December 21, 1994

Andrew Zampini, Vice president of Ancillary Services
St. Francis Hospital, Inc.
Seventh and Clayton Streets
Wilmington, DE 19805

SUBJECT: ROUTINE INSPECTION NO. 030-11759/94-001

Dear Mr. Zampini:

This letter refers to your December 1, 1994 correspondence, in response to our November 7, 1994 letter.

Thank you for informing us of the corrective and preventive actions documented in your letter. These actions will be examined during a future inspection of your licensed program.

Your cooperation with us is appreciated.

Sincerely,

Original Signed By:

John R. McGrath, Acting Chief
Medical Inspection Section
Division of Radiation Safety
and Safeguards

Docket No. 030-11759
License No. 07-16862-01

cc:
Public Document Room (PDR)
Nuclear Safety Information Center (NSIC)
Mitchell S. Rodman, M.D., Radiation Safety Officer

Distribution:
Region I Docket Room (w/concurrences)

DOCUMENT NAME: s:\pending\stfran.rl

OFFICE	DRSS/RI	DRSS/RI	DRSS/RI	DRSS/RI
NAME	Cahill/mc	JMcGrath		
DATE	12/20/94	12/21/94	12/ /94	12/ /94

OFFICIAL RECORD COPY

RETURN ORIGINAL TO REGION I IE:07

Franciscan Health System *
St. Francis Hospital

December 1, 1994

A Ministry
of the Sisters
of St. Francis
of Philadelphia

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC, 20555

SUBJECT: REPLY TO A NOTICE OF VIOLATION

Attached is our response to the Notice of Violation date November 7th, and received by us on November 16th, 1994. This notice of violation is a result of a routine inspection of our facility on October 24, 1994. (Inspection # 030-11759/94-001.

The format of the response is such that the letter designator for each section matches the letter designation of each item on the notice of violation. A copy of the Notice of Violation is attached.

If you have a questions or concerns regarding this response you may contact either Robert G. Stineman, Jr., CNMT, Nuclear Medicine Supervisor, or Dr. Mitchell Rodman, MD, Radiation Safety Officer, at 302-421-4365.

Respectfully:

Andrew A. Zampini
Vice President of Ancillary Services

cc: Regional Administrator, Region 1
U.S. Nuclear Regulatory Commission

Seventh & Clayton Sts.
P.O. Box 2500
Wilmington, DE
19805-0500
Tel (302) 421-4100
Fax (302) 421-4167

APPENDIX A

NOTICE OF VIOLATION

St. Francis Hospital, Inc.
Wilmington, Delaware 19805

Docket No. 030-11759
License No. 07-16862-01

During an NRC inspection conducted on October 24, 1994, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," 10 CFR Part 2, Appendix C, the violations are listed below:

A. 10 CFR 35.70(a) requires that a licensee survey with a radiation detection survey instrument at the end of each day of use all areas where radiopharmaceuticals are routinely prepared for use or administered.

Contrary to the above, as of October 24, 1994, the licensee did not survey with a radiation detection instrument at the end of each day areas around two scanning tables where radiopharmaceuticals were routinely administered.

This is a Severity Level IV violation (Supplement VI).

B. 10 CFR 35.70(b) requires that a licensee survey with a radiation detection survey instrument at least once each week all areas where radiopharmaceuticals or radiopharmaceutical waste is stored.

Contrary to the above, from July 27, 1994 to October 24, 1994, the licensee did not survey with a radiation detection survey instrument at least once each week the remote waste storage room, an area where radiopharmaceutical waste was stored.

This is a Severity Level IV violation (Supplement VI).

C. 10 CFR 35.315(a)(4) requires, in part, that records of dose rates measured in contiguous restricted and unrestricted areas of rooms of patients receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75 be retained for three years.

Contrary to the above, a record of the dose rates measured in contiguous restricted and unrestricted areas of rooms of patients receiving radiopharmaceutical therapy and hospitalized for compliance with 10 CFR 35.75 was not maintained. Specifically, a record of dose rates measured in contiguous unrestricted areas of a room which housed a patient who had been administered a 150 millicurie dose of iodine-131 on July 27, 1994, was not maintained.

This is a Severity Level V violation (Supplement VI).

D. 10 CFR 35.32(b) requires, in part, that the licensee develop procedures for and conduct a review to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

Contrary to the above, from January 27, 1992 to October 24, 1994, the licensee did not conduct a review to verify compliance with the licensee's quality management program.

This is a Severity Level IV violation (Supplement VI).

