"RESPONSE TO APPARENT VIOLATIONS AND INSPECTION REPORT #030-20901/96001(DNMS)"

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ST. FRANCIS HOSPITAL

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INTRODUCTION

St. Francis Hospital (licensee) acknowledges the correspondence of January 3, 1997 and specifically acknowledges the executive summary of Apparent Violations (Exhibit 1). The licensee has undergone a thorough review of the situation which occurred during the inspection of July 15, 1996 in the form of direct interviews with all of the members of the Nuclear Medicine Department. The licensee acknowledges that the report is essentially accurate and that the conduct described by the inspector is essentially accurate. The review of the problem is also ongoing in the sense that the licensee has determined that it requires assistance from an outside consultant. Consequently, the retention of Medical Physics, Inc. of Ann Arbor Michigan has occurred. Evaluation of in-service and refresher education courses is currently ongoing, and a continuing review of the procedures and policies is also currently ongoing.

The licensee would state, with regard to the facts that were relied upon in the report, that it is believed that at no time were any of the values recorded inaccurate or not reflective of the conditions existent on the premises at the time those values were recorded. The licensee acknowledges that the procedures were not followed, but it does believe that the values on the various tests accurately reflected the conditions existing on the premises and that there was no immediate danger to the health and safety of workers or the general public.

It has been determined by management that the root causes for the problems involved in these apparent violations relate to an employee who deliberately disregarded the directives and procedures within the department, and further, that the procedures that were in place for all nuclear technologists needed emphasis and strengthening. Management has determined to increase its supervision of the Nuclear Medicine Department, and to improve its training program as these may also have been attendant causes of the apparent violations.

As a result of these apparent violations, the licensee took immediate corrective actions with regard to its short-term, cross-trained x-ray technologist. (See Exhibit 2) Immediately upon having these matters brought to their attention, the radiation safety officer and his associate personally monitored the radiation safety procedures. The temporary tech was also provided with additional immediate in-service training, including a complete review of the procedure manual and a review of the proper procedures for doing radiation checks and documentation maintenance. The temporary tech was monitored throughout the last three days of his shift work. Since this incident, that individual has not returned to work in the Nuclear Medicine Department. On November 1, 1996 management hired a second certified nuclear medicine technologist. In addition, the Nuclear Medicine Department promulgated two additional policies (Exhibits 3 and 4) which have been reviewed to increase the level of continuing education and to emphasize the daily routine quality assurance and radiation safety checklist. This program requires the countersignature of the

radiation safety officer or other authorized user upon completion by any new hire or technologist. The radiation safety officer will also observe performance training and include a sign-off procedure, which will insure greater emphasis upon this training. A new employee, or a temporary employee, will be monitored for the first week of employment by the radiation safety officer or other authorized user.

In December of 1996, the hospital contacted Medical Physics, Inc. consultants and entered into a relationship whereby they would provide consultation and review of all of the procedures and training with the Nuclear Medicine Department. Subsequently, Medical Physics has been contracted to provide an annual refresher course in nuclear medicine, and also to provide assistance in evaluating the training policies and procedures.

APPARENT VIOLATIONS

1. On July 15, 1996 records of the daily dose calibrator checks, a record required to be maintained, were not accurate in all material respects, which is an apparent violation of 10 CFR 30.9(A). Specifically, results for the dose calibrator constancy check were recorded prior to the test being completed (§4).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate

supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or other authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and

scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. The new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they have read and reviewed policy, procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

2. Failure to perform daily dose calibrator constancy checks on the available dose calibrator at the beginning of the day on July 15, 1996, is an apparent violation of 10 CFR 35.50(b)(1) (Section 4).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or other authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. The new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they read and review policy procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

3. On July 15, 1996, the record of the molybdenum concentration for that days eluent, a record required to be maintained, was not accurate in all material respects, which is an apparent violation of 10 CFR 30.9)a). Specifically, results for the molybdenum concentration test were recorded prior to the test being completed (Section 4).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or other authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. The new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they read and review policy procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

