



Young

ST. MARY'S HOSPITAL
M · I · L · W · A · U · K · E · E

March 25, 1994

Mr. Tom Young
Inspection and Enforcement Section
U.S. Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Mr. Young:

As per recent conversations and your request, we are submitting this additional information:

1. Be advised that the Radiation Safety Committee membership will include all individuals required, which includes the Radiation Safety Officer, authorized user for each group of materials, management's representative, and representative from the nursing staff.

It should be noted that only one individual will be appointed as the management representative and a second individual will be appointed to act as the management representative in the event that the initial management rep is unable to make the meeting. The management representative will be designated by the Vice President of Operations and that individual will be the Administrative Director of Medical Imaging. The second individual who will act as management rep in the event the Director of Medical Imaging is unable to make the meeting, will be the Director of Risk Management. As noted, the primary management representative will be the Medical Imaging Director.

Documentation of the minutes will reflect the attendance of individuals at the meeting and meetings will only be conducted when the appropriate quorum is present.

2. Be advised that the brachy therapy incident, which occurred previously, will be discussed at the next Radiation Safety Committee meeting and documentation of that discussion will be entered into the minutes.

It should be noted that for the future, all recordable or reportable incidents which occur in the Medical Imaging or Radiation Oncology area will be discussed at the meeting and the discussion included in the minutes. That discussion will include any specific recommendations and any corrective action implemented. The discussion of these incidents will be initiated by the Radiation Safety Officer.

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3. As noted in our letter of February 21, 1994, we have instituted the procedure to insure that patient rooms will be wipe tested for removable contamination after radiopharmaceutical therapy procedures.

The radiation survey will be conducted by the Radiation Safety Officer or an individual which he would designate. The records of the surveys will be maintained in the Nuclear Medicine Department for review by regulatory agencies.

To help in preventing any problems for the future in conducting these surveys, the Radiation Safety Officer will be notified of any radiopharmaceutical therapy procedures to be scheduled at the Hospital. The RSO will then make a determination as to who will conduct the appropriate surveys and provide the documentation. The authorized users will not conduct the surveys unless so designated by the Radiation Safety Officer.

4. Be advised that the reports of the semi-annual air flow checks, which include the supply and exhaust rates for the rooms, will be posted in the room or in the corridor leading into the rooms in a conspicuous area. The information contained on these reports will indicate whether the room has negative pressure in existence to comply with the current NRC regulations.

Any questions on the part of the technical staff as to whether a room may not have negative pressure will be brought to the immediate attention of the Nuclear Medicine Team Leader and the Radiation Safety Officer.

To prevent a recurrence of any possible problems with determination of whether or not negative air pressure exists in the room where ventilation scans are performed, the most current copy of the air flow check will be posted. In addition, the Radiation Safety Officer and the Nuclear Medicine Team Leader will collaborate on establishing specific dates at which the air flow checks must be performed and initiating appropriate requisitions to the Engineering Department to have them performed. A follow-up mechanism will be instituted to determine whether or not the air flow checks have in fact been performed and also determine that the negative air flow situation exists. In the event the rooms do not show negative air flow, then the RSO will notify the Nuclear Medicine Team Leader, who will then in turn notify the staff that ventilation studies may not be performed in a particular area where the air flow does not show negative pressure until corrective action has been implemented and retesting indicates that it is now in compliance. This will also be reviewed by the Radiation Safety Officer.

5. Please refer to the items in Number 4 as to corrective action to be taken in this area.

The management oversight program will include reporting mechanisms starting from the Nuclear Medicine Team Leader level to the Vice President of Operations. The Nuclear Medicine Team Leader will have responsibility for determining day to day compliance situations and the Radiation Safety Officer will review these on a regular basis from weekly to monthly, depending upon the particular items. A report will then be issued to the management representative, who will be the Administrative Director of Medical Imaging, who will in turn provide a report on a monthly or quarterly basis to the Vice President of Operations detailing the current status of compliance with NRC regulations and corrective actions taken on any items that are determined to be not in compliance or which require some type of revision.

Documentation of the reports initiated by each of the individuals will be combined in a report submitted by the Administrative Director of Medical Imaging to the Vice President of Operations. They will include reports of review of compliance status, corrective action, implementation and follow-up, and any other reviews to determine that materials are used in a safe manner. Discussions of any of the items contained in these reports will be at the Radiation Safety Committee meetings conducted on a quarterly basis, and any other special meetings which might be needed. Also, any adjunct reports from outside contractors, consultants, etc., will be included in the Radiation Safety Officer's report to the Administrative director of Medical Imaging.

