U.S. NUCLEAR REGULATORY COMMISSION

REGION III

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Report No.:	030-18261/96001(DNMS)		
Licensee:	Citizen's Memorial Hospital 1500 N. Oakland - No. Hwy 83 Bolivar, Missouri 65613		
Date of Inspection:	April 10-11, 1996, with continuing review through June 27, 1996.		
Inspector:	Robert P. Hays, Radiation Specialist		
Approved By:	Monte P. Phillips, Chief Nuclear Materials Inspection Branch 2 Division of Nuclear Materials Safety		

EXECUTIVE SUMMARY

Citizen's Memorial Hospital
NRC Inspection Report 030-18261/96001(DNMS)0

This was a routine inspection of the licensee's radiation safety program and activities authorized by the license. The inspection identified eight apparent violations and one apparent repeat apparent violation as follows:

1. Failure of the licensee to check each dose calibrator for constancy at the beginning of each day of use (Section 4).

2. Failure of the licensee to perform quarterly linearity tests on the dose calibrator (Section 4).

3. Failure of the licensee to perform surveys with a radiation detection survey instrument at the end of each day of use in all areas where radiopharmaceuticals are routinely prepared for use or administered (Section 5).

4. Failure of the licensee to perform surveys for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored (Section 5) This is a repeat apparent violation from the prior inspection.

5. Failure to wear and use individual monitoring devices (Section 6).

6. Failure to monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for radioactive contamination (Section 7).

7. Failure to instruct individuals in the purposes and functions of protective devices employed (Section 8).

8. Failure of the Radiation Safety Committee to conduct quarterly meetings (Section 9).

9. Failure of the Radiation Safety Officer to ensure that radiation safety activities were being performed in accordance with approved procedures (Section 10).

These apparent violations collectively are indicative of a programmatic breakdown of licensed activities. The apparent root cause for these apparent violations was under further NRC review as of the end of the inspection.

Report Details

1. Program Summary

Citizen's Memorial Hospital's license authorizes diagnostic uses of radiopharmaceuticals for uptake, dilution, and excretion studies, and the use of radiopharmaceuticals for imaging and localization studies. The license does not authorize therapeutic use of material (e.g., 10 CFR 35.100 and 35.200 programs only). The Radiation Safety Officer was the only authorized user on the license. The licensee receives precalibrated unit doses from a Syncor Nuclear Pharmacy located in Springfield, Missouri. The nuclear medicine staff consists of one technologist and only one authorized user, who has also served as the Radiation Safety Officer (RSO) since the license was originally issued. An average of 40-60 diagnostic studies using NRC-licensed material are performed each month.

2. Inspection History

Prior to this inspection there have been three inspections conducted. The initial inspection was conducted on September 22, 1983. Two apparent violations of NRC requirements were identified: (1) records of Medical Isotope Committee meetings not properly maintained and (2) records of quarterly linearity checks on the dose calibrator were not properly maintained. The second inspection conducted on September 4, 1986, identified two apparent violations of NRC requirements: (1) failure to perform a linearity check of the dose calibrator, and (2) failure to perform a leak test. The third inspection conducted on October 26, 1992, identified one apparent violation for the failure to perform weekly contamination surveys.

3. Inspection Scope

The inspection consisted of interviews of key personnel associated with the implementation of the radiation safety program, including the nuclear medicine technologist (NMT), the Radiation Safety Officer (RSO), and the Radiology Supervisor. The inspector also reviewed records of area and package surveys, package receipt logs, leak tests, personnel radiation exposure, consultant audit reports, radiation safety committee meeting minutes, and dose calibrator tests.

4. Findings and Observations Associated with Equipment and Instrumentation

Survey instruments were calibrated by the licensee's consultant during annual visits to the licensee's facility. In addition, the consultant performed an accuracy test of the licensee's dose calibrator during the annual visit. No problem was noted with the annual calibrator accuracy test reviewed, however, other required tests were not performed.

