U.S. NUCLEAR REGULATORY COMMISSION

REGION III

Report No. 030-10713/90001(DRSS)

Docket No. 030-10713

License No. 21-16277-01

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

Inspection Conducted: September 27, 1990

Inspector: Bryan A Parker 10/17/90
Bryan A. Parker Date
Radiation Specialist

Reviewed By: Gary L. Shear for 10/17/90
Roy J. Caniano, Chief Date
Nuclear Materials Safety
Section 2

Approved By: John A. Grobe 10/17/90
John A. Grobe, Chief Date
Nuclear Materials Safety Branch

Inspection Summary

Inspection Conducted on September 27, 1990 (Report No. 030-10713/90001(DRSS))
Areas Inspected: This was an announced, special inspection conducted in response to a diagnostic misadministration involving approximately 175 millicuries of a technetium-99m radiopharmaceutical which occurred on September 22, 1990. The inspection included a review of the circumstances surrounding the misadministration as well as a review of the licensee's organization; personnel training; materials, facilities, and equipment; radiological protection procedures; receipt and transfer; area surveys; personnel radiation protection; waste disposal; postings; and independent measurements.
Results: Ten apparent violations of NRC requirements and two areas of concern were identified during the inspection:

A. Apparent Violations

1. Failure to instruct a technologist as required by 10 CFR Part 19, including failure to instruct in NRC regulations and license requirements, License Condition No. 16, (Section 5);

2. Failure to wear TLD finger badge during elution of generator and preparation, assay, and injection of radiopharmaceuticals, License Condition No. 16, (Section 5);

3. Failure to establish a quorum for Radiation Safety Committee meetings (RSO was not in attendance on two occasions), 10 CFR 35.22(a)(3), (Section 4);

4. Failure to perform dose calibrator constancy checks each day of use, 10 CFR 35.50(b)(1), (Section 5);

5. Failure to perform quarterly dose calibrator linearity tests, 10 CFR 35.50(b)(3), (Section 6);

6. Failure to utilize syringe shields during preparation and administration of radiopharmaceuticals, 10 CFR 35.60(c), (Section 5);

7. Failure to perform required area surveys each day of use, 10 CFR 35.70(a), (Section 5);

8. Failure to perform area contamination surveys once each week, 10 CFR 35.70(e), (Section 6);

9. Failure to prepare reagent kit in accordance with manufacturer's instructions, 10 CFR 35.200(b), (Section 5);

10. Failure to measure the molybdenum-99 concentration in each generator eluate, 10 CFR 35.204(b), (Section 5).

B. Areas of Concern

1. Concern was expressed that the licensee, through the Radiation Safety Officer (RSO), was not adequately ensuring that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements. In addition, the licensee, through the RSO, had not adequately investigated deviations from the approved radiation safety practice and implemented corrective actions as necessary (Section 7).

2. Concern was expressed that the licensee's authorized users were not adequately supervising individuals who use licensed material (Section 7).

DETAILS

1. Persons Contacted

*Sheryl Wygant, Assistant Administrator
L. M. Jackowski, D.O., Radiation Safety Officer
*James Brand, Radiology Manager
Randy Payne, Technologist
Sharon Smith, Technologist

*Indicates presence at exit meeting held September 27, 1990.

2. Purpose of Inspection

This was an announced, special inspection conducted in response to a diagnostic misadministration involving approximately 175 millicuries of a technetium-99m radiopharmaceutical which occurred on September 22, 1990.

3. Inspection History

The last inspection of this licensee was conducted February 11, 1987. It was a routine safety inspection and three violations of NRC requirements were identified, including (1) failure to provide annual refresher training to nursing and housekeeping personnel; (2) failure to compare decayed values with measured values on a linearity test; and (3) failure to calibrate a survey meter at the proper interval.