We feel implementation of this system will allow the personnel at this institution to review for radiation safety compliance, regulatory compliance, and overall proper usage of radiopharmaceuticals and provision of adequate radiation safety policies and procedures.

This information will be available for review by regulatory agencies such as the Nuclear Regulatory Commission and Joint Commission on Accreditation of Hospitals Organization.

Should you have any questions or if you require any additional information, please feel free to contact us at your convenience.

Sincerely,

Colleen Mahoney

Colleen Mahoney,
V.P. Operations

Yu Kong Chan, Ph.D.

Yu Kong Chan, Ph.D.
Radiation Safety Officer

Enclosures:

Decay of contaminant activity

Radio-isotope : I-131

Date : 1.27.94

Survey meter Model: Ludlum model 3
44-7

Serial No. : 9538
PR 13064

	Date	Surface exposure rate		Initials
		Bag # 1 ^{smaller} larger	Bag # 2 ^{larger} smaller	
First day	1.27.94	$0.1 \times 0.5 = 0.05$ mR/hr	$1 \times 0.2 - 0.3 = 0.2$ mR/hr	W
Week 1	2.4.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.15 = 0.15$ mR/hr	W
Week 2	2.11.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.15 = 0.15$ mR/hr	W
Week 3	2.18.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.1 = 0.1$ mR/hr	W
Week 4	2.25.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 1.0 = 0.1$ mR/hr	W
Week 5	3.4.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.5 = 0.05$ mR/hr	W
Week 6	3.11.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.5 = 0.05$ mR/hr	W
Week 7	3.18.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.3 = 0.03$ mR/hr	W
Week 8	3.25.94	$0.1 \times 0.3 = 0.03$ mR/hr	$0.1 \times 0.3 = 0.03$ mR/hr	W
Week 9				
Week 10				
Week 11				
Week 12				

Note:

1. The bags of contaminated linen, bed sheets, clothing etc, and the bags of contaminated utensils, disposable trays etc are being kept in the storage room for decay.
2. Only when the exposure rates at the surfaces fall below background or at background level, they can be disposed.
3. Background exposure rate is at the range of 0.01 to 0.02 mR/hr.
4. It may need to keep them for 10 half lives, e.g. I-131 half life is 8 days, 10 half life is 80 days, i.e. 12 weeks.

I-131 Therapy Wipe Test
 (Test for removable contamination)