4. Failure to perform molybdenum-99 concentration measurements for each molybdenum-99/technetium-99m generator elution prior to administering doses to humans on July 15, 1996, is an apparent violation of 10 CFR 35.204(a) and 10 CFR 35.204(b) (Section 4).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or other authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. It is anticipated that the new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they read and review policy procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

5. On July 15, 1996, the record of the area radiation surveys for the end of the day, a record required to be maintained, was not accurate in all material respects, which is an apparent violation of 10 CFR 30.9(a). Specifically, results for the survey were recorded prior to the test being completed (Section 5).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or other authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. The new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they read and review policy procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

6. Failure to perform surveys of the external surface of a labelled package containing a 1.5 curie molybdenum-99/technetium-99m generator for radioactive contamination is an apparent violation of 10 CFR 20.1906(b)(1) (Section 6).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or other authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. The new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they read and review policy procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

7. Failure to perform surveys of the external surface of the package containing a 1.5 curie molybdenum-99/technetium-99m generator for radiation levels is an apparent violation of License Condition 13.A (Section 6).

A. Reason For Violation:

This violation occurred because of the deliberate behavior of the cross-trained temporary technologist. The failure of the technologist to follow established procedures was contributed to by the failure of the hospital to provide appropriate supervisory and educational emphasis of the importance of the procedures and their timely sequence.

B. Corrective Steps Taken And Results:

The initial corrective steps that were taken involved the monitoring of the technologist's activities by the radiation safety officer or authorized user on a daily basis with a countersignature. As this individual only worked in the laboratory for three more days after the apparent violations, this occurred through the week of July 15, 1996. Additional in-service training was provided by the certified nuclear technologist on or about August 1, 1996, including proper procedures for doing radiation checks and documentation. During any absences of the certified nuclear technologist, the cross-trained x-ray technologist had the radiation safety procedures cross-checked by the radiation safety officer or other authorized user.

In November of 1996, management hired an additional (second) certified nuclear medical technician, thereby greatly reducing the likelihood that the cross-trained technologist involved in this incident would be active in the Nuclear Medicine Department. In January of 1997 the cross-trained technologist was terminated from employment with the hospital.

The hospital adopted new department procedures for temporary help and/or new employees (Exhibit 3) and daily routine quality assurance in radiation safety (Exhibit 4) in February of 1997. These policies have been under review and scrutiny by both members of the hospital and the consultant since the fall of 1996, when the apparent violations were brought to the attention of the hospital.

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The hospital's training and reviews will involve intensive emphasis upon radiation safety and procedural compliance. The new worker and refresher training programs will involve radiation safety officer observations and performance training with sign-off procedures, as well as sign-off procedures for technologists when they read and review policy procedures and conditions of the license applicable to that technologist.

D. Date Of Full Compliance:

The licensee believes that it is currently within full compliance as to this apparent violation, and has been within full compliance as of July 16, 1996.

8. The failure to provide an individual working with radioactive material with annual refresher training is an apparent violation of License Condition 13.A (Section 7).

A. Reason For Violation:

It is the position of the licensee that the individual cross-trained technician was provided with an annual refresher course by the certified licensed technologist. However, upon review, it is apparent that there was no countersignature procedure and that the refresher course was not sufficient to clearly emphasize the appropriate procedures and sequence of testing procedures and package handling. The reason for this violation was the lack of a formalized refresher or training policy by the licensee.

B. Corrective Steps Taken And Results:

As indicated above, the implementation of modified policies (Exhibits 3 and 4), as well as immediate refresher training to the individual employee (see Exhibit 2) with regard to radiation safety officer activities taken immediately after this incident were the short-term steps taken to correct the violation. The licensee has contracted with Medical Physics, Inc. to provide the annual refresher course to all members of the Nuclear Medicine Department, and has included within those procedures that the annual refresher course and new hires will involve the technologist reading and reviewing policies, procedures and conditions of the license, which are applicable to that technologist, having a direct contact with the radiation safety officer or physicist, to discuss any questions or concerns, and a signing off by the technologist and the radiation safety officer or physicist to demonstrate that the procedures were reviewed and understood.

The radiation safety officer will then observe, in the form of performance training, that technologist for at least a week, and will also observe the performance and utilize a sign-off procedure of the technologist, on each of the required procedures and tests as outlined in the policy.

