Hahnemann University
Hospital

16 October 1990

Margaret M. McGoldrick
Vice President for
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Malcolm R. Knapp, Director
Division of Radiation Safety
and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pa. 19406

Dear Sir,

We have carefully reviewed the report of your inspection of our facilities on 17-18 July 1990. Our reply to the identified issues is enclosed, outlined as follows:

Section I addresses the Notice of Violation resulting from your inspection.

Section II addresses the ALARA concerns that you voiced to us during your follow-up visit on 2 August, submitted per our informal agreement.

We hope that you find our response satisfactory. Please do not hesitate to call (215) 448-3690 should you require additional information.

Sincerely Yours,

Meg McGoldrick
Acting Senior Vice President
and Chief Health Officer

Docket Nos. 030-02959
030-20830
070-01362

License Nos. 37-00467-34
37-00467-35
SNM-1369

cc. Luther Brady, M.D.
Joe Mintzer, M.S.W.
Ed Tanida, M.B.A.

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SECTION I

Notice of Violation

10CFR35.315(a)(4) and 10CFR35.415(a)(4) require, in part, that licensees, promptly after administering a therapeutic dose of a radiopharmaceutical which requires hospitalization, and promptly after implanting brachytherapy sources, respectively, measure and survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10CFR Part 20.

Contrary to the above, as of July 18, 1990, the licensee did not measure and survey the dose rates in contiguous restricted and unrestricted areas with a radiation measurement survey instrument to demonstrate compliance with the requirements of 10CFR Part 20, promptly after administering a therapeutic dose of a radiopharmaceutical which requires hospitalization and promptly after implanting brachytherapy sources.

Reply to Notice of Violation

Effective 20 July 1990, with our first applicable case following your inspection, we initiated the required monitoring. It has continued without interuption. Results are kept in a binder in the Radiation Safety Office and are available for review in that location. Maintaining compliance with the provisions of 10CFR20.105 is considered as a seperate issue and is dealt with in Part I of Section II of this report.

Our reasons for failure to comply with these regulations arose from our longstanding difficulty in meeting the exposure requirements as listed in 10CFR20.105. These difficulties culminated in our obtaining an amendment from NRC that allowed us to ensure Brachytherapy exposure safety through the "tracking" of patients quartered in continuous areas. (see amendment of 4 March 1983). It was our belief that since we could not meet the requirements of 10CFR20.105, we were exempt from the rules in 10CFR35.315(a)(4) and 10CFR35.415(a)(4) which directed us to demonstrate the compliance that we had already admitted was not always possible. It is now clear to us that we were mistaken in this belief.

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SECTION II

ALARA ISSUES RAISED DURING THE INSPECTION AND FOLLOW-UP VISIT

Three seperate issues were raised during the inspection process. Two concern NRC licensed activities and are interrelated. The third is not NRC regulated but is discussed here in response to the concern voiced by the inspection team.

Part A - High Exposure Readings That Results From Brachytherapy and Radiopharmaceutical Therapy Patients.

High readings in unrestricted areas that result from brachytherapy or radiopharmaceutical therapy patients have been an ongoing problem within the institution. (see letters of 15 November and 21 December 1982 and 16 February 1983) This has been due primarily to our inability to quarter patients in the appropriate rooms and our lack of mobile shielding equipment. Our method of compliance has entailed the "tracking of adjacent patients to ensure maximum yearly exposures <500 mrem. This method was approved as an amendment to our NRC license on 4 March 1983.

Following your recent inspection a committee consisting of administrative, technical and medical representatives met to consider the problem and we are now moving towards full and unconditional compliance with the provisions of 10CFR20.105. The new approach involves a semi dedicated implant suite consisting of two specially prepared rooms. Our new plan is described below.