E. 10 CFR 35.20 requires that each licensee develop and implement a written radiation protection program that includes provisions for keeping doses ALARA. The application dated July 19, 1991 describes the licensee's ALARA program as that contained in Appendix G of Regulatory Guide 10.8, Revision 2, and approved by Condition 14 of the license.

Item 3.a of the ALARA program states that the Radiation Safety Officer will review as least quarterly the external radiation doses of authorized users and workers to determine that their doses are ALARA and that doses received in excess of the licensee's established investigational levels are noted or investigated, and reported to the Radiation Safety Committee.

Contrary to the above, the Radiation Safety Officer did not report several doses received by individuals which were in excess of the licensee's established investigational levels during the period January 1, 1993 to October 24, 1994 to the Radiation Safety Committee.

This is a Severity Level IV violation (Supplement VI).

Pursuant to the provisions of 10 CFR 2.201, St. Francis Hospital, Inc. is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued to show cause why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

REPLY TO NOTICE OF VIOLATION

St. Francis Hospital, Inc.
Wilmington, De., 19805

Docket No. 030-11759
License No. 07-16862-01

VIOLATION A:

The imaging tables that are mentioned are not routinely used for injection. Only patients requiring imaging at the time of injection are injected on the imaging tables. During our last inspection the fact that these tables were not routinely monitored each day was not mentioned as a violation.

As a result of the inspection of October 24 we have changed our monitoring procedures. All imaging tables are now surveyed daily, and wipes are done weekly. This change became effective October 24, 1994.

VIOLATION B

The remote decay storage area is used only for the linen and trash removed from the room of patients having I-131 therapy that is in excess of 30mCi. We have only done two of these patients in the last five years. The most recent was in August of this year. The waste was placed in the storage room and the room was surveyed, the results of which were 0.03 mR/Hr.

Through an oversight on the part of the Nuclear Medicine Supervisor the room was not monitored after this initial reading. Our procedures have been strengthened by reeducation of Nuclear Medicine Staff to prevent another occurrence in the future. This reeducation process has been completed with the appropriate staff. Presently the room contains no waste materials.

VIOLATION C

This is a result of the same therapy administration listed in Violation B. The room, and all adjoining occupied areas were monitored and the results were recorded. The results were recorded by the Radiation Safety Officer as an addendum to the medical report on the patients therapy. Through a computer error this addendum was lost, and was not available for inspection.

A separate form is being developed for recording these readings, which will be maintained in the Nuclear Medicine Department as a part of the

Therapy Dose administration records. This will be completed within the next 30 days. No therapy patients requiring this type of monitoring will be done until this form is completed.

VIOLATION D

This is a result of a misunderstanding of the requirements of the Quality Management program as outlined in 10 CFR, Part 35. The lack of an annual audit of the program was identified as a result of a review of our quality management program that occurred in June of this year. As a result of that review our policy was revised to indicate that a review of the quality management program would be included in our annual radiation safety audit, which is done at the end of the calendar year.

When the inspection on October 24th indicated that an annual audit of the program had not been done an audit was immediately completed. A copy of this audit is attached as Attachment A. Another audit will be included in the Radiation Safety Program audit that will be held the end of this year (1994). We feel we are now in compliance.

VIOLATION E

A review of our radiation exposure records during the period of January 1, 1993 to October 24, 1994 reveals that there were two instances where recorded exposure levels were higher than our Level I trigger. These readings were 160 and 170 mrem/quarter. Our trigger level for Level I is 135 mrems/quarter.

These higher readings were determined to be a result of the badges for the wrist and whole body badge holders being inadvertently switched. This is apparent when looking at the report, since the readings for each of these badges is opposite what is expected. In each case the reported whole body exposure was greater than the wrist exposure. This result could not occur in the employee performing their duties of hot lab preparations and injecting. This was determined by the Nuclear Medicine Supervisor, who reported it verbally to the Radiation Safety Officer, but it was not documented in writing. The incident was not reported to the Radiation Safety Committee.

This problem will be prevented from reoccurring by requiring any suspected discrepancies or problems be reported in writing to the Radiation Safety Officer, who in turn must include these events, and the out come of any investigation in his written report to the Radiation Safety Committee.

ATTACHMENT A

INTERNAL AUDIT OF THE NRC QUALITY MANAGEMENT PROGRAM AT ST. FRANCIS HOSPITAL

OVERVIEW

This is an internal audit of the Quality Management Program (QMP) as is implemented at St. Francis Hospital. The QMP is a Nuclear Regulatory Commission (NRC) mandated program to assure that all patients receiving any radionuclide therapy or any dose of I-131 over 30 uCi are being dosed appropriately. The purpose of this audit is to assure that the program is being properly implemented and followed by all involved personnel.