10 CFR 35.50(b)(1) requires, in part, that a licensee check each dose calibrator for constancy with a dedicated check source at the beginning of each day of use. 10 CFR 35.50(e) requires, in part, that a licensee retain records of constancy tests of

the dose calibrator for three years unless directed otherwise. In addition, 10 CFR 35.50(b)(3) requires, in part, that a licensee test each dose calibrator for linearity at least quarterly. The inspection revealed that for a time period from September 28, 1993, to October 1, 1995, constancy tests had not been performed. In addition, linearity tests had not been performed since July 6, 1992.

The consultant identified the problem with the daily constancy checks in his letter to the licensee dated August 1, 1995. Corrective action was taken in October 1, 1995. The licensee could not locate the 1994 consultant report to determine if the same problem had been identified the previous year, but not corrected. Also, the consultant's report did not identify the licensee's failure to perform quarterly linearity tests.

The failure of the licensee to check each dose calibrator for constancy at the beginning of each day of use for the period from September 30, 1993, through October 1, 1995, constitutes an apparent violation of 10 CFR 35.50(b)(1).

The failure of the licensee to perform quarterly linearity tests on the dose calibrator from July 6, 1992, to the date of this inspection constitutes an apparent violation of 10 CFR 35.50(b)(3).

During the part of this time period between September 30, 1993, and October 1, 1995, the licensee used a generator for preparing radiopharmaceuticals for patient studies. Given that the annual check of the dose calibrator found no deficiencies, there is a good likelihood that the doses prepared were proper, even though the licensee failed to test the calibrator on the daily and quarterly frequencies required.

At the time of this inspection, the licensee was using unit doses supplied by Syncor. Since Syncor would have also verified the dose via its dose calibrator, there is little likelihood that an improper dose was administered during the period the dose calibrator was not tested by the licensee.

5. Findings and Observations Associated with Area Surveys

The inspector found that for a time period between September 29, 1993, and October 1, 1995, daily radiation and weekly contamination surveys had not been performed. License Condition 16 of the license requires the licensee to implement the statements made in the May 30, 1993, application. Item 10.12 of this application stated that the licensee would implement the model procedure for area surveys published in Appendix N to Regulatory Guide (RG) 10.8, revision 2. Item 1.a of Appendix N requires daily radiation surveys and weekly surveys for removable contamination in areas where radiopharmaceutical elution, preparation, and administration are performed. These surveys are also required by 10 CFR 35.70(a) (dose rates) and 10 CFR 35.70(e) (removable contamination). The appendix further requires that the results be recorded in mR/hr for the surveys and in dpm/100 cm^2 for contamination surveys.

The consultant identified the failure to perform these surveys in his letter to the RSO dated August 1, 1995; and corrective action was taken on October 1, 1995. However, this deficiency should have been identified by the RSO at least by November of 1993, and by the consultant's audit in 1994. Appendix N also specifies that the RSO will review and initial the record of these surveys at least monthly. The RSO should have identified that no surveys were being performed based on the fact that nothing was available to be initialed.

Additionally, a Notice of Violation was issued during the previous NRC inspection that found the licensee had failed to perform the weekly surveys from October 2, 1992, to October 26, 1992. The licensee's stated corrective actions in response to that Notice of Violation were instructing the technologist to be more aware of the need for these surveys and requesting the RSO to review all radiation survey records on a weekly basis. These corrective actions were not effective.

Failure of the licensee to perform surveys 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 over the period September 29, 1993, through October 1, 1995, constitutes an apparent violation of 10 CFR 35.70(a) and License Condition 16.

Failure of the licensee to perform surveys for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored between September 29, 1993, and October 1, 1995, constitutes an apparent repeat apparent violation of 10 CFR 35.70(e) and License Condition 16.

At the time of the inspection, the licensee was performing these surveys; however, the data consisted of checkmarks in a column, rather than actual readings. The licensee stated that the checkmark was to be interpreted as less than the minimum detectable values, namely 0.02 mR/hr and 2,000 dpm/100 cm^2, and that if a result greater than one of these values was measured, that value would be recorded instead of the checkmark. The inspector concluded that this methodology met the requirement since the checkmark constituted a defined value.

