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DONALD J. BABB,
CHIEF EXECUTIVE OFFICER

August 13, 1996

Cynthia D. Pederson
United States Nuclear Regulatory Commission
Region III
801 Warrenville Road
Lisle, IL 60532-4351

Dear Ms. Pederson:

Attached is our response to the confirmatory action letter CMH received on April 19, 1996, concerning an NRC inspection conducted on April 10-11, 1996 at our facility. For the present time, we have discontinued all activities involving the use of licensed material by our staff. Nuclear Diagnostics, Inc. is conducting licensed activities at our facility till October 20, 1996. At that time our radiology department construction project should be completed and we will be ready to resume performing activities involving the use of licensed material by our staff. We understand a final inspection and a meeting with the NRC Region III representatives and CMH management must occur prior to resuming nuclear medicine activities at our facility.

Citizens Memorial Hospital has performed a license program implementation review to determine if we are conducting nuclear medicine services in accordance with our license and applicable regulations. We have addressed all the statements, representations, and procedures contained in the documents submitted in the 5/30/93 application (see attached).

After review of our deficiencies and action plan we would like to arrange a time to meet with the NRC Region III representatives to discuss our licensed program review. Let us know when this is convenient for you.

We will gladly discuss any questions you have concerning the stated deficiencies or actions.

Sincerely,

Donald J. Babb
Chief Executive Officer

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IE07

AUG 19 1996

cc: Harold J. Walker
Senior Investigator
Nuclear Regulatory Commission
801 Warren Road
Lisle, IL 60532

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REF NRC 313 Item 8
Personnel Training Program

We will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, revision 2.

Deficiencies Identified

1. No annual refresher training for Radiation Safety Officer (hereafter referred to as RSO), Nuclear Medicine Technologist (hereafter referred to as NMT), or other staff identified as participants.

2. No instruction has been provided whenever there was a significant change in duties, regulations or terms such as changing from generator hot lab operations to central nuclear pharmacy or changing from registered NMT as primary technologist to a non-registered NMT as primary technologist.

Root Cause(s)

1. Lack of participation by the RSO to maintain compliance with NRC regulations.

2. Lack of knowledge of NRC regulations and Citizens Memorial Hospital's Nuclear Medicine procedures by the Director of Radiology from October, 1995 until June, 1996.

3. Lack of leadership and direction from radiology director/registered NMT from 1993 until June, 1995.

4. Lack of attendance at annual refresher course by NMT performing nuclear medicine procedures.

5. Lack of administrative oversight to the radiation safety component of the radiology department.

Action

1. The hospital's Chief Executive Officer has discussed deficiencies and lack of participation by the RSO with the radiologist/RSO. The RSO will be required to attend an annual refresher training seminar. The RSO is scheduled to attend the seminar "*Basic Radiation and Safety Management*" in October, 1996. The CEO and/or Director of Medical Affairs will monitor compliance of attendance. Also, the Radiation Safety Committee (hereafter referred to as RSC) will included identification of yearly compliance.

2. Termination of the radiology director effective 6/28/96. The hospital's goal is to hire a Director of Radiology who is knowledgeable in Nuclear Medicine, familiar with the NRC regulations, and has management experience. The hospital is presently conducting interviews and anticipate the date of hire to be completed by October, 1996.

3. The former director of radiology (prior to the one noted above)/registered NMT has been suspended. When reinstated, he will no longer have leadership responsibilities in the nuclear medicine division.

4. The NMT will attend an annual refresher training seminar. The NMT is scheduled to attend the seminar "*Basic Radiation and Safety Management*" in October, 1996.

5. The Director of Clinical Services will attend an annual refresher course. The Director of Clinical Services is scheduled to attend the seminar "Basic Radiation and Safety Management" in October, 1996.

6. The RSO or NMT will provide in-house in-services through educational presentations, paper programs, videos or featured speakers to other nuclear medicine personnel, housekeeping, nursing, maintenance, and safety and security staff to be completed by October, 1996.

