



Arthur H. Knowlton, M.D.
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THE HOSPITAL OF ST. RAPHAEL
NEW HAVEN, CONNECTICUT 06511
RADIATION THERAPY CENTER

June 23, 1980

United States Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, Pennsylvania 19406

Attention: George H. Smith, Chief
Fuel Facility and Materials Safety Branch

Docket Nos. 030-01238
030-00108
040-8050

Subject: Inspection No. 80-01

Dear Mr. Smith:

In regard to your letter of 5/29/80 concerning the violations sited by Messrs. J. Nicolosi and C. Rowe from their inspection on April 15, 16, 1980 (NRC License No. 06-00200-01 and No. 06-00200-03 and SUB-1037, Docket No. 30-1238 and 30-108 and 40-8050) corrective steps have been taken concerning all sections of Appendix A which we received from you. Enclosed is a detailed answer regarding our violations as sited in Appendix A as well as the corrective steps we have taken in regard to them and the steps we have taken to avoid non-compliance in the future.

RE: Appendix A Part A

1. Concerning Part A, Number 1. We failed to use the TLD ring assigned to the physician who implants brachytherapy sources. Also no surveys of the dose to nurses who administer routine care to the patients with implants of brachytherapy have been made. At the time of our last visitation there were two physicians who worked with radioactive material. They were: Dr. Edward Prokop, Nuclear Medicine and Dr. Arthur Knowlton, Radiation Therapy. In 1978 I was under the impression at the time of the visit (although wrongly so) that the TLD ring only need be worn by the Nuclear Medicine physician and his personnel. That is one who handles more liquid type of radioactive material which is more easily spilled on the hands. We were guilty of this infraction at that time and I did indicate to you it was mandatory for all personnel who prepare, administer and handle radioactive material to wear a ring badge. Later in that paragraph I did state at present all

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personnel of the NUCLEAR MEDICINE DEPARTMENT WHO HANDLE THE RADIOPHARMACEUTICAL (PHYSICIANS & TECHNICIANS) HAVE TLD RINGS DETECTORS. I did not realize that the wearing of a TLD ring also applied to me in the Radiation Therapy Section. I take full responsibility for this infraction. We did not disregard your recommendation in 1978 but actually rigorously enforced Dr. Prokop wearing his ring and I was mistakenly under the impression we were in full compliance by doing this. The present infraction which applies to me will be easy to correct as I am now immediately wearing my TLD ring each time brachytherapy sources are used. We presently have in our section:

Dr. Edward Prokop (Nuclear Medicine)
Dr. Caridi (Nuclear Medicine)
Dr. Knowlton (Radiation Therapy)
Dr. Cardinale (Radiation Therapy)

All of these physicians have been informed of the necessity of wearing the TLD ring whenever radioactive material are handled. The Nuclear Medicine section has constantly done this for the last 2 years since your visitation. As of the present visitation of May 29, 1980 the Radiation Therapy section is now wearing TLD rings when handling radiation material. As noted above it is not a disregard of your recommendation in the past but a lack of education on my part that caused this infraction. Because of our infraction of several years ago we have a meeting every 3 or 4 months between the physicist, the chief physician in the Nuclear Medicine section and myself (Chief, Radiation Therapy) and review our badge readings and other areas in which we have had Nuclear Regulatory infractions. We will thus watch ourselves in this regard as well.

We were also sited because no survey regarding the nurses who administer routine care to the patients with implant sources had been made. I am enclosing a copy of our new nursing instructions for the nurses who carry out routine care of a patient containing radioactive sources. This has recently been approved by the Hospital and will be incorporated in every patient chart. Because we carry out so few radium applications, perhaps 20 a year and they are on different floors, I did not think that any particular nurse would be exposed to the point that she needed a film badge, however, again we were mistaken and we have now arranged for film badges to be worn by all nurses on all shifts who routinely administer care to these patients receiving brachytherapy. We have made arrangements through the Department of Surgery, the Department of Gynecology, the Admissions Office and the Administration that all patients containing radiation be on the same floor, namely, Private 5 or St. Rita's 3. We anticipate

being able to keep track of badges for nurses on these floors and thus monitor them.

Thus corrective steps have been made in that all physicians and other personnel are now wearing their rings at this time. In order to avoid future non-compliance we will review our dosage to these rings every 3 to 4 months at our general meeting. Full compliance has now been achieved in regard to the TLD rings. In regard to the nurses, badges have been assigned to them as of this point and for all future brachytherapy source implantation nurses will be monitored by means of these badges.