During the time period when area surveys and contamination surveys were not performed, the licensee cannot substantiate, particularly when the licensee was using a generator for preparing radiopharmaceuticals, whether the control of licensed material was confined to areas specified in the licensee's procedures. Since Technetium-99m was the predominantly used material, with a half life of a few hours, any contamination that may have occurred in that time frame has decayed by now, and would no longer be present. Surveys conducted by the inspector during the inspection did not reveal any areas of contamination or unusual exposure rate measurements.

6. Findings and Observations concerning the use of Personnel Dosimetry

Upon entering the department, the NRC inspector observed that the staff technologist was not wearing his TLD finger monitor. A review of dosimetry results for the technologist showed that the dose to the hand of the staff technologist performing injections of licensed material indicated a "M" or minimal dose for several quarters, but the records also indicated that the individual had received a whole body dose. Upon questioning, the staff technologist admitted that he routinely did not wear the TLD finger monitor, but provided no explanation as to why. The staff technologist showed the inspector that the monitor had been issued but was kept in a drawer at the secretary's station. The requirement of wearing the ring monitor also had been discussed with the staff technologist during the previous NRC inspection according to NRC documents.

10 CFR 20.1502(a)(1) requires, in part, that each licensee supply and require the use of individual monitoring devices by adults likely to receive, in one year from sources external to the body, a dose in excess of 10% of the limits in 10 CFR 20.1201(a). In addition, License Condition 16 required implementation of Appendix D to RG 10.8, revision 2. Item 3 of Appendix D stated, in part, that all individuals who, on a regular basis, handle radioactive material will be issued a film or TLD finger monitor. Since the staff technologist was the only individual routinely performing injections of radioactive material, he could exceed the 10% limit for extremity exposure, and was therefore required to wear the film or TLD finger monitor.

The failure to wear and use individual monitoring devices constitutes an apparent violation of 10 CFR 20.1201(a) and License Condition 16.

This apparent violation should have been identified earlier by the RSO. Item 1 of Appendix D requires the RSO to promptly review all exposure reports to look for workers or groups of workers whose exposure was unexpectedly high or low. Personnel monitoring records reviewed by the inspector indicated that the dose to the hand of the staff technologist performing injections of licensed material indicated an "M" or minimal dose, which would not be expected given the routine handling of radioactive material.

Not only would the finger monitor indicate how much radiation dose an individual received while handling licensed material, but also it could indicate how well the individual was performing procedures relating to handling and shielding syringes containing licensed material. Since the patient workload at this hospital was low (an average of 40-60 diagnostic studies per month), the likelihood of receiving an overexposure to the extremities was minimal, even during the period when the hospital eluted generators. However, given the lack of monitoring, the actual dose received by the technologist is unknown.

7. Findings and Observations Concerning the Receipt and Opening of Packages

All packages containing radiopharmaceuticals were received from and delivered by Syncor, Springfield, MO. The packages were typically labeled as Department of Transportation (DOT) White-I packages. The package receiving records did not provide any indication concerning the conduct of wipe tests. Upon questioning, the staff technologist stated that he was not performing contamination surveys on the outside of the packages.

10 CFR 20.1906(b)(1) requires that each licensee monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for radioactive contamination. Failure to monitor the external surfaces of a package labeled with a Radioactive White I label for radioactive contamination is an apparent violation of 10 CFR 1906(b)(1).

In all cases, these packages were surveyed and verified to be free of contamination by the radiopharmacy prior to being sent to the licensee. In most cases, no contamination of the package should occur, and the missed surveys, if performed, would have detected no activity. However, in the event of a spill of material occurring during shipment, the failure to perform monitoring of the package when received could result in a potential for the spread of contamination in the nuclear medicine area. The inspectors survey of the area did not detect any contamination, so recently received shipments were most likely contamination free. However, given the relatively short half-lives of the material involved, any activity from a contamination event that may have occurred several months ago would have decayed away by the time of the inspection and been undetectable. If such a contamination event did occur, personnel could have been exposed to unnecessary radiation dose.

8. Findings and Observations Concerning Staff Training

In discussions with the staff technologist concerning the apparent violation associated with linearity tests, the technologist stated that the reason he had not performed the tests was that he had not received training on how to perform the test and was waiting until a sales representative from Syncor could visit the licensee and demonstrate how to perform the test procedure. He also stated that he had not received any annual refresher training at least over the past three years.