7. The hospital has hired a nuclear medicine consultant group who will assist with providing educational updates when significant changes in duties, regulations or terms of licensure are identified.

REF NRC 313 Item 9.2
Calibration of Survey Meters

We have developed a survey instrument calibration procedure for your review that is appended as ATT 9.2.

ATT 9.2
Calibration of survey meters

Survey meters will be calibrated at intervals not to exceed 12 months, and after repairs, by any firm that is approved by the NRC for such calibrations. Instruments will be calibrated on at least two (2) points on each scale range. For our calibration service we will use Stan A. Huber Consultants, Inc., of New Lenox, Illinois, License #IL-01013-01, or another licensed calibration firm. We will maintain a copy of calibration service's radioactive materials license on file.

The licensee shall perform operational and constancy check on survey instrument before each day's use to ensure proper functioning of the devices. For any infrequently used meters, these reference source operational checks shall be taken at least quarterly, per

NRC Regulatory Guide 10.8, Revision 2, Appendix B, as well as after repairs and battery changes to ensure constancy within +/-20% of expected readings.

Deficiencies Identified

1. We have not performed day-of-use (or at least quarterly after September 27, 1993) operational check on our survey instruments. The only operational checks completed were those performed after the annual calibrations.

Root Cause(s)

1. Failure by the NMT to comply with known policies.

2. Lack of knowledge of the RSO and management that these operational checks need to be performed.

Action

1. The NMT was suspended for failure to comply with hospital policy.

2. When CMH resumes activity in the Nuclear Medicine department, these operational checks will be completed as required. The results of these checks will be reviewed by the consultant at least quarterly.

REF NRC 313 Item 9.3
Procedure for Calibrating Dose Calibrator

We have developed a dose calibrator procedure for your review that is appended as ATT 9.3

ATT 9.3
Procedure for Calibrating Dose Calibrator

We shall follow the calibration methods and frequencies for dose calibrators as defined in the NRC Regulatory Guide 10.8, revision 2, Appendix C.

For the linearity test, we will test the dose calibrator over the range of its use between the highest dosage that will be administered to a patient and 30 uCi. The accuracy test will be completed by Stan A. Huber Consultants, Inc., of New Lenox, Illinois, or other licensed calibration firm.

We use a NEN Model NES-356, Cs-137 standard, 100-300 uCi or any approved similar standard for our day-of-use dose calibrator constancy checks. Records of all tests and checks will be maintained in accordance with the regulations.

We request use of the "Calicheck" (Calcorp) system or "Lineator" (Atomic Products) system as an alternate method of performing dose calibrator quarterly linearity checks. The product certifications for these devices are on file with the NRC.

Deficiencies Identified

1. No quarterly documentation of the linearity test since October, 1993.

2. No documentation that the dose calibrator was checked for constancy since September 29, 1993.

Root Cause(s)

1. The NMT said he was not aware that the instrument needed to be checked for constancy because only unit doses were being used at the facility. The technologist did not check for constancy because he assumed that the pre-calibrated doses were always correct. We attribute the cause to be lack of training for the technologist.

2. Again, the NMT was under the impression that linearity testing did not need to be completed since pre-calibrated doses were being utilized. We attribute the cause to be lack of training for the technologist.

Action

1. The NMT will perform linearity tests upon installation and at least quarterly. These tests will check the dose calibrator over the range of its use from the highest dosage that will be administered to a patient down to 30 uCi.

2. Review quarterly logs with the hospital's consultant group and the RSO for completion and accuracy.

3. The NMT will complete a constancy test on the dose calibrator prior to assaying doses to be administered to patients. This documentation will be reviewed monthly by the consultant (via fax) for one year.

4. The NMT will receive training prior to re-opening and annually thereafter.

5. The RSO will review and sign the linearity test once test is completed.

REF NRC 313 Item 9.4
Personnel Monitoring
We will establish and implement the model personnel external monitoring program published in Appendix D to Regulatory Guide 10.8, Revision 2.