2. We failed to adequately survey for license material in trash cans and shipping containers prior to disposing of their contents to the normal trash. A new survey procedure has been instituted to assure compliance with 10 CFR space 20.301; there is now a check off list for the survey of packages containing radioactive materials before opening them and a survey of the package after the removal of the radioactive material. Example of the work sheet is enclosed. Corrective steps have now been taken and we are now in full compliance. At our general meeting approximately 3 times a year we will also review these work sheets and our procedures to insure our continued compliance in this regard.

RE: Appendix A Part B

An instructional course in the risks from radiation exposure as well as the regulations of the NRC as set forth in 10 CFR Chapters 19, 20 and 35 and the provisions of our license as set forth in the license and of our letters of application will be given to all of the personnel who are working in the Nuclear Medicine section and brachytherapy preparation and storage areas. Specific emphasis will be placed on the procedures for opening and monitoring the packages and the necessity for properly monitoring their persons for contamination after working in areas where licensed material was used. We will also emphasize requirements for:

1. Personnel monitoring their hands for contamination after each and every procedure with licensed material.
2. Daily radiation surveys of the elution preparation and injection areas and recording the data.
3. Daily constancy checks on the dose calibrator.
4. Proper monitoring of the material prior to disposal in the normal trash.

This course will be given on July 9, 1980 and semi-annually thereafter. We will document this.

A course on the proper procedures for the nursing staff concerning the care of brachytherapy patients will also be given on July 15th and annually thereafter. The course will include the risks associated with radiation exposure as outlined in the appendix to the Regulatory Guide 08-902-1. Thus corrective steps have been taken in regard to these infractions and we will avoid future non-compliance by continuing these courses and by reviewing their scheduling in our meetings every 3 to 4 months. Full compliance will be achieved as of July 15, 1980 when all personnel working with nuclear materials have been instructed.

RE: Appendix A Part C

1. In regard to monitoring the hands of those who work in Nuclear Medicine after each procedure, new provisions have been made for a survey meter to be constantly in the hot lab area so that all personnel can check for contamination after drawing up any radio-pharmaceutical and before they leave the hot lab area.
2. In regard to the daily surveys of elution, preparation and injection areas a new check off list has been instituted which allows for surveys of the various rooms of the department as well as wipe tests of the different areas. An example of the check off list is enclosed.
3. In regard to a constancy check on our dose calibrator daily constancy checks with new sources - (Co-57, Co-60, Cs-137) are being done of the dose calibrator and logged in the appropriate manual.

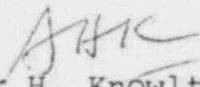
In regard to the above three items we are now in full compliance. We will review our steps in each 3 or 4 months at our meeting to make sure we continue in this regard.

In your letter you also were concerned about the air supply and exhaust to and from the room where xenon-133 studies are done. We are discussing improvement of the negative pressure in the room where the xenon-133 studies are done with the engineering department. Likewise on the day of inspection food was stored in the refrigerator located in the restricted area. It is our written policy that no food or beverages of any kind be permitted in a restricted area. All employees at the time of hiring are made aware of this and all other policies. The individuals with access to the restricted area have again been informed of this policy. Refusing to comply will result in suspension or dismissal of the individual.

To avoid future items of non-compliance besides the semi-annual courses in radiation safety given to the personnel involved we will have meetings every 3 to 4 months on a regularly scheduled basis including the physicist, the Chief of the Nuclear Medicine section and myself (Chief of Radiation Therapy). At such meeting we will also review new communications from the NRC and make adjustments in our operations.

Thus, I hope the steps we have taken will avoid future non-compliance of our license conditions and the rules and regulations of the NRC. Please advise if there are any further questions regarding these efforts at compliance.

Sincerely yours,


Arthur H. Knowlton, M.D.
Director
Radiation Therapy Center

AHK/sle

NURSING INSTRUCTIONS FOR PATIENTS
TREATED WITH BRACHYTHERAPY SOURCES

Patient _____

Record Number _____

Physician _____

Room Number _____

Isotope Activity _____

Isotope _____

Time/Date Administered _____

Time/Date to be Removed _____

EXPOSURE RATES in m R/hr
bedside _____
3 feet from bed _____
10 feet from bed _____

Observe and Enforce the following checked instructions:

- Wear film badge
- Wear rubber gloves
- Place laundry in linen bag and save
- Housekeeping may not enter room
- No visitors
- No pregnant visitors
- No visitors under 18 y/o
- Place patient in private room
- A dismissal survey must be performed before patient is discharged
- Other _____