A routine inspection performed in July 1983 identified six violations, including (1) failure of Radiation Safety Committee to meet quarterly; (2) failure to adequately train nurses; (3) failure to wipe the final source container of incoming packages; (4) failure to perform adequate area wipe tests; (5) failure to calibrate a survey meter at the proper interval; and (6) failure to check all commonly used settings on the dose calibrator for constancy each day of use.

A routine inspection conducted in May 1980 identified eight violations of NRC requirements, including (1) failure of the Radiation Safety Committee to meet quarterly; (2) failure to leak test a check source; (3) failure to perform linearity tests at the proper interval; (4) failure to calibrate a survey meter at the proper interval; (5) failure to wear a ring badge; (6) failure to establish written procedures for personnel training for performing molybdenum-99 breakthrough tests; (7) failure to include birthdates on dosimetry records; and (8) failure to submit required reports to the Commission.

4. Licensed Program/Organization

West Shore Hospital, located in Manistee, Michigan, operates a small nuclear medicine program which performs approximately 30-40 studies per month, a majority of which are technetium-99m (Tc-99m) related. The licensee receives a 1660 millicurie (mCi) molybdenum-technetium (Mo-Tc)

generator every two weeks from an authorized manufacturer/distributor. The licensee is also authorized for diagnostic unit dose radiopharmaceuticals and iodine-125 (I-125) seeds for therapeutic permanent implants. The licensee is not using byproduct material in the form of unit doses at this time and has not performed any I-125 implants since the previous inspection in 1987. The licensee has two full-time technologists who, among other duties, perform nuclear medicine studies during the week. Also, since approximately February 1990, the licensee has been using a cross-trained X-ray technologist to cover nuclear medicine studies on the weekends.

The Radiation Safety Officer (RSO) for West Shore is L. M. Jackowski, D.O. Dr. Jackowski is the principal user of four authorized users named on the license.

The Radiation Safety Committee (RSC) at West Shore is comprised of the RSO, a representative of management, a representative of nursing, the Radiology Manager, and a technologist. A consultant periodically attends RSC meetings as a non-voting member. A review of RSC meeting minutes indicate that the licensee's RSC meetings are adequate, with the following exception. 10 CFR 35.22(a) requires, in part, (1) that the RSC must meet at least quarterly; and (2) that in order to establish a quorum and to conduct business, at least one-half of the Radiation Safety Committee's membership must be present, including the Radiation Safety Officer and the management's representative. Based on a review of records and a discussion with the RSO, it appears that the licensee failed to meet the quorum rule for at least two RSC quarterly meetings in that the RSO failed to attend meetings held during the first quarters of 1988 and 1989. The failure of the licensee to conduct RSC meetings as required constitutes an apparent violation of 10 CFR 35.22(a).

One apparent violation of NRC requirements was identified.

5. Incident Summary

On Saturday, September 22, 1990, a hepatobiliary scan was ordered at West Shore for an 84-year-old female patient diagnosed with pancreatic carcinoma. The technologist on call and assigned to perform the scan was a cross-trained X-ray technologist who had received two weeks of training in the nuclear medicine department in February 1990. The training was provided specifically so that the technologist could cover weekend call and mainly consisted of a review of the technical aspects of nuclear medicine (i.e. generator elution, use of dose calibrator, camera set-up, etc.). Since the February 1990 training, the technologist had performed two nuclear medicine procedures prior to the September 22 incident. Of those two procedures, the Radiology Manager personally supervised the technologist during one occasion and "coached" the technologist through another via telephone.

License Condition No. 16 states that the license is based on the licensee's statements and representations listed in certain referenced documents. Item 12, "Personnel Training Program", of the referenced application dated August 27, 1980, requires all personnel to receive proper instruction in the items specified in 10 CFR Part 19.12, including (1) pertinent NRC regulations; (2) the rules and regulations of the license; and (3) the pertinent terms of the license before assuming their duties with or in the

vicinity of radioactive materials. Interviews of the technologist involved in the incident and other members of the West Shore staff indicated that the technologist never received any of the aforementioned required training and the nuclear medicine technical training provided in February 1990 appears to have been minimal. Based on the interviews with licensee representatives, it appears that before or subsequent to assuming duties with licensed materials in February 1990, the licensee failed to provide proper instruction to the technologist in the items specified in 10 CFR Part 19.12, including (1) pertinent NRC regulations; (2) the rules and regulations of the license; and (3) the pertinent terms of the license. The failure of the licensee to provide proper training to the technologist constitutes an apparent violation of License Condition No. 16.