Date : 1, 27, 94

Initial : W

Patient Name: Pochatko, J

Room : 772

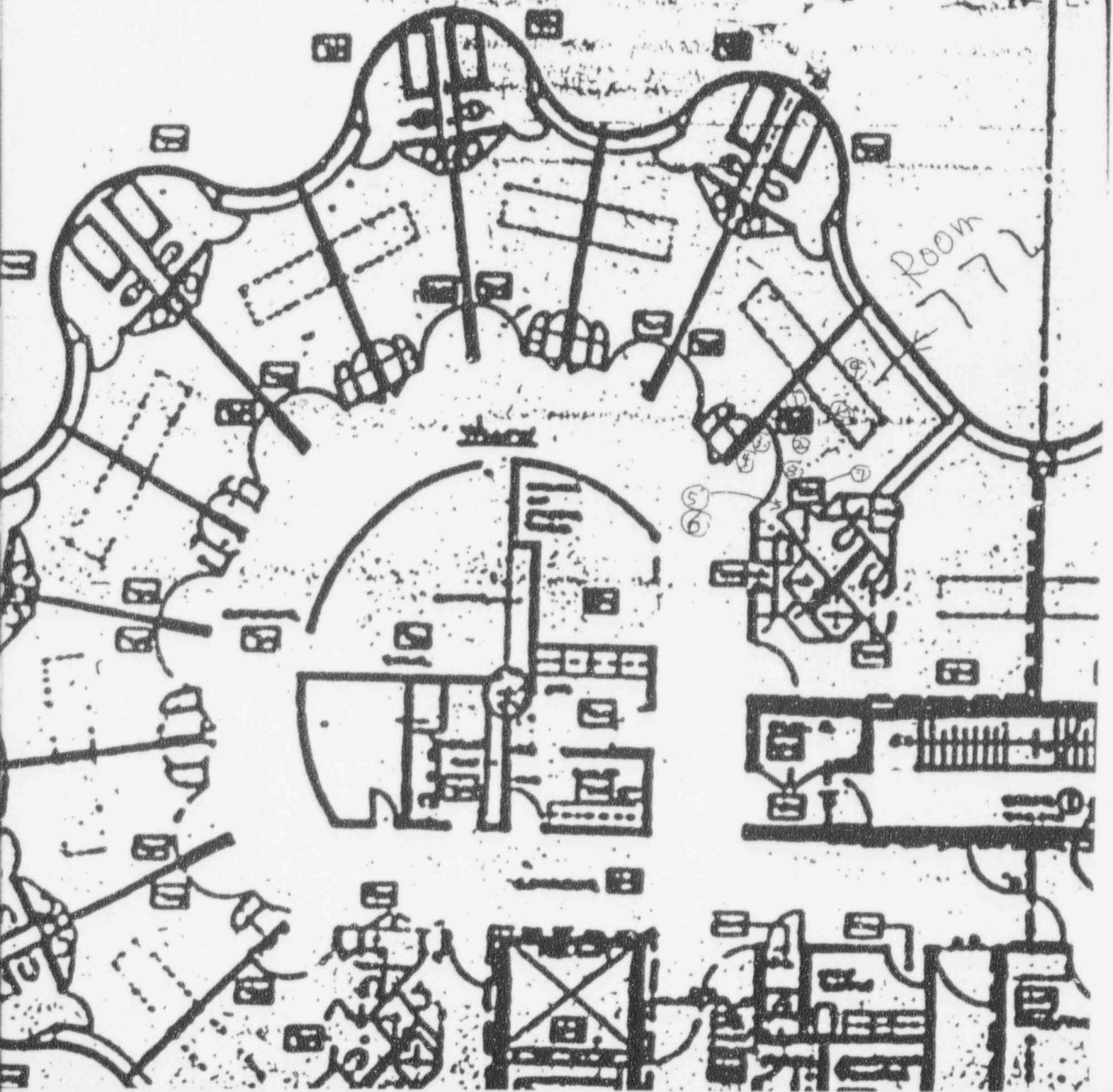
	Location	Final Net Counts (cpm)
Wipe No.1	<u>Telephone</u>	<u>39</u>
Wipe No.2	<u>small table by bedside</u>	<u>72</u>
Wipe No.3	<u>door handle 1</u>	<u>26</u>
Wipe No.4	<u>door handle 2</u>	<u>26</u>
Wipe No.5	<u>bathroom door knob 1</u>	<u>81</u>
Wipe No.6	<u>bathroom door knob 2</u>	<u>81</u>
Wipe No.7	<u>Sink, left knob</u>	<u>170</u>
Wipe No.8	<u>Sink right knob</u>	<u>170</u>
Wipe No.9	<u>bed rail 1</u>	<u>121</u>
Wipe No.10	<u>bed rail 2</u>	<u>121</u>

Counting Instrument: ISS Data 20 wells counter

Counted by: Yu Rong Chan, Date : 1, 27, 94

1. Clean contaminated area.
2. Use alcohol-wipe or alcohol saturated cotton swap to wipe suspected area: door knob, telephone, headboard, utensil, etc.
3. The wiped area should be about 100 cm².
4. Take wipe sample to Nuclear Medicine to count. The net count should be less than 200 cpm.
5. If net count exceeds 200 cpm, repeat steps 1-4, until it is below 200 cpm.

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RADIATION SAFETY COMMITTEE MEETING

TUESDAY MARCH 15, 1994

- I. **CALL TO ORDER:** The meeting was called to order at 1300 hours. Members in attendance were:

Dr. Phillip Ruetz
Lynn Schuster
Kim Swinghamer

Dr. Yu Kong Chan
Joe Morton
Peggy Liben
Patrick Dailey (recorder)

Members absent were:

Dr. Gandhavadi

Jim Roberts

Members in attendance exceeded the 50% requirement to establish a quorum.

- II. **APPROVAL OF MINUTES FROM PREVIOUS MEETING:** Members reviewed and accepted the minutes of the previous meeting of December 6, 1993.

III. **BUSINESS OF THE SESSION:**

OLD BUSINESS:

- A. **NRC REPLY** - Dr. Chan informed members that he has spoken with Thomas Young of NRC to address the reply to the NRC relevant to the (4) violation charges. Mr. Young stated that we must respond to these charges by April 1st.
- B. **INCIDENT OF SEPTEMBER 1991** - Dr. Chan informed members that the concern of the NRC relevant to this incident was that it was not discussed by the committee during a formal meeting. The Radiotherapy incident of September 1991 was reviewed by the RSO, Administrative Representative, Nursing, and members determined proper procedures were followed.
- C. **AMENDMENT NO. 37 TO LICENSE** - Dr. Chan informed members he has discovered an error in the license with respect to depleted Uranium. He has called the NRC and a corrected amendment is forthcoming.
- D. **RSO'S ROUTINE REPORTS** - Dr. Chan stated there were no accidents, incidents, spill, misadministrations, radiation contamination, and no overdoses to patients or staff.

