

U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-10713/90002(DRSS)

Docket No. 030-10713

License No. 21-16277-01

EA 90-172

Licensee: West Shore Hospital
1465 East Parkdale Avenue
Manistee, MI 49660

Inspection Conducted: September 27, 1990

Meeting At: Region III Office, Glen Ellyn, IL

Meeting Conducted: October 22, 1990

Type of Meeting: Enforcement Conference

Inspectors:

Bryan A. Parker
Bryan A. Parker
Radiation Specialist

10/30/90
Date

Reviewed By:

Roy J. Caniano
Roy J. Caniano, Chief
Nuclear Materials Safety
Section 2

10/30/90
Date

Approved By:

John A. Grobe
John A. Grobe, Chief
Nuclear Materials Safety Branch

11-2-90
Date

Meeting Summary

Meeting on October 22, 1990 (Report No. 030-10713/90002(DRSS))

Areas Discussed: Included a review of apparent violations and areas of concern identified during a recent NRC inspection and a discussion of the enforcement options available to the NRC.

DETAILS

1. Persons In Attendance

West Shore Hospital

Burton Parks, Administrator
Lawrence Jackowski, D.O., Radiation Safety Officer
James Brand, Radiology Manager
Richard Wilson, Jr., General Counsel

U.S. Nuclear Regulatory Commission - Region III

C. E. Norelius, Director, Division of Radiation Safety and Safeguards
W. L. Axelson, Deputy Director, Division of Radiation Safety and Safeguards
J. A. Grobe, Chief, Nuclear Materials Safety Branch
R. J. Caniano, Chief, Nuclear Materials Safety Section 2
C. D. Pederson, Director, Enforcement and Investigation Coordination Staff
C. H. Weil, Enforcement Coordinator
B. A. Parker, Radiation Specialist
M. F. Kurth, Radiation Specialist

2. Enforcement Conference Summary

An Enforcement Conference was held in the Region III office on October 22, 1990. The conference was a result of the findings from the September 27, 1990, special inspection which identified ten apparent violations of NRC requirements and two areas of concern. The inspection report (No. 030-10713/90001(DRSS)) was transmitted to the licensee via letter dated October 18, 1990. The attendees of this conference are noted in Section 1 of this report.

The purpose of this conference was to: (1) discuss the apparent violations, the significance, cause, and the licensee's corrective actions; (2) determine whether there were any escalating or mitigating circumstances; and (3) obtain other information which would help determine the appropriate enforcement action.

The licensee representatives presented a written response including corrective actions for each of the apparent violations (enclosed) and stated that they were in agreement with the NRC's understanding of the facts pertaining to the apparent violations, with one exception. With regard to an apparent violation pertaining to a failure to conduct weekly area removable contamination surveys on approximately 16 occasions, the licensee's understanding of the number of missed occasions differed from that of the NRC. The licensee agreed that they would look further into matter and contact the NRC if there is a discrepancy.

The corrective actions presented to the NRC included more orientation and training for new employees scheduled to work with licensed material; and additions to the licensee's computerized quality assurance system to remind staff to hold required meetings and perform required tests. Two errors in the licensee's corrective actions were identified by NRC staff members during the conference and were addressed to the licensee: (1) NRC regulations no longer allow for a maximum amount of molybdenum-99 per patient dose, but only for a maximum amount of molybdenum-99 per millicurie (mCi) of technetium-99m (Tc-99m) (see Enclosure - Attachment H); and (2) The licensee's procedure for a biliary scan should read "inject 4 to 8 mCi Tc-99m Mebrofenin" instead of "inject 4 to 8 mCi Tc-99m" (see Enclosure - Attachment G). In addition, a concern was raised by the NRC regarding the licensee's newly established procedure for analyzing wipe tests. The licensee agreed that they would correct the aforementioned errors and look further into the matter concerning the wipe test analysis method.