After receiving the order for the scan, the technologist contacted the Radiology Manager at home by telephone to seek guidance. The Radiology Manager told the technologist to prepare the dose as recommended in the procedures manual and to call back if the technologist had any questions. The technologist referred to the procedure for a hepatobiliary scan as directed and found that an 8 mCi dose of Tc-99m Mebrofenin was needed. Tc-99m Mebrofenin is prepared by adding free Tc-99m to a Choletec reagent kit. The technologist then eluted the Mo-Tc generator and placed the eluate into the dose calibrator which, according to the technologist, read 392 mCi.

10 CFR 35.50(b)(1) requires a licensee to check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. An interview with the technologist involved indicated that no constancy check was performed on the dose calibrator on Saturday, September 22, 1990. In addition, a review of constancy records revealed that on six other weekend occasions between April 29, 1990, and September 22, 1990, when licensed material was used, the licensee failed to check the dose calibrator for constancy. The failure of the licensee to properly check the dose calibrator for constancy on at least seven occasions constitutes an apparent violation of 10 CFR 35.50(b)(1).

After eluting the generator, the technologist withdrew approximately 4 milliliters (ml) of the eluate and injected it into a Choletec reagent kit vial to prepare the Tc-99m Mebrofenin. When questioned later by inspectors as to why 4 ml was chosen instead of some calculated activity, the technologist indicated that the thought was "that should be enough" and no thought was given to the actual amount of activity injected into the Choletec vial.

10 CFR 35.200(b) requires a licensee to elute generators and prepare reagent kits in accordance with the manufacturer's instructions. The manufacturer's instructions for preparing the Choletec reagent kit call for the addition of a maximum of 100 millicuries of Tc-99m. Further, 10 CFR 35.200(c)(1) allows a licensee to depart from the manufacturer's instructions for eluting generators and preparing reagent kits provided

that the licensee has a written directive made by an authorized user physician that directs a specific departure for a particular patient, or patients, or for a radiopharmaceutical, and which includes the specific nature of the departure, a precise description of the departure, and a brief statement of the reasons why the departure from the manufacturer's instructions for preparing the radiopharmaceutical would obtain medical results not otherwise attainable or would reduce medical risks to particular patients because of their medical condition.

It appears that on September 22, 1990, the amount of Tc-99m injected into the Choletec vial was considerably more than 100 mCi. A review of the incident conducted by the licensee's consultant on September 25, 1990, indicated that the total amount of Tc-99m injected into the Choletec vial appears to be 2.5 ml (1.0 ml injected into patient and 1.5 ml leftover in Choletec vial after the incident). The estimated dose administered to the patient, as will be explained later, is 175 mCi. Therefore, the initial amount of Tc-99m injected into the Choletec vial is estimated to be approximately 440 mCi. However, no written directive was made by an authorized user physician that directed such a departure from the manufacturer's instructions. The failure of the licensee to prepare the Choletec reagent kit in accordance with the manufacturer's instructions constitutes an apparent violation of 10 CFR 35.200(b).

10 CFR 35.204(b) requires a licensee to measure the molybdenum-99 (Mo-99) concentration in each eluate or extract, otherwise known as a "moly breakthrough test." An interview with the technologist involved in the incident indicated that the technologist attempted to perform what was thought to be a moly breakthrough test, but was unable to due to improper methodology. On Saturday, September 22, 1990, the technologist had available, but failed to utilize, the specially-designed lead container necessary to measure the Mo-99 activity in an eluate. Also, the technologist used an improper method for calculating Mo-99 concentration. Either of the aforementioned actions could lead to an invalid measurement. In addition, a review of records revealed that on Saturday, August 18, 1990, a moly breakthrough test was not performed, although the generator was eluted and licensed material was administered. The failure of the licensee to measure the Mo-99 concentration in each eluate as required constitutes an apparent violation of 10 CFR 35.204(b).