Deficiency Identified

1. No documentation present to show all exposure reports to assess unexpectedly high or low exposures were reviewed by the RSO.

Root Cause(s)

1. Lack of participation by the RSO to maintain compliance with the NRC regulations.

Action

The NMT, upon receiving radiation dosimetry reports, will show report to the RSO who will review, sign, and date report. Any irregularities will be identified by the RSO and a summation report presented to the RSC. Necessary interventions regarding high doses will be addressed with the individual by the RSC.

REF NRC 313 Item 9.5
Transporting of Imaging Equipment
Not applicable

REF NRC 313 Item 10.1
Radiation Safety Committee

We will establish and implement the model procedures for establishing and operating a Radiation Safety Committee that was published in Appendix F to Regulatory Guide 10.8, Revision 2.

Deficiencies Identified

1. Radiation Safety committee did not meet between October, 1993 through June, 1996.

Root Cause(s)

1. The RSO failed to schedule meetings on a quarterly basis.

2. The Director's of Radiology failed to question lapse of meetings during this period.

Action

1. The RSO has been informed of his responsibility to call and conduct quarterly RSC meetings. For a minimum of one year, these meetings will be held monthly, beginning in August, 1996 to develop the hospital's Radiation Safety Program. The hospital's Nuclear Medicine consultant will be requested to attend a quarterly meeting to provide information concerning their visit and inspections, and to provide necessary updates and educational programs to their committee.

2. We are in the process of interviewing candidates for the Director of Radiology position who will be knowledgeable of the NRC requirements and will monitor the timeliness of the meetings. The current registered NMT has been suspended and the Director of Radiology has been terminated for failure to monitor program.

3. The Director of Clinical Services will be involved to assist the RSO in scheduling a monthly date for the first twelve months (and then quarterly thereafter), locating a meeting room, notifying the consultant, typing the agenda for the RSO, and recording meeting minutes.

4. The Radiation Safety Committee will include the following personnel:

    Jay Crabtree, M.D., Radiation Safety Officer
    Victor Wainscott, Nuclear Medicine Technologist
    Karen Keeton, Director of Clinical Services
    Ginger Holt, Director of Medical Records
    Sherry Welch, Director of Safety and Security
    Donald J. Babb. Chief Executive Officer
    Director of Radiology (when position filled)

We do reserve the right to change personnel on this committee as long as we meet the minimum requirements outlined in 10 CFR 35.22.

REF NRC 313 Item 10.2
ALARA

We will establish and implement the model ALARA program that was published in Appendix G to Regulatory Guide 10.8, Revision 2.

Deficiencies Identified

1. Failure to perform an annual review of the radiation safety program including:
   a) review and update of policy and procedure manual by the RSC
   b) quarterly review of occupational radiation exposure by RSO with a summary report prepared for the RSC
   c) quarterly review or records of radiation surveys in restricted and unrestricted areas by RSO and preparation of a summary report to be presented to the RSC

2. Briefing and educational sessions to inform workers of ALARA program efforts were not scheduled.

Action

1. The RSC will begin the annual review of the radiation safety program's policies and procedures to assess accuracy and compliance in the monthly radiation safety committee meetings.

2. The RSO will perform quarterly reviews of occupational radiation exposure reports as indicated by his signature on the Radiation Dosimetry report and prepare a summary report to be included in the quarterly RSC meetings.

3. The RSO will review quarterly records of radiation surveys in restricted and unrestricted areas and prepare a summary report to be included in the quarterly RSC meeting.

4. The RSO will schedule briefings and educational sessions to be provided by himself, designated speakers, or consultants to inform workers of ALARA procedures when working with radioactive materials. Educational programs will be identified and scheduled at a minimum of once per quarter. The RSO, NMT, and Director of Clinical Services will attend the "Basic Radiation Safety and Management Seminar" in October, 1996 to become familiar with conducting an effective radiation safety program.