During the conference, the Radiation Safety Officer indicated that he was unfamiliar with many of the newer 10 CFR Part 35 requirements which became effective on April 1, 1987 and also had not been providing sufficient oversight of the day-to-day operations of the licensed program. The NRC representatives stressed the importance of aggressive oversight of a radiation safety program on the part of both the licensee management and the Radiation Safety Officer. In addition, the NRC pointed out that it is unacceptable on management's part to completely depend on their staff or consultant to bring all problems to management's attention. In response to this, the licensee indicated they would provide additional oversight of the licensed program by licensee management and the Radiation Safety Officer.

The NRC representatives closed the meeting after a discussion about the NRC Enforcement Policy and that further enforcement sanctions were possible. In addition, as requested by the licensee, the NRC provided copies of regulatory guides pertaining to personnel training.

Enclosure: Corrective Action Plan
dated October 22, 1990

WEST SHORE HOSPITAL
NRC Enforcement Conference
Corrective Action Plan
October 22, 1990

A. Apparent Violations

1. Instruction of Technologist

In retrospect, I have concluded that a two week training program in nuclear medicine technology, which is what the other three of us received, may not be sufficient for some individuals. I had Sharon Smith trained by Randy Payne, an experienced nuclear medicine technician, for the above period of time. At the end of the training period I asked Mr. Payne if she was capable of functioning on her own. He replied she would do all right, but that we may have to help her from time to time, i.e. answer questions. At the time of the incident she stated she thought she knew what she was doing.

Sharon Smith was immediately, after the incident in question, prohibited from working in the nuclear medicine lab. She subsequently resigned from the Hospital effective 9/27/90.

West Shore still has, in addition to myself, two trained and competent individuals who will continue to work in the nuclear medicine lab. They are Randall Payne, with six years of experience, and Lawrence Foster, who has eight years of experience. Because they are being utilized in other areas also, i.e. CT, diagnostic x-ray, and/or ultrasound, and we now have one less nuclear medicine technician, we have eliminated night and weekend "on call" nuclear medicine procedures for the foreseeable future. This will prevent us from over extending these remaining individuals and allow adequate time per the following to appropriately and adequately train another individual and/or to hire a qualified and experienced nuclear medicine technician.

Future trainees will receive at least eight weeks of full time education prior to working independently in the nuclear medicine lab. In addition, the trainee will receive instruction from our Radiation Physicist on radiation safety and quality control procedures including applicable NRC and licensure requirements. When this has been completed, the trainee will be required to demonstrate their capabilities to the Radiation Safety Officer. Once the Radiation Safety Officer is satisfied with their competence, he will document by signature in the orientation manual (Att. A) that this person is properly trained and prepared to work independently.

2. TLD Finger Badge

Ms. Smith did not have a ring badge because of oversight on my part. The other individuals working in the nuclear medicine lab have ring badges and have had since they started performing nuclear medicine procedures (Att. B). In an effort to prevent reoccurrence of this circumstance and other omissions, a checklist has been developed to be used with all trainees (Att. C). The list will be reviewed and signed for completion of all items by the trainee, trainers, and Radiation Safety Officer.

3. Radiation Safety Officer Attendance at Radiation Safety Meetings

In the past, Radiation Safety meetings were scheduled the last month of each quarter. This periodically caused scheduling difficulties in trying to get all of the necessary people together for the meeting in a short period of time. This past April we changed that practice and now schedule Radiation Safety meetings the first month of each quarter in order to allow more time for rescheduling, if necessary, in order to strive to assure that all parties will be in attendance (Att. D). Dates for these meetings have been entered into our QA computer program to prompt us when they are due. Since this change the Radiation Safety Officer hasn't missed any meetings.

- 4. Daily Dose Calibrator Constancy Checks,
- 6. Syringe Shield, &
- 7. Daily Area Survey

These violations involved Ms. Smith exclusively, and she had no explanation other than the last sentence of paragraph one of #1 above. Since she resigned, the other actions in this plan have been instituted, and the remaining technicians understand and appropriately handle these matters, there should be no further problems.