License Condition 16 of the license requires the licensee to implement the statements made in the May 30, 1993, application. Item 8 of this application stated that the licensee would establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, revision 2. Appendix A of Regulatory Guide 10.8, revision 2, states, in part, that personnel will be instructed during annual refresher training, and such training will include applicable regulations and license conditions, potential hazards, and appropriate radiation safety procedures. The failure to provide annual refresher training to the staff technologist constitutes an apparent violation of License Condition 16.

As noted above, the failure to provide annual refresher training was a direct contributor to one of the apparent violations associated with linearity tests of the dose calibrator. In addition, the training may have prevented some of the apparent violations described in this inspection report from occurring.

9. Findings and Observations Concerning Radiation Safety Committee (RSC) Activities

The inspector determined that the last meeting of the RSC was on October 10, 1993. Since that time, no RSC meetings had been held. The Radiation Safety Officer (RSO) stated that since the hospital staff was small, they would discuss things informally, such as in the hallway, rather than have a formal meeting. There was no set frequency for these discussions.

License Condition No. 16 requires the licensee to comply with the statements and representations made in the application dated May 30, 1993, and attachments thereto. Item 10.1 in that application states that the Radiation Safety Committee (RSC) will be established and implemented in accordance with the model procedures contained in Appendix F of Regulatory Guide 10.8, Revision 2. Those procedures require that the RSC shall ensure: (1) licensed material will be used safely, (2) in compliance with NRC regulations and the license, and (3) that the use of licensed materials is consistent with the ALARA philosophy and program. In addition, the committee shall identify program problems and solutions.

10 CFR 35.22(a)(2) requires that the Radiation Safety Committee meet at least quarterly. However, the inspector determined that the most recent meeting of the RSC was on October 10, 1993.

Failure of the RSC to conduct quarterly meeting since October 10, 1993, constitutes an apparent violation of 10 CFR 35.22(a)(2). As a result, none of the activities required to be performed by the committee per License Condition 16 were accomplished.

The apparent root cause of the RSC's failure to meet was attributed to the RSO. The RSO believed that RSC business could be conducted with other committee members without having formal meetings. However, failure of the RSC to formally meet also created a lack of communication between management and individuals involved with the radiation safety program. During the exit meeting with the Chief Executive Officer (CEO), he stated that he was not aware of the problems in the radiation safety program.

10. Conclusions

The inspector identified several apparent violations of NRC requirements in the conduct of the licensee's radiation safety program. These can be summarized as follows: (1) failure to check each dose calibrator for constancy at the beginning of each day of use; (2) failure to perform quarterly linearity tests on the dose calibrator; (3) failure to perform surveys with a radiation detection survey instrument at the end of each day of use in all areas where radiopharmaceuticals

are routinely prepared for use or administered; (4) failure to perform surveys for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored (repeat); (5) failure to wear and use individual monitoring devices; (6) failure to monitor the external surfaces of a package labeled with a Radioactive White I, Yellow II, or Yellow III label for radioactive contamination; (7) failure to instruct individuals in the purposes and functions of protective devices employed; and (8) failure of the RSC to conduct quarterly meetings.

Several of the apparent violations identified involved activities that should have routinely been under the oversight of the RSO. In the case of the dose calibrator tests, both for constancy and linearity, the RSO was required to review the results and initial them. License Condition 16 included the requirement to follow licensee procedure ATT 9.3, which specified that the licensee would follow the methods and frequencies for calibration of the dose calibrator as specified in Appendix C to RG 10.8, revision 2. Item 8 of Appendix C requires the RSO to review and sign the records for the linearity tests. However, given that the linearity tests were not being performed, so no records were being provided to be signed, the RSO did not identify this deficiency.

License Condition 16 included the requirement to implement the model personnel external exposure monitoring program published in Appendix D to RG 10.8, revision 2. Item 1 of Appendix D requires the RSO to promptly review all exposure reports to look for workers or groups of workers whose exposure was unexpectedly high or low. While the RSO stated that he reviewed the records, it is clear from Section 6 above that no action was taken when an exposure was unexpectedly low. The purpose for the RSO review was to identify radiation safety program deficiencies so that they could be corrected. Had the RSO questioned the abnormally low result for the staff technologist, he would have learned that the dosimetry was not being worn.