Description of Facility

Rooms 1964 and 1965 in the North Hospital Tower comprise the new implant suite and are depicted in Appendix A, "Brachytherapy Suite Floor Plan," of this report. Although these rooms were set aside for brachytherapy and radiopharmaceutical therapy in the original building design, until recently it has not been possible to quarter radiotherapy patients in this area on anything but a "space available" basis. Recent reallocations of hospital space have changed this. We now reserve these rooms. In a meeting called by hospital administration on 16 August, patient scheduling was reviewed. Since that date it has become hospital practice to admit all brachytherapy and radioiodine ablation patients to these rooms.

The physical characteristics of this space are as follows. Floors both above and below these rooms consist of 8 inches of pre-poured concrete slab with an additional 2 inch concrete topping. This is in contrast to floors in the remainder of the building that consist of 4.5 inches of concrete. Transmission factors for the extra thick flooring are 2.6 % for Cesium-137 and 1.7 % for Iridium-192. The cross hatched barriers shown in Appendix A are 8 inch solid concrete masonry walls. This contrasts with double thichness plasterboard in other areas of the building. The masonry walls have transmission factors 5.3 % for Cesium and 3.8 % for Iridium. Both floor and walls transmit about 1 % of the radiation from Iodine-131

In addition to the fixed structural shielding, we have purchased three mobile leaded shields. These are 24 X 36 inches in dimension and contain 1 inch thickness of lead. Lead transmission is about 7 % for Cesium and 5 % for Iridium. Transmission for I-131 radiations is less than 1 %. The solid lines (at bedside) shown in the "Floor Plan" indicate the shield positions that we are currently utilizing. These two shields are stored permanently on the 19th Floor. The third shield is stored in the Radiation Safety Office and is used as a back-up shield. It may be used as additional shielding if such is necessary or in situations where it is not possible to quarter a patient in one of the shielded rooms or in which we have more than two patients at the same time. So far this problem has not arisen. The movable shields have been in use since their procurement on 29 August 1990.

Staff Preparation

All nursing personnel exposed to ionizing radiation receive a yearly in-service lecture on general Radiation Safety Procedures. On 22 August the nurses of 19 North Tower received a specialized presentation dealing with the new brachytherapy suite. It is our plan to continue with the general lecture series, with perhaps added stress on other sources such as x-ray machines and diagnostic nuclear medicine patients. Specialized lectures on brachytherapy and radioiodine ablation therapy will likely be limited to the 19th Floor (West), the site of the rooms.

We are also in the process of rewriting our "Nursing Manual for Patients Containing Radioactive Material" and the 19 North Tower nurses are involved in this, particularly in the sections dealing with activities that we plan to limit to that floor. The completed manual will be the topic of our next in-service effort.

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Radiation Safety Survey Results

The radiation safety survey for this facility consists of a series of survey readings taken while patients were quartered in the facility. These comprise readings from eight implant cases and one ablation. All occurred during the time period 14 August to 04 October. The location of each monitoring site is depicted in Appendix B and C for rooms 1964 and 1964 respectively.

The highest reading recorded in Rm 1964 resulted from a patient quartered in Rm 1965 and containing 75 mgRaeq of Cesium-137. The reading was 0.5 mr/hr (F). The exposure rate in the vestibule area was 1.9 mr/hr (E). That in room 1966 was 0.8 mr/hr (H).

The highest reading recorded in room 1965 resulted from an ablation patient quartered in room 1964 and containing 102 mCi of Iodine-131. This reading was 0.4 mr/hr (D). The rate in the vestibule area was 0.6 mr/hr. It is interesting to note that of late our typical ablation doses have ranged as high as 200 mCi so that these rates could effectively be doubled, but still lie within regulatory limits.

The highest sustained exposure readings for other unrestricted areas were measured on 04 October at a time when both rooms contained brachytherapy patients. A patient in room 1964 contained 54 mgRaeq of Iridium-192. One in room 1965 contained 80 mgRaeq of Cesium-137. The exposure rates in both rooms 1963 and 1966 (A & H) were both 0.8 mr/hr. The composite rate for the hallway area (C & G) varied between 1.1 and 1.6 mr/hr with the highest reading at point G near the door to room 1965. We do have some concern as to a composite reading of 3.1 mr/hr measured at point E in the vestibule area and we consider this point to be the weakest point in our present shielding plan. Although we have not as yet experienced another like situation, our tentative plans for the next occurance are:

1. In the event that both rooms contain radioactive patients, we will post the outside door to the vestibule area, in effect, making the vestibule part of the restricted area.