In addition, a new employee will be monitored for the first week of their employment by the RSO or authorized user. The monitoring will consist of a sign-off and observation of all of the procedures as denominated in the exhibit.

C. Corrective Steps That Will Be Taken To Further Violations:

The licensee believes that the retention of the consultant to provide the programs and to provide review and testing of competency will insure a greater emphasis on supervision by the radiation safety officer, and will provide for a higher level of proficiency in the employees.

D. Date Of Full Compliance:

The licensee believes that the implementation of the policies and the implementation of the retention of Medical Physics, Inc. and their consultants has corrected this action, and that the full compliance with the license condition was attained by August 1, 1996.

9. The failure of the license to adequately instruct an individual in the principles of radiation safety appropriate to the individual's use of byproduct material and the failure of the licensee to require a supervised individual to follow written radiation safety procedures in an apparent violation of 10 CFR 35.25(a)(1) and (2) (Section 8).

A. Reason For Violation:

The licensee denies that the individual was not adequately instructed in the principles of radiation safety as he deliberately chose to ignore those instructions. The licensee admits that its policies and procedures did not appropriately emphasize, nor appropriately supervise, the individual to compel that individual to follow the safety procedures and required procedures. The reason for this violation is

apparently a failure to appropriately emphasize and to appropriately supervise the importance of procedural compliance.

B. Corrective Steps Taken And Results:

Corrective steps were taken immediately upon bringing this to the attention of management. The licensee instructed its radiation safety officer or licensed physicist to monitor the behavior of the cross-trained technician, including review of the procedures and activities throughout the remaining three days of his involvement in the Nuclear Medicine Department. Subsequently, the individual was provided with a review of the safety policies and procedures as indicated in Exhibit 2 by the licensed technologist.

In addition, the hospital has reviewed its policies and procedures and implemented new policies requiring sign-off or countersignature by the radiation safety officer or the licensed physicist. (See Exhibits 3 and 4)

C. Corrective Steps That Will Be Taken To Avoid Further Violations:

The in-service instruction will provide testing of competency, as well as review of policies and procedures for all of the employees who are working in the Nuclear Medicine Department.

D. Date Of Full Compliance:

The licensee believes that full compliance was achieved with regards to the individual involved in this incident on July 16, 1996. Full compliance with the improved educational program has been accomplished by February 3, 1997.

SUMMARY

It is the position of the licensee that it has carefully reviewed the apparent violations and taken appropriate actions to alleviate the immediate problems, while looking deeper into the prevention of future problems. In its analysis of these apparent violations, management has determined that there were a combination of causes involved here. The combination consisted of actions taken by a cross-trained employee that were deliberate in failing to follow the existing procedures. Coincidentally, management also believes that there was a lack of emphasis and procedural safeguards in place to protect against an employee who would not follow the regulations or procedures. Consequently, management has taken steps to change the educational levels of the employees working in the department by hiring an additional certified technologist, and by utilizing the services of an independent consultant to assist in formalizing its ongoing educational requirements, and in formalizing its own supervisory requirements by its radiation safety officer or other licensed employee.

OSF ST. FRANCIS HOSPITAL

Dated: 2-21-97 By: Roger Burgess
Roger Burgess
Chief Executive Officer

Dated: 2/20/97 By: Leon Kinasiewicz MS.
Leon Kinasiewicz
Radiation Safety Officer

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EXECUTIVE SUMMARY

St. Francis Hospital
Escanaba, Michigan
NRC Inspection Report 030-11102/96001(DNMS)

This was a routine, unannounced inspection of the licensee's radiation safety program and activities authorized by the license. The inspection identified nine apparent violations as follows:

1. On July 15, 1996, records of daily dose calibrator checks, a record required to be maintained, were not accurate in all material respects, which is an apparent violation of 10 CFR 30.9(a). Specifically, results for the dose calibrator constancy check were recorded prior to the test being completed (Section 4).

2. Failure to perform daily dose calibrator constancy checks on the available dose calibrator at the beginning of the day on July 15, 1996, is an apparent violation of 10 CFR 35.50(b)(1) (Section 4).