AUDIT PERFORMED BY: Robert G. Stineman, Jr., CNMT
Nuclear Medicine Supervisor

AUDIT REVIEWED BY: Dr. Mitchell Rodman, MD
Radiation Safety Officer.

AUDIT PERIOD: 1/01/93 thru 10/31/94

TOTAL NUMBER OF PATIENTS INCLUDED: 34

AUDIT RESULTS:

The records of 34 patients who had either Sr89 therapy or doses of I-131 in excess of 30uCi were reviewed. The following is a break down of the types:

Sr89 Therapy:	4
I-131 Therapy:	28
I-131 WB Imaging:	2

All doses to be administered were determined by the administering User, either Dr. Rodman or Dr. Yoo. The order was verbally given to a Nuclear Medicine Technologist, and was followed up with a written order. The written order is the ordering and administration form developed for use in the department. The exception to this was for the 2 Whole Body imaging procedures. The dosage for these procedures is documented in the Department Procedure Manual as 3.0 mCi.

At the time the requested dosage was ordered from the RadioPharmacy the person placing the order entered the activity ordered and his/her name on the administration form.

At the time of dose administration the identity of all patients was confirmed by the administering individual. Identity was verified by both verbal response from the patient, and at least one other form of written identification, such as a drivers license.

ATTACHMENT A

All doses administered were within +/- 10% of the ordered dose.

All therapy doses were assayed and verified by the administering user immediately before administration. The approved Users for I-131 and Sr89 therapy at this facility are Drs.; Rodman and Yoo.

The person administering the dose signed the bottom of the administration form, thereby verifying that all steps had been taken.

The forms are filed alphabetically in a binder located in the Nuclear Medicine Department.

PROBLEMS IDENTIFIED

The physician ordering the therapy dose is not properly signing and dating the form at the time the order is given to the Technologist. NRC QMP regulations require that the dosage order be signed, and dated by the approved User (Dr. Rodman or Yoo) at the time it is given to the Technologist. This is to assure that there is no misunderstanding as to the size of the dose to be ordered.

The department administration form has not included a separate signature and date line for the Physicians order of the therapeutic dose. It was not, therefore, documented that the written order had been provided prior to the administration of the therapy. The form also did not provide for separate referring and ordering Physicians. The form has been revised and the updated form is attached.

Both Users will be advised of the importance of signing the order form appropriately. All Technologists will be instructed not to accept any form for ordering a dose that is not properly signed and dated.

ATTACHMENT A

I-131 & Sr89 ORDERING & ADMINISTRATION RECORD
(I-131 DOSES > 30 UCI)

PROCEDURE DATE: _____

PATIENT NAME : _____

M.R. # _____ D.O.B.: _____

SEX: M___ F___ LMP: _____

NURSING: ❒ YES ❒ NO

DIAGNOSIS: _____

REFERRING PHYSICIAN: _____

APPROVED USER: ❒ RODMAN ❒ YOO

RADIONUCLIDE: ❒ ^{131}I ❒ ^{89}Sr

DOSE: _____mCi

USER's SIGNATURE: _____ DATE: _____

RADIOPHARMACY ORDER PLACED BY: _____

DOSAGE RECEIVED: _____ mCi DOSAGE GIVEN: _____mCi

ROUTE OF ADMINISTRATION: ❒ P.O. ❒ I.V.

ADMINISTERING PHYSICIAN: _____

PHYSICIAN's SIGNATURE: _____ DATE: _____

PATIENT IDENTIFICATION VERIFICATION

PATIENT RESPONDED VERBALLY TO NAME: ❒ YES ❒ NO

PATIENT I.D. VERIFIED BY AT LEAST ONE OF THE FOLLOWING:

❒ PHOTO DRIVERS LICENSE

❒ OTHER PHOTO I.D

❒ SOCIAL SECURITY CARD

❒ VOTER REGISTRATION CARD

❒ OTHER: _____

FORM COMPLETED BY : _____

(revised 11/01/94)

St Francis Hospital

TO: Rodman Mitchell ID#: 00230 Department: MD

FROM: St Francis Hospital
Attn Linda Smith
Radiology Department
7Th & Clayton Street
Wilmington DE 19805

September 17, 1994

SUBJECT: Level 1 Radiation Exposure

The intent of an ALARA program ("as low as reasonably achievable") is to maintain exposure to radiation at levels that are as low as feasible. Our radiation safety program is based on the premise that radiation exposure is not risk free and therefore, exposure should be kept to levels below the limits permitted by the State, the Nuclear Regulatory Commission and other regulatory agencies. ALARA is critical to current radiation protection philosophy.