5. Quarterly Dose Calibrator Linearity Tests

On the two occasions missed, the technicians response was that he simply forgot to perform the tests. The one test was performed in January instead of December when discovered by me. Dates that linearity tests are due are now posted on the wall in the nuclear medicine lab. The technologist has been reminded of his responsibility to perform these tests on schedule and that disciplinary action will occur if he fails to comply in the future. Furthermore, we have entered the dates for these tests into our QA computer program which will prompt me to review compliance when they are due each quarter (Att. E).

8. Weekly Contamination Survey

When Mr. Payne was on surgical leave, I didn't realize the significance of the test and didn't perform it weekly. The Radiation Physicist subsequently explained the importance and together we developed a written policy and procedure to assure these tests are performed on time and properly (Att. F).

9. Reagent Kit per Manufacturer's Instructions

This violation is especially perplexing because the Hospital has a written policy and procedure regarding dosages which is posted on the wall of the nuclear medicine lab (Att. G). In addition, Ms. Smith was informed by me on the telephone prior to the incident to use 7 Mci of 99M Tc Disofenin which is in accordance with the manufacturer's suggested dose of 4-8 Mci. Again, she had no explanation other than that in #1 above, first paragraph, last sentence.

10. Measure of Molybdenum Concentration

The Hospital's written policy and procedure on MO 99 checking was reviewed with Ms. Smith during training by Mr. Payne (Att. H). As repeatedly explained above, Ms. Smith's response to why she didn't do it right was she thought she knew what she was doing. Future trainees will be instructed about this policy and procedure during their training by the Radiation Physicist. Furthermore, this will be included in their competency test by the Radiation Safety Officer.

Along with the above actions, the Hospital is instituting check lists for each exam performed in the nuclear medicine lab. Enclosed is the check list for hepatobiliary scans (Att. I).

B. Areas of Concern

1. The Radiation Safety Officer states that he was not aware that Ms. Smith would be performing these procedures independently.
2. Refer to section A, 1, paragraph 1 (the last three sentences) and paragraph 2 above.

Prior to the study Ms. Smith called me and stated the hepatobiliary scan was ordered. We discussed the procedure and I told her to use 7 Mci of 99M Tc Cholotec. I then told her to elute the generator and call me back before she performed the next step. I didn't hear from her for a period of time and called her back. She said everything was going fine, the patient was injected and under the camera, and she was beginning the scan. I then stated good, call me if you have any problems. The first I knew she was having problems was when she called back and said all that is on the film is a white spot.

Along with her training, she performed two prior nuclear medicine procedures. The first procedure I assisted her through in person. During the second procedure, I provided coaching by telephone. Her performance on both procedures indicated she generally knew what she was doing. Furthermore, in nuclear medicine as well as diagnostic radiology she had a history during her eleven months of employment of asking questions when she didn't understand and before she had a problem. Why she didn't this time, and how she came up with calculations so different than would have been correct, I do not understand.

ATTACHMENT A

October 1990

WEST SHORE HOSPITAL
NUCLEAR MEDICINE

TITLE: Authorization to work in the Nuclear Medicine Lab.

POLICY: To document technicians with delegated authority to work in the Nuclear Medicine Lab.


PROCEDURE: The below listed technologists at West Shore Hospital have received proper training in standard procedures, Quality Assurance procedures, and Radiation Safety procedures, and are deemed capable to work independently in the Nuclear Medicine Lab.