2. In the event that room 1965 contains an radioactive patient and 1964 does not, we will use the third, backup movable shield to lower the exposure rate at point E. It would most likely be placed at the foot of the bed. Note the the door from 1965 to the vestibule is not normally used.

   (We foresee no situation in which the reverse is true, since the position of the movable shield in room 1964 already

shields the vestibule area.

Personnel Monitoring

Previously, film badges have been assigned to floor nurses on an as needed basic. Beginning in November of this year, all floor nurses on 19 North Tower (West) will be assigned permanent film badges.

To date, we do not have film badge reports describing employee exposures accrued with the facility fully operational. A review of old exposure records; however, leads us to believe that this area will not present a challenge to our ALARA program.

Brachytherapy and Ablation Patients in Other Hospital Rooms

It would not be reasonable to conclude that every radioactive patient will be assigned one of these rooms. Two instances in which this exception could occur are:

1. There are more than two patients scheduled for these rooms at the same time.

2. For medical reasons, a non-radioactive patient in 1964 or 1965 cannot be transferred in order to make room for an implant/ablation patient.

In these situations we will have no option other than to assign these patients to regular rooms as was done in the past. In these cases we will still excercise our patient "tracking" option in order to ensure no yearly patient exposures >500 mr. Two changes from the past protocol; however, are:

1. The availability of the movable shields will decrease the exposure in adjacent unrestricted areas.

2. Through our "tracking," program, we will attempt to limit exposure of adjacent patients to once per calender year. Previously we had limited these patients to two such exposures per year.

Summary

During the next twelve months we expect to schedule about 50 admissions to these rooms. Operating procedures and policies will be continuously updated as we gain experience.

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Part B - Administration of I^{131} Thyroid Ablation Doses

For some time there has been a difference of opinion as to which location is best for the administration of ablative radioiodine doses, the Nuclear Medicine Hot Lab or the patient room. There are good arguments backing each position.

Prior to the July NRC inspection, policy in the Nuclear Medicine Department was such that all ablative doses were administered in the Nuclear Medicine Hot Lab. At the time of your follow-up visit on 2 August, we agreed to administer these doses in the patient rooms on a trial basis through the month of September. We would at that time evaluate our experience and make our final decision.

To this writing we have had only one ablation patient. We have however, gained some experience with in-room dose administration and early results do look promising. The administered dose was 102 millicuries and was given in the form of four capsules. Air monitoring was performed in order to assess the quantity of iodine vapor that escapes while the capsules are open to the air. The results were essentially background level. The Nuclear Medicine staff involved in the procedure showed no increase in thyroid burden over the low levels to which we have been accustomed. Thyroid monitoring of the nurse who provided the bulk of nursing care showed acceptable results as well. Film badge reading for the Nuclear Medicine staff were essentially unchanged. Readings for the nursing staff are not yet available although we expect no changes.

Summary

Based on the above results we have amended our policies such that all ablative radioiodine doses will be administered within the patient room. We do; however, plan to re-evaluate this policy as we gain more experience. We will certainly keep the NRC informed.

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Part C - High Employee Exposures in Cardiac Catheterization Area

As do all other institutions that have Cardiac Catheterization Sections, we find that individuals performing these studies accrue the highest film badge readings of any occupationally exposed group. The interpretation of exposure readings is difficult for these individuals and readings that would cause great alarm in other areas are so common as to be the rule in Cardiac Catheterization. It was clear to us that the NRC is not accustomed to seeing film badge readings of this magnitude.