After preparing the Tc-99m Mebrofenin in the Choletec vial, the technologist assayed the solution in the dose calibrator and, according to the technologist, it read 150.6 mCi. The technologist then withdrew approximately 1 ml of the solution into a syringe and placed the syringe into the dose calibrator. When questioned later as to why 1 ml was chosen instead of some calculated activity, the technologist indicated that the thought was to assay the dose and then "back it down until it was about 8 mCi" and no thought was given to the actual amount of activity drawn up in the syringe. According to the technologist, the reading on the dose calibrator from the syringe was approximately 8 mCi and it was not felt that the dose needed to be "backed down." Sometime during the preparation of the dose, the Radiology Manager called by telephone to check on the technologist's progress. The technologist informed the Radiology Manager that there were no problems and that the patient was prepared for the scan. The technologist then injected the patient with the 1 ml dose and began the patient's scan.

10 CFR 35.60(c) requires a licensee to use a syringe radiation shield when preparing a kit and to use a syringe radiation shield when administering a radiopharmaceutical by injection unless the use of the shield is contraindicated for that patient. On September 22, 1990, the licensee failed to use a syringe radiation shield when preparing the Choletec reagent kit and administering the Tc-99m Mebrofenin radiopharmaceutical by injection and the use of the shield was not contraindicated for that patient. The failure of the licensee to use the syringe shield constitutes an apparent violation of 10 CFR 35.60(c).

License Condition No. 16 states that this license is based on the licensee's statements and representations listed in certain referenced documents. Item 15, "General Rules for the Safe Use of Radioactive Material", of the referenced application dated August 27, 1980, requires TLD finger badges to be worn during elution of generator and preparation, assay, and injection of radiopharmaceuticals. Interviews with the technologist involved in the incident and other members of the West Shore staff indicated that the technologist did not wear a TLD finger badge during elution of the generator and preparation, assay, and injection of radiopharmaceuticals on at least three occasions during the period of February 1990 through September 22, 1990. The technologist was provided a whole body film badge, which was worn during work with licensed materials. The failure of the licensee to wear personnel dosimetry as required constitutes an apparent violation of License Condition No. 16. A contributing factor to this apparent violation is a lack on the part of licensee to issue the technologist a TLD finger badge.

During the scan of the patient, the technologist noticed that a "bright spot" was forming on the scanning screen instead of the clear image of the patient's liver area which would be expected. The technologist re-checked for the proper patient set-up and equipment settings. Finding no problems, the technologist called the Radiology Manager at home again and explained the situation. The Radiology Manager told the technologist that it sounded as if a misadministration had occurred and that he would proceed to the hospital to investigate the matter.

10 CFR 35.70(a) requires a licensee to 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. An interview with the technologist involved in the incident indicated that no area surveys were performed on Saturday, September 22, 1990. In addition, a review of area survey records revealed that on six other weekend occasions between April 29, 1990, and September 22, 1990, when licensed material was used, the licensee failed to perform area surveys. The failure of the licensee to perform area surveys as required on at least seven occasions constitutes an apparent violation of 10 CFR 35.70(a).

On Monday, September 24, 1990, Region III received a telephone call from the licensee's consultant with a question concerning the reporting requirements for diagnostic misadministrations. During the course of conversation, it was revealed that an apparent diagnostic misadministration had occurred at West Shore on September 22. This information was confirmed on September 25, 1990 during a telephone conversation between the licensee and Region III and the licensee's required written

report was received by Region III on October 1, 1990. Initial information set the administered dose as approximately 135 mCi of Tc-99m Mebrofenin with an intended dose of 8 mCi. Based on the consultant's review of the incident, the estimated administered dose was 183 mCi. Based on the inspection findings and subsequent calculations, Region III estimates the administered dose to be approximately 175 mCi.

