The Community Hospital

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TELEPHONE 219/836-1600

June 2,1994

W. L. Axelson, Director
Division of Radiation Safety
and Safeguards
USNRC Region III
801 Warrenville Road
Lisle, IL 60532-4351

RE:13-15882-01

Dear Sirs:

We are responding to your letter dated May 27,1994 which we received on May 31,1994 requesting a response to inspection findings of May 3rd and 4th, 1994 by Jamnes Cameron, USNRC Region III.

A. Nuclear Medicine Technologist not wearing gloves during an injection.

CORRECTIVE ACTION

1. All Nuclear Medicine Technologists (NMTs) have attended the hospital's annual inservice training on universal precautions since the inception of a universal precautions policy. The NMTs received their most recent annual mandatory inservice training on universal precautions during the first week of April 1994. During this inservice, it was emphasized that it is hospital policy that all hospital personnel must wear gloves during all invasive procedures. All NMTs have participated in the CLIA review in April, 1994 (includes infection control).

2. The NM technologist who did not wear gloves during an injection of radiopharmaceuticals has been disciplined.

3. The NM technologist who did not wear gloves during an injection of radiopharmaceuticals has received additional training for universal precautions May 2,1994 and radiation safety with radiopharmaceuticals on May 3,1994.

4. The Director of NM has initiated a QA program for glove use. This program calls for no fewer than four random unannounced inspections a month. Any incident of non-glove wearing while handling radioactive material will be reported to the RSO at once. The results of this QA program will be reported to the RSC on a quarterly basis. The frequency of these random inspections will be reviewed by the RSO on a quarterly basis and adjusted as necessary.

B. Failure to submit a QMP program for radiopharmaceuticals to the USNRC.

CHRONOLOGY OF EVENTS

1. A QMP program for radiopharmaceuticals and brachytherapy (the Department of Radiation Therapy was currently under construction) was prepared by Stan A. Huber Consultants, Inc. (SAHCI) for Community Hospital in January, 1992. This program was reviewed and approved by the RSC at its January 21,1992 meeting. The QMP for therapeutic radiopharmaceuticals was implemented immediately by the Nuclear Medicine (NM) Department. This QMP for brachytherapy was to be implemented upon obtaining approval for brachytherapy sources.

2. The QMP for radiopharmaceuticals was to be submitted to the USNRC immediately. The QMP for brachytherapy was to be submitted to the USNRC along with the license amendment request to authorize brachytherapy sources.

3. It was the understanding of Community Hospital that the QMP for radiopharmaceuticals was sent to Region III, USNRC by SAHCI for Community Hospital.

4. The QMP for radiopharmaceuticals in the Nuclear Medicine Department was reviewed quarterly by SAHCI, beginning in April, 1992. This quarterly QMP review for NM has been performed continuously from its inception to the present.

5. The QMP for brachytherapy was submitted to Region III, USNRC in our March 24,1992 amendment request to authorize the use of brachytherapy sources and remote afterloading sources.

6. Region III, USNRC responded to CH on June 24,1992 requesting that we submit a QMP for remote afterloading devices. On June 30,1992 we submitted our QMP for remote afterloaders to Region III, USNRC. Since Region III did not request a QMP for radiopharmaceuticals at this time, we presumed that our QMP for radiopharmaceuticals had been accepted.

7. The QMP in Radiation Therapy was initiated with the first brachytherapy procedure in the department (August 1992). The first QMP review in RT was performed in December 1992 and has been continued at quarterly intervals.

8. On May 2, 1992, during a routine USNRC license inspection, the inspector informed CH that we had not submitted a QMP for radiopharmaceuticals. The inspector also informed us that the QMP that we had was not adequate.

CORRECTIVE ACTION

9. The CH QMP was revised and submitted to Region III, USNRC in a letter dated May 3,1994. The revised QMP submitted to Region III, USNRC included the radiopharmaceutical section.

10. As of May 6, 1994, the current QMP was reviewed with all authorized users and NM technologists. The review was conducted by the RSO and/or the Director of Nuclear Medicine (co-authors of the QMP).

11. As of May 4, 1994 any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131 given in the Nuclear Medicine Department will be audited by the Radiation Safety Officer (or qualified delegate). The RSO (or qualified delegate) shall be notified by the NM Department prior to any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131. In all cases the audit will be performed by someone who did not participate in the procedure. The audit will be performed using the original documentation.

12. As of May 4, 1994 each therapeutic dosage of a radiopharmaceutical, brachytherapy or remote afterloader procedure performed in the Radiation Therapy Department will be audited by member of the RSC who did not participate in the procedure. This audit will be performed no less frequently than quarterly.

13. As of May 4, 1994 revised forms for the written directive have been used for any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131, any brachytherapy procedure, or any remote afterloader procedure. These revised forms make the written directive clearer and easier to audit.

    The written directive by an authorized user will include all items as specified in Community Hospital's current QMP.

    The authorized user will verify that the specific details of the administration are in accordance with the written directive as specified in Community Hospital's current QMP.

    Any changes from the written directive deemed necessary during the procedure will be documented in the patient's chart.

    Any unintended deviations from the written directive will be documented and evaluated at the time of occurrence. The authorized user(s) will evaluate the incident and provide corrective actions as needed to improve the program.