Radiation Safety Officer/Physician

department extension 3131

off duty telephone

HOSPITAL OF ST. RAPHAEL-CLINICAL IMAGING-DEPT. OF NUC MED
RADIOACTIVE SHIPMENT RECEIPT AND DISPOSAL OF PACKAGES

- A. MATERIAL SHIPPED _____
- B. DATE _____
- C. TECHNOLOGIST _____
- D. SURVEY INSTRUMENT _____
- E. CONDITION OF THE PACKAGE _____
- F. LABELED TRANSPORT INDEX _____
- G. SURVEY AT PACKAGE SURFACE _____ mR/hr
- H. SURVEY 3" FROM SURFACE _____ mR/hr
- I. BACKGROUND _____ mR/hr
- J. SURVEY RESULTS OF PACKAGING CARTON AFTER REMOVAL
OF THE SHIPMENT AT SURFACE _____ mR/hr
- K. PACKAGE DISPOSED OF THROUGH TRASH? _____ YES
If _____ NO, state reason and action taken

If NRC or carrier notification required, give time,
date and persons notified.

L. LEAD CONTAINER SURVEY AFTER VIAL IS REMOVED

_____ mR/hr

To notify the NRC call:
U.S. Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406
337-5216

HOSPITAL OF ST. PAPAHEL

CLINICAL IMAGING-DEPT. OF NUCLEAR MEDICINE

DAILY PROTECTION SURVEY

Monitoring with survey meter

AREA

MR/hr - bkg

BACKGROUND= _____

- A. Hot Lab counter
- B. Hot Lab Tray
- C. Hot Lab Floor
- D. Picker 6l Tube
- E. Hallway
- F. Picker 4/11
- G. Rectilinear Scanner

Wipe Test counted with test tubes at survey meter

Background Cts/min _____

Cts/min - bkg

- A. Hot Lab counter
- B. Hot Lab Tray
- C. Hot Lab Floor
- D. Picker 6l Tube
- E. Hallway
- F. Picker 4/11
- G. Rectilinear Scanner

All wipe samples were obtained using an alcohol swab-

Date: _____ Technologist: _____

	F Picker 4/11		Hot Lab	B A
				C Picker 6l Tube 6l Tube D
G Rectilinear		E Hallway		
			office	

HOSPITAL OF ST. RAPHAEL-CLINICAL IMAGING-DEPT. OF NUC MED
RADIOACTIVE SHIPMENT RECEIPT AND DISPOSAL OF PACKAGES

- A. MATERIAL SHIPPED Caesium-137 I
B. DATE 3 June 80
C. TECHNOLOGIST Banks
D. SURVEY INSTRUMENT Hydra III
E. CONDITION OF THE PACKAGE OK
F. LABELED TRANSPORT INDEX .1
G. SURVEY AT PACKAGE SURFACE .2 mR/hr
H. SURVEY 3" FROM SURFACE .08 mR/hr
I. BACKGROUND .06 mR/hr
J. SURVEY RESULTS OF PACKAGING CARTON AFTER REMOVAL
OF THE SHIPMENT AT SURFACE .06 mR/hr
K. PACKAGE DISPOSED OF THROUGH TRASH? YES
If NO, state reason and action taken

If NRC or carrier notification required, give time,
date and persons notified.

L. LEAD CONTAINER SURVEY AFTER VIAL IS REMOVED

.02 mR/hr

To notify the NRC call:
U.S. Nuclear Regulatory Commission
Region I
631 Park Avenue
King of Prussia, PA 19406
337-5216

HOSPITAL OF ST. RAPHAEL

CLINICAL IMAGING-DEPT. OF NUCLEAR MEDICINE

DAILY PROTECTION SURVEY

Monitoring with survey meter

AREA		MR/hr - bkg
BACKGROUND=	<u>.06</u>	
A. Hot Lab counter	.07	.01
B. Hot Lab Tray	.09	.03
C. Hot Lab Floor	.06	0
D. Picker 6l Tube	.06	0
E. Hallway	.05	-.01
F. Picker 4/11	.04	-.02
G. Rectilinear Scanner	.04	-.02

Wipe Test counted with test tubes at survey meter

	Background Cts/min	Cts/min - bkg
A. Hot Lab counter	<u>175</u> 200	25
B. Hot Lab Tray	200	25
C. Hot Lab Floor	175	0
D. Picker 6l Tube	175	0
E. Hallway	150	-25
F. Picker 4/11	150	-25
G. Rectilinear Scanner	150	-25

All wipe samples were obtained using an alcohol swab-

Date: 6/12/80 Technologist: TRK