Randall Payne RT

Lawrence Foster RT/RS

James Brand RT/RDMS

Approved



E. A. Jackowski, D.O.
Radiologist, Radiation Safety Officer

D:ATHWNMD
TXTNUMED

ATTACHMENT B

ATTACHMENT C

RADIOLOGY DEPARTMENT
 ASSOCIATE ORIENTATION CHECKLIST
 10/90

ASSOCIATE, _____

NUCLEAR MEDICINE	Initial	Date
1) TLD Ring Badge	_____	_____
2) Elution of Generator	_____	_____
3) MO 99 Test	_____	_____
4) Dose Calibrator Constancy Test	_____	_____
5) Daily Area Survey Procedure	_____	_____
6) Weekly Swipe Test	_____	_____
7) Diagnostic Procedures Manual	_____	_____
8) IV Injection Procedure	_____	_____
9) Universal Precautions	_____	_____
10) Departmental Policies	_____	_____
11) Physicist Instruction	_____	_____
12) RSO Interview/Test	_____	_____
13) Quality Assurance Program	_____	_____
14) Fire Alarms & Extinguishers	_____	_____
15) Flood Study Operation	_____	_____
16) Code Blue Alarm	_____	_____

Signatures: ASSOCIATE _____
 Trainee _____
 Trainer _____
 Radiation Safety Officer _____

ATTACHMENT D

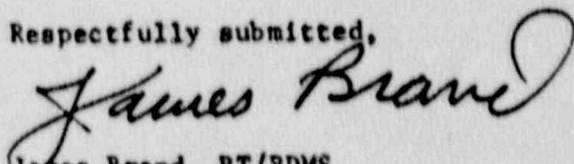
Radiation Safety Committee

Tuesday-March 13, 1990

Present: James Brand, Radiology Supervisor, Mr. Parks, Administrator,
Sheryl Wygant, R.N., Dr. Jackowski, Radiologist, RSO.

- 1) Reviewed minutes from meeting held on January 22, 1990.
- 2) Reviewed film badge reports. Randall Payne had one high reading of 50 mr. I have discussed the situation with him and gave him recommendations on how to lower his future doses.
- 3) The Physicist has noted that our December meeting was late as it was held in January. He explained that the NRC finds this to be unacceptable. In order to rectify the matter, I suggested that we start having our meetings in the first month of each quarter instead of the last month of the quarter. This motion was approved. Future Radiation Safety Meetings will be in January, April, July, and October.
- 4) We reviewed the December MPC report again and I reported that all concerns from that report have been corrected.
- 5) Mr. Parks noted that we are planning to move the Nuclear Medicine Lab to the third floor. I will contact the Physicist in order to impliment the paper work.
- 6) No further business. Meeting adjourned. The next meeting will be held in April of 1990.

Respectfully submitted,



James Brand, RT/RDMS
Radiology Supervisor

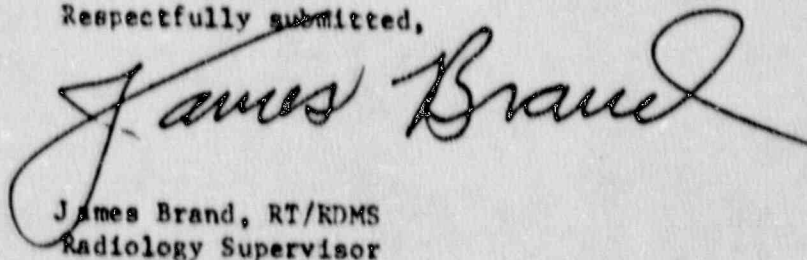
Radiation Safety Committee

Tuesday-April 10, 1990

Present: James Brand, Radiology Supervisor, Mr. Parks, Administrator,
Sheryl Wygant, R.N., Dr. Jackowski, Radiologist, RSO.

- 1) Reviewed minutes from meeting held on March 13, 1990.
- 2) Reviewed film badge reports. All film badge readings were within the acceptable limits of 125 mrem/quarter. *AIARA Level 2*
as per administration
- 3) We will be sending in to the NRC for a license ammendment so that we can move the Nuclear Medicine Department to the third floor.
- 4) I discussed with Mrs. Wygant the possibility of having the film badges from surgery put on a card in a location that would make it easier for me to locate each badge for updating.
- 5) I have contacted the Physicist with regards to the possibility of having lead in the walls of the proposed temporary mammography suite.
- 6) No further business. Meeting adjourned. The next meeting will be held in July of 1990.