Permissable exposure level is:

Whole body deep 5000 mrem/yr, 1250 mrem/qtr.

For the 08/01/94 to 08/31/94 wear period, your cumulative quarterly radiation exposure is now:

Whole body deep 130 mrem.

Our level 1 investigation limit is:

Whole body deep 125 mrem to 374 mrem.

Monitored personnel are notified when their exposure meets this level's criteria.

Your dose is relatively low, and below regulatory limits, but does indicate a need to review work procedures in order to, if feasible, further reduce your exposure. Apply the basic rules of time, distance and shielding to keep your exposure as low as possible.

St Francis Hospital

TO: Rao Sadashiva ID#: 00241 Department: MD

FROM: St Francis Hospital
Attn Linda Smith
Radiology Department
7Th & Clayton Street
Wilmington DE 19805

August 12, 1994

SUBJECT: Level 2 Radiation Exposure

The intent of an ALARA program ("as low as reasonably achievable") is to maintain exposure to radiation at levels that are as low as feasible. Our radiation safety program is based on the premise that radiation exposure is not risk free and therefore, exposure should be kept to levels below the limits permitted by the State, the Nuclear Regulatory Commission and other regulatory agencies. ALARA is critical to current radiation protection philosophy.

Permissable exposure level is:

Whole body deep 5000 mrem/yr, 1250 mrem/qtr.

For the 06/01/94 to 06/30/94 wear period, your cumulative quarterly radiation exposure is now:

Whole body deep 490 mrem.

Our level 2 investigation limit is:

Whole body deep 375 mrem and above.

Monitored personnel are notified when their exposure meets this level's criteria.

Your dose is above our level 2 limit, and indicates a need to review work procedures in order to, if feasible, further reduce your exposure. Apply the basic rules of time, distance and shielding to keep your exposure as low as possible.

PATIENT SUMMARY FOR DRUG AND/OR PROCEDURE CHARGES
Period 01/01/93-10/23/94 DE1-ST. FRANCIS HOSPITAL
Drug: 0510 METASTRON All Procedures

10/24/94

NMBR	STUDY NUMBER	ADMINISTRATION DATE & TIME	PROC NMBR	PROCEDURE DESCRIPTION	PATIENT NAME	PATIENT NUMBER	PATIENT STATUS	PT. AGE	REFERRING PHYSCIAN	DRUG CODE	DRUG DESCRIPTION	VENDOR	ACTIVITY DISPENSED	TOTAL VOLUME	VALUE	TIME VALUE	INITIAL
** Patient Exam Date - 09/15/93																	
1	20308	09/15/93@ 14:00	0000050	METASTRON THERAPY	BELL, EDWARD T. JR.	00-00-53-4	IN	69	JAMES LOUGHRAN	0510-005	METASTRON	MEDI+PHYSICS	4.1900mCi	4.19mCi	2000.00	1.00	RGS
** Subtotal **																	
1															2000.00	1.00	
** Patient Exam Date - 11/19/93																	
1	21490	11/19/93@ 9:45	0000050	METASTRON THERAPY	KAY, MARY L.	17-57-58-2	OPD	71	MARVIN DORPH	0510-005	METASTRON	MEDI+PHYSICS	3.3086mCi	3.31mCi	2000.00	1.00	RGS
** Subtotal **																	
1															2000.00	1.00	
** Patient Exam Date - 12/09/93																	
1	21827	12/09/93@ 10:30	0000050	METASTRON THERAPY	BARNES, RUFUS	03-09-52-6	OPD	72	JOSE GUECO	0510-005	METASTRON	MEDI+PHYSICS	2.9900mCi	2.86mCi	2000.00	1.00	
** Subtotal **																	
1															2000.00	1.00	
** Patient Exam Date - 10/05/94																	
1	26553	10/05/94@ 10:15	0000050	METASTRON THERAPY	MARVEL, KENNARD A.	13-69-54-5	OPD	77	SIAMAK SAMII	0510-005	METASTRON	MEDI+PHYSICS	4.0398mCi	3.94mCi	2800.00	1.00	
** Subtotal **																	
1															2800.00	1.00	
*** Total ***																	
4															8800.00	4.00	