REF NRC 313 Item 10.3
Leak Test Procedures

We have developed a leak test procedure for your review that is appended as ATT 10.3

Deficiencies

1. We did not leak test our facility's by-product material sealed sources with activity greater than 100 uCi between July, 1994 and July, 1995. The leak test which should have been completed during January, 1995 was not performed.

Root Cause(s)

1. The NMT was under the pretense that the leak tests were to be completed by the Department Director who was not aware these tests needed to be performed.

Action

1. The consultant will perform the leak tests for at least one year to get a regular schedule established. We expect that the schedule will be set after two leak testing intervals. After one year, wipe testing of sealed sources may be obtained by a representative of the hospital.

2. Analysis of the semi-annual leak tests will be completed by Stan A. Huber Consultants, Inc., or an equivalently licensed firm.

REF NRC 313 Item 10.4
Safe Use of Radioactive Pharmaceuticals

We will establish and implement the model safety rules published in Appendix I to Regulatory guide 10.8, Revision 2. When hands and clothing are monitored for contamination, only a survey meter will be used. When radiopharmaceuticals are transported between the hot lab and a remote injection or imaging room, they will be shielded in a lead syringe holder or pig.

Deficiencies

1. Failure to wear a laboratory coat or other protective clothing at all times in area where radioactive materials are used.

2. Failure to wear disposable gloves at all times when handling radioactive materials.

3. Failure to monitor hands for contamination in a low background area with a calibrated survey instrument following each procedure or before leaving the area.

4. Failure to wear a finger exposure monitor during the elution of generators; during the preparation, assay and injection of radiopharmaceuticals, and when holding patients during procedures.

Root Cause(s)

1. Failure to comply with hospital policies and NRC regulations.

Action

1. The NMT was suspended for non-compliance with policy. When CMH resumes activities in Nuclear Medicine, the NMT will follow the outlined rules and regulations. The RSO will spot check to see that the NMT is in compliance. Compliance with procedures will be addressed on annual performance appraisals of the NMT.

REF NRC 313 Item 10.5
Spill Procedures

We will establish and implement the model spill procedure published in Appendix J to Regulatory Guide 10.8, revision 2.

No deficiencies identified.

REF NRC 313 Item 10.6
Ordering and Receiving of Radioactive Materials

We will establish and implement the model guidelines for ordering and receiving radioactive material that was published in Appendix K to Regulatory guide 10.8, revision 2.

No deficiencies identified.

REF NRC 313 Item 10.7
Opening Packages Containing Radioactive Materials

We will establish and implement the model procedure for opening packages that was published in Appendix L to Regulatory Guide 10.8, revision 2. We will notify the Nuclear Regulatory Commission in case of loss, theft, damage, or fire affecting radioactive material.

Deficiencies

1. Failure to perform the wipe test on incoming packages by the NMT.

Root Cause(s)

1. In September, 1993, the wipe test instrument failed to be accurate. Administration did not approve purchase of a new instrument due to the lack of understanding of the importance of the instrument.

Action

1. Purchased wipe test instrument in August, 1995 after consultant report. Clinical Services director facilitated identifying the need for the instrument which resulted in equipment purchase. Since October, 1995 when the wipe test equipment was received and in-serviced, the NMT has performed and documented the wipe test procedure on all incoming packages. The NM consultant will review wipe test logs for completion and accuracy on a monthly basis (via fax).

REF NRC 313 Item 10.8
Record of Unit Dosage Use

We will establish and implement the model procedure for a unit dose record system that was published in Appendix M to Regulatory Guide 10.8, revision 2.

Deficiencies

1. From the period of September 29, 1993 until August, 1995, the radiopharmaceutical usage records were found to be incomplete compared to what is required by the radioactive materials license

Root Cause(s)

1. Lack of training on the part of the NMT. The NMT was unsure how to proceed since the hospital had changed from a generator to unit dose.