Following your July visit, Hospital Administration called a meeting of representatives of all parties involved in the operation of the Cardiac Catheterization area. We met to consider methods in which employee exposures could be lowered and the interpretation of film badge readings simplified. We have also been working closely with our Commonwealth inspection team and have found their input to be very helpful. We did formulate a tentative plan of action and we have summerized it below for your review. It should be noted that this is very much a **tentative** plan of action and is subject to change as we evaluate the results of our program.

1. Beginning with the October badge, staff in cardiac catheterization will wear **only one** monitor, this to be worn at the level of the collar or sleeve and **outside** any protective devices that are utilized. Previously one badge was worn under the lead apron, the second at the level of the collar or sleeve but **outside** any protective devices. This action was initiated at the suggestion of the state inspectors who felt that:

   a) a badge worn under the apron is all but useless, since the lead aprons are virtually 100% effective.

   b) badges are frequently switched, so that it is impossible to interpret the readings.

   in addition:

   c) the shielded badge reading may give a false sense of security to individuals who are receiving high exposures to unshielded portions of the body.

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2. Use of aprons, thyroid shields, leaded glasses or goggles and a leaded sleeve shield on the dependant side will be mandatory for all machine operators. (effective ASAP for sleeve shields, 09/12/90 for other devices)

3. Use of aprons and thyroid shields are mandatory for all other individuals present in the room. (effective 09/12/90)

4. We have initiated an investigation into more effective and useable in-room structural shielding, either ceiling or floor mounted. To date at least one x-ray supply company has indicated a desire to help us investigate our needs and propose remedies.

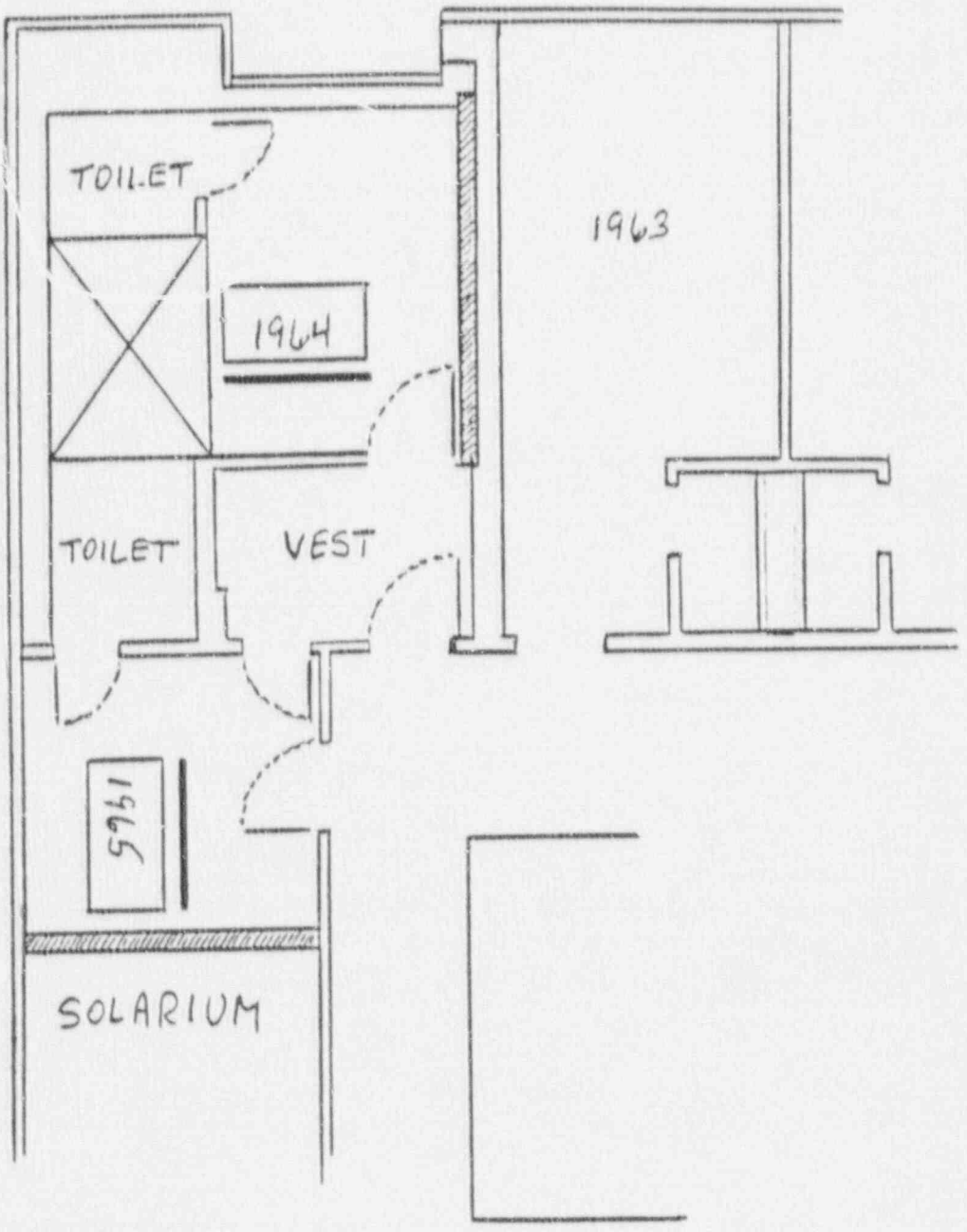
5. We will improve and expand our in-service efforts for residents and fellows working in this area.