Respectfully submitted,



James Brand, RT/RDMS
Radiology Supervisor

ATTACHMENT E

STATISTICS/INDICATORS

(Title/Definition

Months Rev./Rep.)

QA cont.

QA - Ultrasound

1) Difference

between ultrasound

and surgical

findings

(Sep., Dec.,

Mar., Jan.)

95%

RISK MANAGEMENT

1) Incidents

(monthly)

2) Concerns/Opp.

(monthly)

3) Claims

(monthly)

4) Survey

Written

(monthly)

5) Emp. Incidents

(monthly)

QUALITY CONTROL

Radiology:

1) Film repeats

(monthly)

2) Processor

Clean/main.

(monthly)

3) Linearity Tests

(Apr, Jul, Oct, Jan)

	STD's	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	AVG
1) Incidents (monthly)	0	0	0	0	0	3								
2) Concerns/Opp. (monthly)		0	0	0	0	0								
3) Claims (monthly)	0	0	0	0	0	0								
4) Survey Written (monthly)	95%	0	0	0	0	0								
5) Emp. Incidents (monthly)		0	0	0	0	0								
1) Film repeats (monthly)	5%	3.9%	3.3%	4%	4.25%	2.7%								
2) Processor Clean/main. (monthly)	90%	100%	100%	100%	100%	100%								
3) Linearity Tests (Apr, Jul, Oct, Jan)			X				X							

ATTACHMENT F

October 1990

WEST SHORE HOSPITAL

NUCLEAR MEDICINE

TITLE Weekly Wipe Test

PROCEDURE A weekly wipe test of designated areas shall be performed each Friday in the following manner.

1. Use alcohol swabs in cabinet to swipe.
2. Swipe each designated area which is labeled 1-8, refer to room map in front of log book. Put each individual swipe in a baggie (found in bottom cabinet).
3. Turn on Thyroid Uptake probe.
4. Set appropriate window settings A. Upper window 999
 B. Lower window 0
(140 Kev 20% window)
5. Take a background reading (10 minutes) and divide reading by 10 for an average background reading. Record on weekly swipe chart in survey log.
6. Place each bag in Thyroid cylinder and start for 1 minute.
7. Subtract background from each reading and multiply the net by a correction factor of 3.0. This will be the disintegration per minute.
8. Record in weekly swipe test log in daily survey log.
9. Action level 2000 DPM.
10. If you obtain a reading of 2000 DPM in any area, then you must decontaminate that area with Radiac Wash, dispose of contaminated materials in lead vault, and redo the swipe of that area until it is below 2000 DPM.

Approved _____

Distribution _____

D: WKWIPT
TXTNUMED

WEEKLY WIPE SURVEYS

Instrument: _____

Serial#: _____

Efficiency Factor: _____

H.V. or Peak: _____

Room: _____

Trigger Level: 2000 DPM

Date: _____

See Map for Area Locations.

Area#	1 min ct. CPM	1 min bkg. CPM	ct. - bkg. NET CPM	Efficiency Factor	Disintegrations DPM
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					
13					
14					
15					
16					
17					
18					
20					

ATTACHMENT G

January, 1988

WEST SHORE HOSPITAL

NUCLEAR MEDICINE

TITLE: Biliary Scan

POLICY: To assure consistent quality scans

PROCEDURE: A. Materials

1. 4 to 8 mci ^{99m}Tc Choletec (Mebrofenin). Increased Bilirubin=Increased mci.
2. Scintillation camera
3. Diverging collimator
4. Hospital cart