Action

1. In October, 1995, the problem was resolved by the NMT through a training session by our consultant. For each unit dosage received from a supplier, a record is now made of the:
    a) radionuclide
    b) generic name or its abbreviation or trade name
    c) date of receipt
    d) supplier
    e) lot number or control number, if assigned
    f) activity in millicuries or microcuries as recorded on the unit dosage or packing slip and its associated time
    g) date of administration or disposal
    h) if administered:
        *prescribed dosage (unless already recorded in clinical procedure manual)

*measured activity in millicuries or microcuries and date and time of measurement
*patient name and identification number if one has been assigned

i) if discarded, the date and method of disposal and
j) initials of the individual who made the record

REF NRC 313 Item 10.10
MO-99 Concentration Records

We will establish and implement the model procedure for measuring and recording molybdenum concentration that was published in Appendix M3 Regulatory Guide 10.8, revision2.

No deficiencies noted.

No longer have a generator since 1993. Use unit doses supplied by Syncor International Corporation, Springfield, MO.

M2 Records of Multidose Vial Use

We will establish and implement the model procedure for a multidose vial record system that was published in Appendix M2 to Regulatory guide 10.8.

No deficiencies identified.

REF NRC 313 Item 10.12
Area Survey Procedures

We will establish and implement the model procedures for area surveys that was published in Appendix N to Regulatory Guide 10.8, revision 2. A survey meter will be used to monitor hands and clothing for contamination. Please note: If Tc99m cardiolite is used in the stress area, a day-of-use survey will be performed.

Deficiencies

1. Failed to survey and document Radiopharmaceutical elutions, preparations, and administration areas at the end of each day of use with a radiation detection survey meter since September 29, 1993. The NMT was responsible for this duty.

2. Failure to survey for removable contamination once each week all areas where radiopharmaceuticals are routinely prepared for use, administered, or stored as identified in CFR 35.70(e) and (f).

Root cause(s)

1. The NMT believed the surveys were not needed with additional equipment following a discussion with the Radiology Director concerning the procedure and documentation of the surveys. Lack of training on the part of the NMT.

Action

1. Suspension of the radiology director, removal from responsibilities associated with nuclear medicine.

2. Suspension of the NMT. Following suspension and resumption of nuclear medicine activities by CMH, the NMT will be responsible for performing and documenting surveys in area and at the end of each day of use. The RSO will spot check to see that the NMT is in compliance. Compliance with surveys will be addressed on annual performance evaluations. Our consultant will review logs monthly (via fax) for compliance and accuracy for a period of one year.

3. The NMT will be responsible for performing and documenting the surveys for removable contamination. This documentation will be reviewed by the consultant at least monthly by the consultant (via fax for at least one year) and the RSO at least weekly. The RSO will sign the results of these surveys to confirm that the documentation has been reviewed.

REF NRC 313 Item 10.13
Air Concentration Control

Not applicable.

REF NRC 313 Item 10.14
Radiopharmaceutical therapy

Not applicable

REF NRC 313 Item 10.15
Implant therapy

Not applicable.

REF NRC 313 Item 11.1
Waste Disposal

We will establish and implement the general guidance and model procedures for waste disposal that were published in Appendix R to Regulatory Guide 10.8, revision 2.

Deficiencies

1. There are no disposal records being kept.

Root Cause

1. The NMT was returning all unit dose syringes to the pharmacy. Any other syringes and miscellaneous materials (alcohol wipes, cotton balls, etc.) were left unaccounted for. The NMT did not realize he needed to account for these materials.

Action

1. Unit dose syringes and unused doses will be returned to the pharmacy as before.

2. We will store miscellaneous contaminated items for decay. These materials will not be disposed until the following requirements are met:

    a) Hold material for a minimum of ten half-lives
    b) Monitor materials at the container surface before disposing as ordinary trash and determine that its radioactivity cannot be distinguished from the background radiation level with a radiation detection survey meter set on its most sensitive scale and with no interposed shielding; and
    c) All radiation labels are removed or obliterated