3. On July 15, 1996, the record of the molybdenum concentration for that days eluent, a record required to be maintained, was not accurate in all material respects, which is an apparent violation of 10 CFR 30.9(a). Specifically, results for the molybdenum concentration test were recorded prior to the test being completed (Section 4).

4. Failure to perform molybdenum-99 concentration measurements for each molybdenum-99/technetium-99m generator elution prior to administering doses to humans on July 15, 1996, is an apparent violation of 10 CFR 35.204(a) and 10 CFR 35.204(b) (Section 4).

5. On July 15, 1996, the record of the area radiation surveys for the end of the day, a record required to be maintained, was not accurate in all material respects, which is an apparent violation of 10 CFR 30.9(a). Specifically, results for the survey were recorded prior to the test being completed (Section 5).

6. Failure to perform surveys of the external surface of a labelled package containing a 1.5 curie molybdenum-99/technetium-99m generator for radioactive contamination is an apparent violation of 10 CFR 20.1906(b)(1) (Section 6).

7. Failure to perform surveys of the external surface of the package containing a 1.5 curie molybdenum-99/technetium-99m generator for radiation levels is an apparent violation of License Condition 13.A (Section 6).

8. The failure to provide an individual working with radioactive material with annual refresher training is an apparent violation of License Condition 13.A (Section 7).

9. The failure of the licensee to adequately instruct an individual in the principles of radiation safety appropriate to the individual's use of byproduct material and the failure of the licensee to require a supervised individual to follow written radiation safety procedures is an apparent violation of 10 CFR 35.25(a)(1) and (2) (Section 8).

The apparent root cause for these violations was under further NRC review as of the end of the inspection.

OSF
ST. FRANCIS HOSPITAL

August 2, 1996

Sam Mulay
Radiation Specialist
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle IL 60532

Dear Mr. Mulay:

This is a response to our conference call on August 1, 1996. The x-ray technologist we spoke of works in the nuclear medicine department approximately three weeks per year when Mr. Roy Djerf is on vacation. Prior to any future work in this department he will receive additional in-service training by Mr. Djerf including proper procedures for doing radiation checks and documentation. He will also review the procedure manual. During Mr. Djerf's absence, the x-ray technologist will have the radiation safety procedures checked by Dr. Stephen Manier or by myself.

I hope this has addressed you concerns from the inspection on July 15, 1996.

Sincerely,

Leon Kinasiewicz, M.D.
Radiation Safety Officer

cc: Mr. Monty Phillips, U.S. Nuclear Regulatory Commission
Mr. Roger Burgess, Administrator, St. Francis Hospital

Exhibit 2

OSF
ST. FRANCIS HOSPITAL

MEDICAL IMAGING DEPARTMENT POLICY AND PROCEDURE MANUAL

SECTION: NUCLEAR MEDICINE

Effective Date: 10-1-96
Reviewed/Revised: 2-13-97

Subject: Temporary and/or New Employees

The purpose of this policy is to define the procedure used to determine the competency of new or temporary employees in the Nuclear Medicine Department in regard to Radiation Safety.

1) During the first week the Radiation Safety Officer (RSO) or authorized user will observe the new technologist as he/she elutes the generator, checks the Mo-99/Tc-99 ratios and performs the dose calibrator constancy checks. The RSO or authorized user will also observe the technologist In his/her general safety procedures.

2) At the end of the first day the RSO or authorized user will observe the radiation survey that is done to check the daily ambient exposure rates in the department.

3) The RSO or radiologist will counter initial all surveys done by the technologist.

4) If the RSO or authorized user is satisfied with demonstrated competency of the technologist after the first week of observation he/she need only countersign the readings on the survey sheet At the end of each month from that point on.