Following the aforementioned notifications, Region III contracted with a medical consultant, Edward B. Silberstein, M.D., on September 25, 1990, to review the circumstances surrounding the misadminstration and evaluate the possible health effects on the patient. Dr. Silberstein's report to Region III (Attachment) indicates that no health effects should be expected as a result of the overdose. As preliminary estimates set the administered dose at approximately 135 mCi, Dr. Silberstein's dosimetry to vital organs is based upon that number. Interpolation of Dr. Silberstein's dose estimates for 175 mCi only slightly increases the organ doses by a factor of 1.3 (i.e. bladder - 36 rad instead of 28 rad; upper large intestine - 26 rad instead of 20 rad; kidneys - 11 rad instead of 8.5 rad; etc.). Therefore, the NRC agrees with Dr. Silberstein's conclusion that there should be no adverse health effects.

Dr. Silberstein also indicated that the technologist involved was "inadequately trained...in the basic concepts of Nuclear Medicine, including the use of the generator [and] dose calibrator" and recommended that all technologists who handle radioactive material be required to meet the minimum standards as recommended by the Society of Nuclear Medicine.

Seven apparent violations of NRC requirements were identified.

6. Other Areas Inspected

In addition to the areas mentioned above, the following areas were also inspected.

Except as noted in Section 5 of this report, the training provided to personnel appears to be adequate. All housekeeping, security, maintenance, and nursing personnel have received initial and annual refresher training as required.

The materials, facilities, and equipment maintained by the licensee appear to be adequate, except as noted below. The materials possessed and used by the licensee are all as authorized and leak tests and inventories of sealed sources (check sources) are performed and recorded as required. The survey instruments possessed by the licensee are operable and properly calibrated. With regard to the licensee's dose calibrator, the required accuracy and geometry dependence tests on the dose calibrator are performed and recorded as required. However, an apparent violation regarding dose calibrator constancy checks is noted in Section 5 of this report. 10 CFR 35.50(b)(3) requires a licensee to test each dose calibrator for linearity at least quarterly over the range of its use from the highest dosage that will be administered to a patient and 10 microcuries. Based on a review of dose calibrator records and discussions with licensee representatives,

it appears that the licensee failed to test the dose calibrator for linearity during the first and fourth quarters of 1989. In addition, since the inception of the requirement on April 1, 1987, the licensee has failed to perform linearity tests down to 10 microcuries. The failure of the licensee to perform dose calibrator linearity tests as required constitutes an apparent violation of 10 CFR 35.50(b)(3).

Except as noted in Section 5 of this report, all radiological protection procedures appear to be adequate. The use of personnel dosimetry, lab coats, gloves, and syringe shields was observed during the inspection.

Receipt, transfer, and disposal records are maintained as required. The licensee receives one generator every two weeks on Friday and employs the decay-in-storage method for their radioactive waste.

Except as noted in Section 5 of this report, the area radiation surveys appear to be adequate. With regard to area contamination surveys, 10 CFR 35.70(e) requires a licensee to survey for removable contamination once each week all areas where radiopharmaceuticals are prepared for use, administered, or stored. A review of survey records revealed that on sixteen occasions during the period of February 22, 1989, and June 15, 1990, the licensee failed to survey for removable contamination on a weekly basis in the aforementioned areas. This accounts for approximately 25% of the total number of weeks in that time period. The failure of the licensee to perform area contamination surveys as required constitutes an apparent violation of 10 CFR 35.70(e).

Personnel radiation protection (except for the lack of use of a TLD finger badge by a technologist previously discussed) appears to be adequate. A review of dosimetry records revealed that the maximum extremity doses received in 1988, 1989, and 1990 (to date) are 2720, 0, and 140 millirem (mrem), respectively. The maximum whole body doses received in 1988, 1989, and 1990 (to date) are 50, 60, and 0 mrem, respectively.