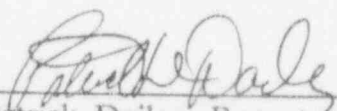
E. RADIATION EXPOSURE REPORT: -

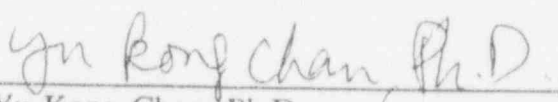
1. No overexposure to staff.
2. Dr. Chan reviewed with ALARA principle level I and level II actions.
3. The number and names of persons exceeding level I and level II were listed in the quarterly report.
4. Nuclear Pacemaker patients are being contacted every (6) months.

NEW BUSINESS

- A. RADIATION INSTALLATION REGISTRATION -** Dr. Chan received the new registration early this year and it will expire 12/31/94. Dr. Chan distributed copies of the new registration for files.
- B. RADIATION SAFETY COMMITTEE MEMBER APPOINTMENT -** The list is being retyped for Dr. Ruetz's signature.
- C. XENON STUDY -** Dr. Chan indicated we have just received the report from Clasman Corp. The report is posted in the department. If any work is performed or work is in progress on the airflow system, and it is unclear if negative pressure has been achieved, the area will be posted. Negative airflow tests are performed every (6) months. If negative pressure does not exist, we will be notified immediately. No Xenon Studies will be performed until negative pressure is achieved.
- D. DEPARTMENT OF HEALTH AND HUMAN SERVICES , HEALTH CARE FINANCE ADMINISTRATION INSPECTION RESULTS -** Our Mammography Program was inspected in February and determined free of any deficiencies.
- E. STATE OF WISCONSIN -** All our X-ray units were inspected in March by The State of Wisconsin and found to be free of deficiencies.
- F. LAB/SURGERY REMODELING PROJECT -** The project involved a radiograph being taken of the floor between the Lab and Surgery by MQS Company. Dr. Chan has requested a copies of MQS's license, procedures, the floor plan, established boundary, and exposure time table. Dr. Chan also requested a copy of the actual exposure record during this radiographic procedure. All of these copies are on file with the Radiation Safety Officer. All affected areas were notified of the testing (2) days prior to any radiographic procedure. All affected areas were posted as "DO NOT ENTER - RADIATION HAZARD" during times when radiographic procedures were expected to be performed.

- G. **GI LAB** - Upon receiving a report from an X-Ray Tech that one physician uses an unusually long fluoro time during a procedure, Dr. Chan initiated a log book to monitor fluoro time. Dr. Chan recommends that we educate Cardiologists and GI specialists to minimize radiation exposure while doing fluoro.
- H. **MONITORING VISITING PHYSICIAN RADIATION EXPOSURE** - Members discussed this issue at length. Dr. Ruetz recommended Dr. Chan check with our legal department to determine steps necessary to monitor exposure to visiting physicians who do not possess a St. Mary's film badge.
- I. **RSO'S NOTES TO NURSING STAFF** - Dr. Chan reminded Nursing Staff that the room for brachytherapy or iodine therapy will not be released for admission of new patients until all sealed sources are accounted for, the room is decontaminated and wipe tested, and the RSO declares the room is clear.
- J. **IODINE THERAPY PROCEDURES** - The staff and RSO must be notified as soon as procedure is scheduled so the appropriate Policy and Procedure can be put into action. Dr. Chan indicated that Radiation Safety Check List in 10.8 appendix P will be followed. Dr. Chan recommended placing a box of gloves and shoe covers immediately outside patient's door.
- K. **REPORT ON ADMINISTRATIVE ISSUE CHANGES** - Joe informed members of the requirement from Colleen for Dr. Chan to report to the Director of Medical Imaging on a monthly basis of all radiation issues. The following week, Joe will make a formal presentation to Colleen in his update which will include Dr. Chan's report. This will allow for a direct reporting line from QC Techs, through Ron Edwards, Dr. Chan, and Joe, to Colleen. Joe reiterated that we will be replying to NRC by April 1st.
- L. **ADJOURNMENT** - The meeting adjourned at 1422 hours.


Patrick Dailey, Reporter


Yu Kong Chan, Ph.D.
Radiation Safety Officer