5) The technologists will review sign the "Nuclear Medicine Technologist Performance Training Radiation Safety and Operating Procedures" written instruction annually. The documents to be reviewed are from the "Guide to Preparation of Medical Licenses" and include:
-NRC Reg. 8.13 and 1.29
-Rules for safe use of radiopharmaceuticals
-Radioactive spill procedure
-Ordering and receiving radioactive materials
-Procedure for safely opening packages containing radioactive material
- Records of byproduct material use
-Procedure for waste disposal
-Procedure for monitoring and controlling air concentrations
-Quality management program

NUCLEAR MEDICINE NEW EMPLOYEE POLICY AND PROCEDURE

The technologists will be observed annually by the RSO or authorized user performing the routine radiation safety/required tasks, including:

-Dose calibrator constancy check
-Survey meter operational check
-Package check-in and applicable limits
-Radiation level survey
-Removable contamination wipe test
-Hand/clothing monitoring
-Proper use of syringe shield, gloves, lab coat
-Waste disposal
-Spill response
-Patient identification
-Patient dosage assays
-IV injection
-Well Counter peaking and set-up
-Kit preparation
-Xenon-133 trap check, clearance time and posting.

The RSO or authorized user will indicate acceptable performance of these tasks by signing the competency training form.

APPROVED BY:

_____

MEDICAL IMAGING MANAGER

Ron D Kwasniewski MP

_____

RADIATION SAFETY OFFICER OR AUTHORIZED USER

OSF
ST. FRANCIS HOSPITAL

MEDICAL IMAGING DEPARTMENT POLICY AND PROCEDURE MANUAL

SECTION: NUCLEAR MEDICINE

Effective Date: 10-1-96
Reviewed/Revised: 2-13-97

Subject: Routine Quality Control and Radiation Safety

The following procedures must be done on a routine basis in the order listed below for Quality Control and Radiation Safety. Please refer to other sections of this manual or license application for actual instructions.

PROCEDURE:

1) Dose calibrator constancy check
2) Generator elution
   A. Total activity assay
   B. MO-99 break-through test (with uCi Mo-99 per mCiTc-99 noted)
3) Radiation surveys
   A. Daily ambient exposure rate
   B. Daily survey meter operational check
   C. Daily personnel monitoring for hand/clothing contamination (and whenever deemed necessary)
4) Weekly wipe tests
5) Package receipt procedures
6) Emergency spill procedure
7) General rules for safe use of radioactive materials
8) All tests are to be documented on the proper forms
9) RSO is to be notified of any abnormal readings or events

APPROVED BY:

_____
MEDICAL IMAGING MANAGER

Leon B Kwasniewski M.P.
_____
RADIATION SAFETY OFFICER OR AUTHORIZED USER

OSF
ST. FRANCIS HOSPITAL

NUCLEAR MEDICINE TECHNOLOGIST PERFORMANCE TRAINING
RADIATION SAFETY AND OPERATING PROCEDURES

WRITTEN INSTRUCTION

I have read the following documents and understand their content. If I have any questions in the future regarding these matters, I realize I may request additional information from my supervisor, the Radiation Safety Officer, or a physicist at Medical Physics Consultants, Inc., (313) 662-3197. These items can be found in your license application or in NRC Regulatory Guide 10.8 "Guide to Preparation of Medical Licenses".

____ NRC Reg. Guide 8.13 "Instruction Concerning Prenatal Radiation Exposure"
____ NRC Reg. Guide 8.29 "Instruction Concerning Risks from Occupational Exposure"
____ Rules for Safe Use of Radiopharmaceuticals
____ Radioactive Spill Procedure
____ Ordering and Receiving Radioactive Materials
____ Procedure for Safely Opening Packages Containing Radioactive Material
____ Records of Byproduct Material Use
____ Procedure for Waste Disposal
____ Procedure for Monitoring and Controlling Air Concentrations
____ Quality Management Program

Signed_____Date_____

COMPETENCY TRAINING

The above individual has been observed in the acceptable performance of the routine radiation safety/required tasks checked below. Any discrepancies observed have been discussed with the individual.

____ Dose calibrator constancy check
____ Survey meter operational check
____ Package check-in and applicable limits
____ [illegible] level survey
____ [illegible]ble contamination wipe test
____ [illegible]thing monitoring
____ [illegible]se of syringe shield, gloves, lab coat
____ [illegible] disposal
____ [illegible]esponse
____ [illegible]tient identification
____ Patient dosage assays
____ IV injection
____ Well Counter peaking and setup
____ Kit preparation
____ Xenon-133 trap check, clearance time and posting location

Observed by_____Title_____Date_____