WATERBURY HOSPITAL HEALTH CENTER
64 ROBBINS STREET
WATERBURY, CT 06721

Jenny M. Johansen, Chief
Medical Inspection Section
Division of Radiation Safety and Safeguards
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406-1415

Reference:
License No.: 06-02406-01
Docket No.: 030-01251
Routine Inspection No.: 030-01251/94-001 Conducted on March 22 & 23, 1994
Your letter dated 4/12/94

Dear Ms. Johansen:

In response to your request, our procedure for administration of radiopharmaceuticals to cardiology patients is attached.

The attached copy of our revised Quality Management Program (GJR.05RQMPBY.S4A. Rev 5/1/94) is submitted as required under 10 CFR 35.32.

The is our Reply to the cited Notice of Violation:

A. The meeting subsequent to the cited radiation safety committee meeting of 8/19/93, where a required quorum was not established due to absence of the R.S.O., a valid quorum was established on 2/16/94. Future meetings will also comply with this quorum requirement. Full compliance established 2/16/94.

B. The inadvertent disposal of 94 uCi of Tc-99m on 2/17/94 is believed to have come from one trash can located in the treadmill room of the Cardiology Stress lab. Prior to this time, the trash cans in the remaining Prep room and gamma camera room in this area were routinely monitored for contamination using a low level GM survey meter. Subsequent to this incident, starting 2/17/94, all trash cans in this three room area of Cardiology are surveyed at the end of each [illegible] for contamination. Full compliance established 2/17/94.

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C. The initial geometry test documentation which we could find for the dose calibrator was dated 5/13/93 which was after its installation date of 12/1/92. In the future, this test will be performed prior to installation of a new dose calibrator. Full compliance will be established at the next appropriate opportunity.

D. Records of the geometrical dependence test of the dose calibrator, the linearity tests of the dose calibrator, sealed source leak tests, and sealed source inventories were signed by the Radiation Safety Officer on 4/20/94. In the future, these records will be reviewed and new records signed by the R.S.O. on a quarterly basis. Full compliance established 4/20/94.

Please let us know if you require any additional information.

Sincerely,

John Tobin
President

Susan E. Sylvestre
Assistant Vice President

cc: U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555

WATERBURY HOSPITAL HEALTH CENTER
NUCLEAR CARDIOLOGY Tc-99m RADIOPHARMACEUTICAL ADMINISTRATION

Our stress cardiolite patients are scheduled every half-hour beginning at 7:00am and running until 10:30am. We receive these 8 individual doses from Mallinckrodt calibrated for their appropriate times : 7:00, 7:30, 8:00 etc. Upon receipt, we cross-check each dose label and container for correct pharmaceutical and correct calibration time with our "Patient-prescription record" that is shipped with the doses from Mallinckrodt. Once this is done, we calibrate our doses using Capintec's CRC-15R dose calibration. It has a pre-calibration feature which allows us to calculate the dose for a specific time. For each dose, we will print out a "Patient dose ticket" which contains the following information: the radiopharmaceutic being used, the mCi amount the dose will be reading at a specific time; ex. 7:00am, 7:30, 8:00 etc., the date and time we're printing this ticket. Therefore, each pre-calibrated dose has a corresponding ticket that has also been preassayed. Before patient administration, we check each label on each dose container to assure that each patient is getting their appropriately timed dose, and this information is again cross-checked on our "Patient Prescription Record" which also has the calibration time and dose printed on it.

The same procedure is repeated for our 8 afternoon rest cardiolite patients. We receive 8 doses pre-calibrated for 11:30 - 3:00pm every half hour. Again we check our shipment for correct pharmaceutical, the time of calibration and "Patient prescription form." Again each dose is assayed in pre-calibration mode, and before patient administration we cross-check each dose container label with our dose ticket. This assures each patient is receiving their appropriately timed and assayed dose.

QUALITY MANAGEMENT PROGRAM

QUALITY MANAGEMENT PROGRAM OBJECTIVE

THIS QUALITY MANAGEMENT PROGRAM IS ESTABLISHED TO PROVIDE A HIGH CONFIDENCE THAT RADIOACTIVE MATERIAL OR RADIATION FROM RADIOACTIVE MATERIAL WILL BE ADMINISTERED AS DIRECTED BY THE AUTHORIZED USER.

