882	0.019

As you can see, even in the worst case, the extra dose delivered to this patient was less than 2% of the treatment dose. In addition, as I stated in my original report, the additional dose to the treatment area was only about 1 rad. This occurrence was definitely not a misadministration.

Since the incident occurred on April 29, 1985, approximately 33 hours of my work time have been devoted to its followup. These hours include my own investigation of the incident, several phone calls to your office, the preparation and proof reading of two written reports to your office, search and retrieval of pertinent records of the incident 2.5 months later in preparation for the inspector's visit, and an entire afternoon spent with the inspector. I suspect that before the NRC closes this case, I will have devoted at least a full week to this matter. That is an inordinate amount of time to spend on a comparatively minor incident, caused by a very unusual combination of events each of which had not occurred in this hospital previously, and which had negligible impact on patient and personnel. I strongly question the appropriateness of an on-site inspection for an incident resulting in doses to such limited areas and of such limited magnitudes that 10 CFR 20.403 may not even apply. I realize that the NRC must fullfill its charge to regulate the use of certain sources of ionizing radiation, and to investigate possible improper uses. However, I am sure you also realize that much of your successfull enforcement depends upon the willingness of licensees to report unusual occurrences or possible violations. The NRC's response in this instance encourages the opposite. Now that you have the results of the inspector's investigation, and my 2 written reports, it is my hope that this case can

be closed with little additional effort. I had informed Mr. Lasuk of steps that I had taken to insure that a similar situation would not occur here again. These steps included informal discussions with the radiation therapist involved and a few other radiation therapists who were likely to perform brachytherapy procedures. I had also distributed a copy of May 3, 1985 report to Drs. Horwitz, Fine, Levy and Murdock, the physicians most likely to do brachytherapy implants in the future. In addition, I had held informal discussions with the radiation safety personnel and had given them a copy of the report. As an extra step on this date I have distributed the attached memorandum to all physicians licensed for group VI who currently practice at this hospital, namely Drs. Fine, Milburn, Horwitz, Murdock, Mahalingam, Aron, Levy, Ho, Morand, Compaan and Thomson. A second memo (also attached) has been given to the radiation safety personnel indicated.

I hope the above response is adequate.

Sincerely,

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

PAF/sk

Enc.

7-15-85

CALCULATION OF LINEAR SOURCES

PATIENT NAME - [redacted] SOURCE TYPE - 137 CS
DISTRIBUTION TITLE - ANT 0.50 MM FILTRATION

GRID: X= -5.0 TO 5.0 BY 0.50
Y= 7.0 TO -2.5 BY -0.50

CALCULATION PLANE ORIENTATION:
X= 0.0 Y= 0.0 Z= 0.0
ANG1= 0.0 ANG2= 0.0 ANG3= 0.0

TOTAL MGM RADIUM EQUIVALENT = 89.6
WEIGHT FACTOR = 10.0

SOURCE NUMBER	ACTIVITY (MGM RA)	ACTIVE LENGTH	TOTAL LENGTH	SOURCE END POINT COORDINATES X1	Y1	Z1	X2	Y2	Z2
1	14.9	1.00	1.20	-1.42	5.66	0.76	-1.27	4.54	0.67
2	14.9	1.00	1.20	-0.47	5.43	0.85	-0.49	4.27	0.77
3	14.9	1.00	1.20	-0.92	5.12	0.34	-0.81	4.02	0.20
4	14.9	1.00	1.20	-0.12	2.34	0.21	-0.16	1.17	0.12
5	15.0	1.50	2.00	-2.01	-0.75	-0.94	-2.10	-1.84	0.86
6	15.0	1.50	2.00	1.56	-0.83	-0.92	1.42	-1.85	0.94

POINT DOSE CALCULATIONS FOR PATIENT RANDALL, R

POINT	X	Y	Z	DOSE RATE	LABEL	% CONTRIBUTION FROM SOURCE # 1	2	3	4	5	6
1	-0.9	5.7	0.8	439.99	APEX	49	32	16	1	0	0
2	-1.7	4.9	0.6	818.21	TOP RT S	73	9	15	1	0	0
3	-0.1	4.9	0.6	629.06	TOP LT S	10	67	19	1	0	0
4	-1.3	3.6	0.5	215.86	MID RT S	15	22	46	10	2	1
5	-0.0	3.5	0.5	182.66	MID LT S	14	31	36	12	2	2
6	-1.1	1.7	0.2	164.87	BOT RT S	3	5	6	73	6	4
7	0.3	1.7	0.2	569.72	BOT LT S	1	1	1	92	1	1

rads/hr

AVG = 431.5 rads/hr × 62.3 hours = 26,882 rads average to surface of uterine wall

@ surface

RTT. 7/19/85

Form S194 R-2 J

The Jewish Hospital

MEMORANDUM

TO: Radiation Therapy Physicians

DATE: July 18, 1985

FROM: Paul A. Feller, Ph.D., R.S.O.
Director - Physics Services

SUBJECT: PROCEDURES FOR BRACHYTHERAPY SOURCE REMOVAL

As a reminder to those of you who perform radioactive implants, the following is a review of required procedures at The Jewish Hospital.

If requested by the radiation therapist, the radiation safety office will provide a trained staff member (usually Mr. Krugh, Ms. Myser or me) to accompany the radiation therapist to the patient's room, perform the radiation survey and take charge of returning the sources to the brachytherapy safe. If you do not think it necessary to involve the radiation safety personnel, please be reminded that you are then personally responsible for the following: (1) Removal of sources from the patient; (2) performing a source count and radiation survey of the patient, patient's bed, wastebaskets and room; (3) signing and dating the source removal certification portion of the survey form on the patient's chart; and (4) returning the sources to the brachytherapy room.

If you request assistance from the radiation safety office, but a representative is not present at the scheduled time of source removal, you should either: (a) remove the sources from the patient and immediately conduct a source count and/or a radiation survey or (b) attempt to contact Mr. Krugh, Ms. Myser or me in the Oncology Center (ext. 2290), and wait for a representative to arrive before removing the sources.

Unless you perform the source count and radiation survey yourself, please do not sign the source removal certification.

Please be aware also that the radioactive sources are your responsibility until you turn them over to the radiation safety person. Radiation safety personnel have been 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.

Thank you for your cooperation.

PAF/sk

Form S194 R-2 J

The Jewish Hospital

MEMORANDUM

TO: Mr. Kent Krugh,
Ms. Lucretia Myser,
Deputy Radiation Safety Officers

DATE: July 18, 1985

FROM: Paul Feller, Radiation Safety Officer

SUBJECT: BRACHYTHERAPY SOURCE REMOVAL

I have sent on this date to all therapy physicians a memorandum which summarizes their responsibilities and those of radiation safety personnel in brachytherapy source removal. If you are going to be late arriving for a scheduled source removal, please attempt to notify and inform the physician regarding the length of the delay. If you arrive at the patient's room at the scheduled time but the therapist is delayed and you wish to leave the area, leave word with the unit clerk at the nursing station to contact you immediately when the radiation therapist arrives.

Thanks.

PAF/sk