6. The Radiation Safety Office will make frequent unnanounced visits to ensure ongoing compliance with these provisions.

7. Hospital administration has become wholly committed to implementing a strong ALARA Program in this area.

Again, we must stress that it is much too early to begin assessing results. We do feel; however, that we are moving in a positive direction in regards to good ALARA practices.

Appendix A
Brachytherapy Suite Floor Plan



Appendix B

SHIELDED ROOM SURVEY FOR PATIENTS IN RM 1964 NORTH TOWER

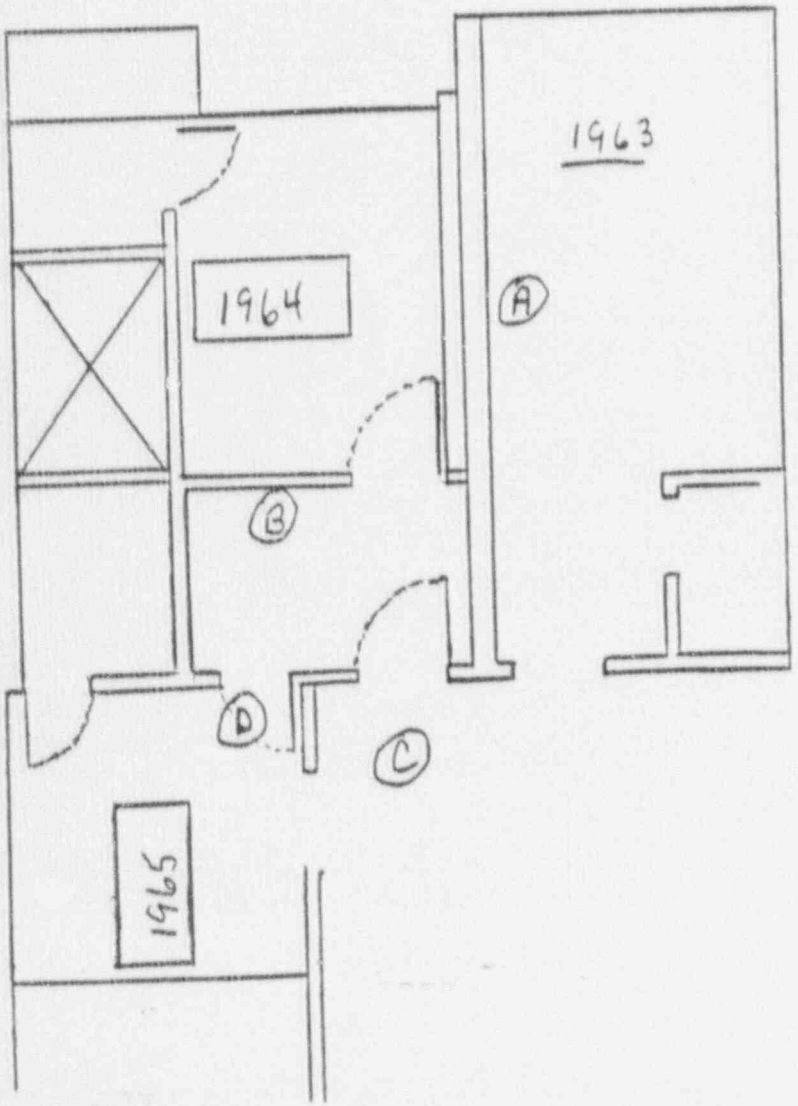
Patient Name _____ Date _____

Room Number _____

Type & Location of Loading _____

Activity Implanted _____