All postings and labeling appear to be adequate. NRC Form-3, "Notice to Employees", is posted as well as copies of the license and regulations. The hot lab area is appropriately posted and labels are utilized as required.

Two apparent violations of NRC requirements were identified.

7. Management Oversight of the Radiation Safety Program

10 CFR 35.21(a), in part, requires the licensee, through the Radiation Safety Officer (RSO), to ensure that the radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operations of the licensee's byproduct material program. 10 CFR 35.21(b), in part, requires the licensee's RSO to investigate deviations from approved radiation safety practice and implement corrective action as necessary. The inspectors expressed concern that the licensee's RSO has not ensured that the radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operations of the licensee's byproduct material program. In addition, the licensee's RSO did not identify and investigate

deviations from approved radiation safety practice and implement corrective action as necessary. Evidence of these problems includes: occasional absence from Radiation Safety Committee meetings; insufficient attention devoted to the licensee's personnel monitoring program in that the technologist involved in the incident worked with licensed material from February 1990 until the date of the incident without being issued a required TLD finger badge; insufficient attention devoted to the dose calibrator constancy and linearity tests records, and daily and weekly area survey records in that deviations from approved practice, mainly during weekend uses of licensed material and absences of principal technologists, were not identified, investigated, and corrective action implemented.

10 CFR 35.25(a) requires a licensee that permits the receipt, possession, use, or transfer of byproduct material by an individual under the supervision of an authorized user as allowed by 10 CFR 35.11(b) to (1) instruct the supervised individual in the principles of radiation safety appropriate to that individual's use of byproduct material; (2) require the supervised individual to follow the instructions of the supervising authorized user, follow the procedures established by the RSO, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material; and (3) periodically review the supervised individual's use of byproduct material and the records kept to reflect this use. 10 CFR 35.25(b) states that a licensee that supervises an individual is responsible for the acts and omissions of the supervised individual.

Inspectors expressed concern that, with respect to the technologist involved in the incident, the licensee (1) gave inadequate instruction in the principles of radiation safety appropriate to that individual's use of byproduct material; (2) required the individual to follow the instructions of the supervising authorized user, follow the procedures established by the RSO, and comply with the regulations of this chapter and the license conditions with respect to the use of byproduct material, yet failed to adequately train the individual to the degree necessary to fulfill the aforementioned requirements; and (3) never periodically reviewed the individual's use of byproduct material and the records kept to reflect this use. Evidence of these problems includes: the apparent lack of training of the technologist discussed in Section 5 of this report; a lack of knowledge exhibited to the inspectors by the technologist involved in the incident of the technical aspects of nuclear medicine (i.e. little or no knowledge as to reasons for, or the importance of, molybdenum-99 breakthrough tests, dose calibrator constancy checks, package insert compliance, area surveys, syringe shield use, activity calculations, etc.).

The lack of RSO attentiveness and lack of adequate management/authorized user supervision of the technologist involved in the incident appear to be significant contributing factors to the cause of the apparent violations discussed in this report and the misadministration.

Two areas of concern were identified.

8. Independent Measurements

Independent measurements were conducted by the inspectors using a Xetex survey instrument, Model 305B, NRC Serial No. 008996, last calibrated June 25, 1990. All measurements conducted in the hot lab/imaging area appeared to compare with the licensee's readings and were within 10 CFR Part 20 limits.

No violations of NRC requirements were identified.

9. Exit Meeting

At the conclusion of the inspection, an exit meeting was held with those individuals indicated in Section 1 of this report. The results of the inspection, apparent violations, review of the September 22, 1990, misadministration, and NRC Enforcement Policy were discussed. The licensee did not indicate that any information reviewed during the inspection was proprietary in nature.

Attachment:
Medical Consultant report