B. Patient Preparation

1. Patient is to have a fat free meal the evening before the exam and is to be NPO after midnight.
2. Instruct patient as to the procedure

C. Procedure

1. Set camera controls
 - a. 300,000 counts
 - b. Proper intensity 480-70mm, 475-Polaroid
 - c. Proper orientation (x-y exc)
 - e. Check to see that camera is set (peaked) for ^{99m}Tc
2. Inject 4 to 8 mci ^{99m}Tc
3. Position patient so that the liver is visible towards the top of the image
4. Take films at the following intervals:
5 min--15 min--25 min--35 min--45 min--60 min.,
 - a. If the biliary system AND gallbladder are not visualized at 60 min., films will be taken at one (1) hour intervals up to four (4) hours until the gallbladder is visible or radionuclide can be seen in the small bowel.
5. All views to be done in the anterior position

D. Key Points

A perfusion type Liver Scan study may be done in the first five (5) minutes after injection of the radionuclide. After this time, the drainage of the radionuclide into the biliary tree may show as a false positive Liver Scan.

E. Contraindications

1. An allergic type reaction may be possible with multiple injections of Disofenin
2. Radiopharmaceuticals are contraindicated in pregnancy and during lactation and in persons less than 18 years of age unless, in the judgment of the physician the situation requires their use.

Approved: *L.M. Jacobowski*

Distribution: _____

Rev 1/79
1190 *js*

F: BILIARY
D: P&P NUC MED

Orig. 6-85

ATTACHMENT H

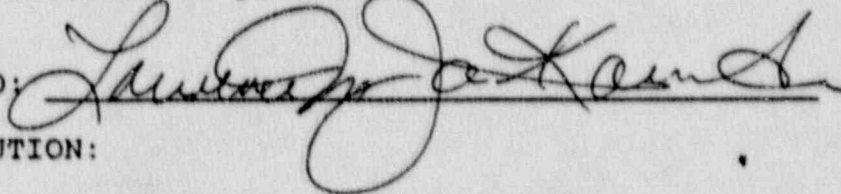
January 1988

WEST SHORE HOSPITAL
NUCLEAR MEDICINE

TITLE: 99Mo (Molybdenum) Breakthrough Test Procedures

POLICY: To ensure patients do not receive more than allowable levels of Molybdenum 99.

- PROCEDURE:
1. Each generator elution will be measured in the dose calibrator for Molybdenum breakthrough with the results being recorded on the dose distribution record.
 2. After measuring the elution for 99Tc, the elution vial will be removed from the dose calibrator and placed directly into the lead shield provided. The cap will be placed on the shield and the shield returned to the dose calibrator well. The calibrator dial will then be set to 99Mo and several minutes will be allowed for the uci reading to stabilize.
 3. The 99Tc in mci and the 99Mo in uci will then be recorded in the dose distribution record.
 4. Return elution vial to the elution shield.
 5. The following formula will be used to determine 99Mo breakthrough:
$$\frac{\text{-uci 99Mo}}{\text{mci 99Tc}} = \text{uci 99Mo per mci 99Tc}$$
 6. This number will then be entered in the dose distribution record.
 7. Amounts of .15 uci 99Mo per mci 99Tc or 5 uci 99Mo per patient dose will not be allowed and shall not be administered to patients.

APPROVED: 

DISTRIBUTION:

D: 99Mo

F: TXTNUMED

Orig. July 1985 Reviewed: 1/87

1/87 gs
1/87 gs

NUCLEAR MEDICINE DEPARTMENT

PROCEDURE CHECK LIST:

Patient Name _____

Date _____

Procedure _____

Initial

1) Room Area Survey

2) Dose Calibrator Constancy Check

3) Flood Study Performed

4) TLD Ring Badge Worn

5) Syringe Shields Used

6) uci MO^{99} / MCI ^{99m}Tc

Total

Amount and Type of Reagent Used

Technologist _____