10 CFR 35.21(a) requires that the licensee, through the Radiation Safety Officer, ensure that radiation safety activities are being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program. Given the number and duration of the apparent violations identified, and the specific examples of activities requiring specific oversight that had not been conducted, this requirement was not met. The failure of the RSO to ensure that radiation safety activities were being performed in accordance with approved procedures and regulatory requirements in the daily operation of the licensee's byproduct material program constitutes an apparent violation 10 CFR 35.21(a).

The RSO's apparent failure to ensure that radiation safety procedures and activities were being performed was a major contributing factor in the breakdown of the licensee's radiation safety program.

11. Exit Meeting

At the conclusion of the onsite inspection, the inspector met with the CEO of the hospital. The inspector and members of NRC Region III Division of Nuclear Materials Safety Management (via telephone) summarized the scope and preliminary findings of the inspection. The CEO's immediate corrective action was to close down the licensee's nuclear medicine department and obtain the services of Nuclear Diagnosis, Inc. a mobile nuclear medicine vendor. The licensee also agreed to conduct a comprehensive audit of the nuclear medicine program to identify deficiencies, and develop corrective actions for those deficiencies prior to resuming licensed activities. This was confirmed by way of a Confirmatory Action Letter issued by the NRC on April 16, 1996. The licensee did not identify any information as proprietary in nature.

List of Persons Contacted

Donald C. Babb, Chief Executive Officer (CEO)
Jay B. Crabtree, M.D., Radiation Safety Officer (RSO)
Oliver McSweeney, Radiology Supervisor
Victor Wainscott, Technologist
Doug Stevenson, Ultrasound Technologist

List of Acronyms Used in This Report

CEO	Chief Executive Officer
dpm	disintegrations per minute
mR/hr	millirem per hour
NMT	Nuclear Medicine Technologist
RG	Regulatory Guide
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
TLD	thermoluminescent dosimeter

SYNOPSIS

This investigation was initiated by the U.S. Nuclear Regulatory Commission (NRC), Office of Investigations (OI), Region III (RIII), on April 22, 1996, to determine: 1) Whether the licensee knowingly failed to conduct required quarterly radiation safety committee meetings; 2) Whether the licensee knowingly failed to conduct annual radiation safety program reviews; 3) Whether the licensee failed to perform required quarterly linearity tests of the dose calibrator; 4) Whether the licensee knowingly failed to provide annual refresher training to supervised individuals; 5) Whether the Nuclear Medicine Technologist (NMT) is deliberately not wearing finger (ring badge) dosimetry; 6) Whether the Radiation Safety Officer (RSO) is deliberately not performing duties required by 10 CFR 35.21; 7) Whether or not routine records relating to use of licensed material, such as daily surveys, package surveys, and sealed source inventory records, may have been falsified.

Based on the evidence developed during the investigation, the following conclusions are listed chronologically to compare to the above listed eight (8) allegations:

(1) Based upon the evidence developed during the investigation, it is concluded that the RSO deliberately failed to conduct required Quarterly Radiation Safety Committee Meetings.

(2) Based upon the evidence developed during the investigation, it is concluded there is insufficient evidence to substantiate alleged deliberate failure to conduct Annual Radiation Safety Program Reviews.

(3) Based on the evidence developed during the investigation, it is concluded that the NMT deliberately failed to perform required quarterly linearity tests of the dose calibrator.

(4) Based on the evidence developed during the investigation, it is concluded that the RSO deliberately failed to provide annual refresher training to supervised individuals.

(5) Based on the evidence developed during the investigation, it is concluded that the NMT deliberately failed to wear Finger (Ring Badge) Dosimetry.

(6) Based on the evidence developed during the investigation, it is concluded that the RSO deliberately failed to perform the duties of RSO as required by 10 CFR 35.21

(7) Based on the evidence developed during the investigation, it is concluded that the allegation of alleged falsification of routine records relating to use of licensed material, such as daily surveys, package surveys, and sealed source inventory records, is unsubstantiated.