    After administering the dose, the authorized user will date and sign a written record of the calculated administered dose in the patient's chart or in another appropriate record.

    Sample forms are attached as addenda.

14. QMP audits will be reviewed at the quarterly RSC meetings.

15. The QMP will be reviewed at least annually by the RSC. Updates shall be forwarded to the USNRC in a timely manner.

16. All USNRC notices and correspondence are to be routed to the RSO. The RSO will review them in a timely manner. After review by the RSO, the RSO will proceed with the appropriate action. The RSO will place the notice on the agenda of the next quarterly RSC meeting unless more immediate action is required.

17. Each notice or piece of correspondence shall be assigned a check list by the RSO. This check list shall be placed in the current RSC meeting file for items that must be reviewed by the RSC at its next meeting. This check list shall be maintained by the RSO. This check list shall help insure that all USNRC notice and correspondence are properly handled.

C. Previous Inspection Record. The Community Hospital's inspection record over the past two inspection cycles has been excellent.

1. February 21,1991: No items of violation were observed.

2. February 27,1988: One item of violation was observed: "Training of ancillary personnel has not been performed as required. License Condition No. 19."

D. There have been no misadministrations at Community Hospital due to the policies and procedures that have been in place since the current Medical Director of Nuclear Medicine has been at the hospital.

1. There has only been one authorized user of therapeutic radiopharmaceuticals in the Nuclear Medicine Department since 1988.

2. The authorized user has personally consulted each patient prior to each therapy, prescribed the dose, and given the dose.

3. The current Director of Nuclear Medicine has personally assisted the authorized user in each therapeutic dosage of a radiopharmaceutical or each dosage of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131 radiopharmaceutical therapy procedures since assuming that position in 1988.

4. The current policy concerning the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131 specifically states that only the authorized user shall give any therapeutic dosage of a radiopharmaceutical or any dosage of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131 to patients. This policy also states that only qualified Nuclear Medicine Technologists familiar with pertinent hospital policies and procedures, USNRC rules, and license conditions shall assist the authorized user in any therapeutic dosage of a radiopharmaceutical or any dosage of quantities

greater than 30 microcuries of either Sodium Iodide I-125 or I-131 procedures (ordering dose, calibrator check, dose preparation, etc.). Therapeutic doses of a radiopharmaceutical or any dose of quantities greater than 30 microcuries of either Sodium Iodide I-125 or I-131 are not done unless both the authorized user and a qualified Nuclear Medicine Technologist familiar with pertinent hospital policies and procedures, USNRC rules, and license conditions) are present.

E. There have been no misadministrations at Community Hospital due to the policies and procedures that have been in place since the opening of the Radiation Therapy Department.

1. There has only been one authorized user of radiopharmaceuticals, brachytherapy sources, or HDR remote afterloader sources in the Radiation Therapy Department.

2. The authorized user has personally consulted each patient prior to each therapy, prescribed the dose, and given the dose, inserted sources or initiated a HDR treatment.

3. The current Director of Medical Physics has personally assisted the authorized user in each of the radiopharmaceutical, brachytherapy, or remote afterloader therapy procedures since the Department was opened in 1992. The current Director of Medical Physics is certified in Therapeutic Radiological Physics (1984) and in Diagnostic and Medical Nuclear Physics (1987) by the American Board of Radiology and has been trained by Nucletron in the use of the Nucletron Planning System and the Nucletron uSelectron HDR remote afterloading system.

4. The current policy concerning the administration of therapeutic radiopharmaceuticals, brachytherapy, or remote afterloader therapy procedures specifically states that only the authorized user shall give therapeutic radiopharmaceuticals, load brachytherapy sources, or initiate remote afterloader therapy procedures.

a. This policy also states that only a qualified Medical Physicist familiar with pertinent hospital policies and procedures, USNRC rules, and license conditions shall assist the authorized user in therapeutic radiopharmaceutical procedures (ordering dose, calibrator check, dose preparation, etc.). Therapeutic radiopharmaceutical procedures are not done unless both the authorized user and a qualified Medical Physicist familiar with pertinent hospital policies and procedures, USNRC rules, and license conditions are present.

b. This policy also states that only a qualified Medical Physicist familiar with pertinent hospital policies and procedures, USNRC rules, license conditions, and formally trained by Nucletron for remote HDR afterloader procedures shall assist the authorized user in remote HDR afterloader procedures. Remote HDR afterloader procedures are not done unless both the authorized user and a qualified Medical Physicist familiar with pertinent hospital policies and procedures, USNRC rules, license conditions, and formally trained by Nucletron for remote HDR afterloader procedures) are present.

c. This policy also states that only a qualified Medical Physicist familiar with pertinent hospital policies and procedures, USNRC rules, and license conditions shall assist the authorized user in brachytherapy procedures (ordering dose, calibrator check, source preparation, etc.). Brachytherapy procedures are not done unless both the authorized user and a qualified Medical Physicist familiar with pertinent hospital policies and procedures, USNRC rules, and license conditions are present.

Sincerely,

John Gorski, Director
Ancillary Services

Wayne Wcislo, Director
Nuclear Medicine

Eric Zickgraf, MS, CRP, Director
Medical Physics
Radiation Safety Officer

ez/jg
cc: RSO