All readings made with Victoreen Panoramic Survey Meter
Model 470A S/N 4365



Exposure Readings

3 feet _____

6 feet _____

Pt. A _____

Pt. B _____

Pt. C _____

Pt. D _____

*all readings taken at 1 foot from applicable barrier.

Appendix C

SHIELDED ROOM SURVEY FOR PATIENTS IN RM 1965 NORTH TOWER

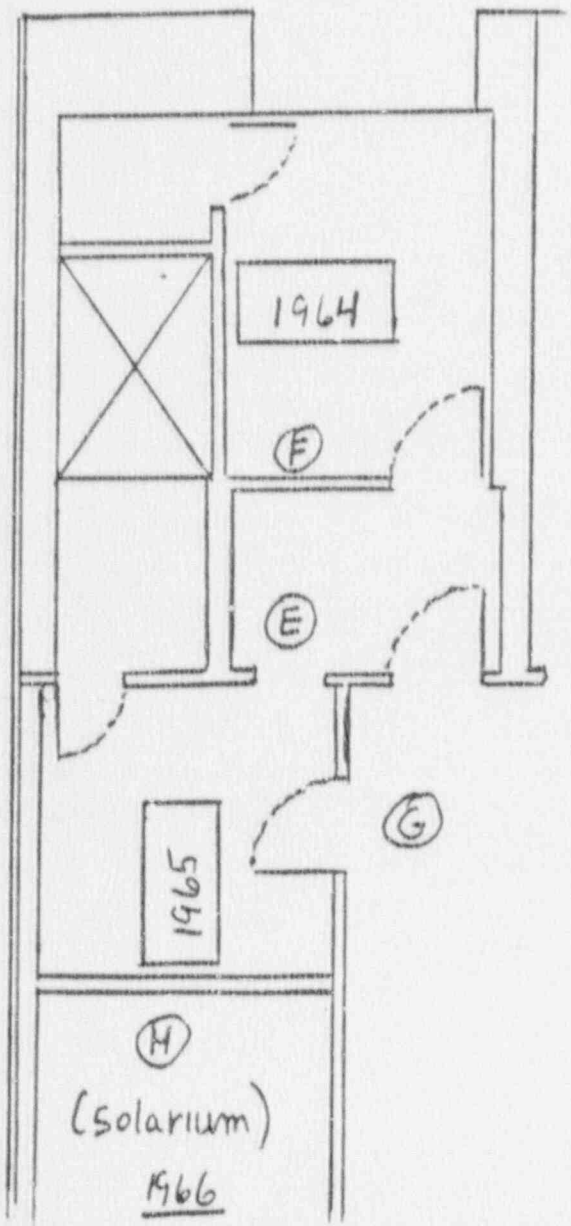
Patient Name _____ Date _____

Room Number _____

Type & Location of Loading _____

Activity Implanted _____

All readings made with Victoreen Panoramic Survey Meter
Model 470A S/N 4365



Exposure Readings

3 feet _____

6 feet _____

Pt. E _____

Pt. F _____

Pt. G _____

Pt. H _____

* all readings taken at 1 foot from applicable barriers.