APPLICABLE RADIOACTIVE ISOTOPES UTILIZED IN THIS FACILITY

(1) Radiopharmaceutical dosage greater than 30 microcuries I-131 sodium iodide.
(2) Therapeutic radiopharmaceutical dosage of Sr-89.
(3) Brachytherapy (sealed sources).
(4) Diagnostic radiopharmaceuticals, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131.

MODIFICATIONS TO THE QUALITY MANAGEMENT PROGRAM

The institution may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The institution must furnish the modifications to the appropriate NRC Region Office within 30 days after modification has been made.

DEFINITION OF TERMS

DIAGNOSTIC CLINICAL PROCEDURES MANUAL means a collection of written procedures that describes each method (and other instructions and precautions) by which the licensee performs diagnostic clinical procedures; where each diagnostic clinical procedure has been approved by the authorized user and includes the radiopharmaceutical dosage, and route of administration.

MISADMINISTRATION means the administration of:

(1) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131:
  (i) Involving the wrong patient or wrong radiopharmaceutical, or
  (ii) When both the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage and the difference between the administered dosage and prescribed dosage exceeds 30 microcuries.

(2) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131:
  (i) Involving the wrong patient, wrong radiopharmaceutical or route of administration; or
  (ii) When the administered dosage differs from the prescribed dosage by more than 20 percent of the prescribed dosage.

(3) A gamma stereotactic radiosurgery radiation dose: N/A

(4) A teletherapy radiation dose:N/A

(5) A brachytherapy radiation dose: N/A
  (i) Involving wrong patient, wrong isotope, or wrong treatment site (excluding for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site);
  (ii) Involving a sealed source that is leaking;
  (iii) When, for a temporary implant, one or more sealed sources are not removed upon completion of the procedure; or
  (iv) When the calculated administered dose differs from the prescribed dose by more than 20% of the prescribed dose.

(6) A diagnostic radiopharmaceutical dosage, other than quantities greater than 30 microcuries of either sodium iodide I-125 or I-131, both:
  (i) Involving the wrong patient, wrong radiopharmaceutical, wrong route of administration, or when the administered dosage differs from the prescribed dosage; and
  (ii) When the dose to the patient exceeds 5 rems effective dose equivalent or 50 rems dose equivalent to any individual organ.

PRESCRIBED DOSAGE means the quantity of radiopharmaceutical activity as documented:
(1) In a written directive, or
(2) Either in the diagnostic clinical procedures manual or in any appropriate record in accordance with the directions of the authorized user for diagnostic procedures.

PRESCRIBED DOSE means
(1) For gamma stereotactic radiosurgery: N/A
(2) For teletherapy: N/A
(3) For brachytherapy, either the total source strength and exposure time or the total dose, as documented in the written directive.

RECORDABLE EVENT means the administration of:
(1) A radiopharmaceutical or radiation without a written directive where a written directive is required;
(2) A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
(3) A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I-125 or I-131 when both:
  (i) The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and
  (ii) The difference between the administered dosage and prescribed dosage exceeds 15 microcuries;
(4) A therapeutic radiopharmaceutical dosage, other than sodium iodide I-125 or I-131, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;
(5) A teletherapy radiation dose N/A
(6) A brachytherapy radiation dose when the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.

WRITTEN DIRECTIVE means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, except as specified in paragraph (6) of this definition, containing the following information:

(1) For any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131: the dosage;

(2) For a therapeutic administration of a radiopharmaceutical other than sodium iodide I-125 or I-131: the radiopharmaceutical, dosage, and route of administration;

(3) For gamma stereotactic radiosurgery: N/A

(4) For teletherapy: N/A

(5) For high-dose-rate remote afterloading brachytherapy N/A

(6) For all other brachytherapy:

(i) Prior to implantation: the radioisotope, number of sources, and source strengths; and

(ii) After implantation but prior to completion of the procedure; the radioisotope, treatment site, and total source strength and exposure time (or equivalently, the total dose).

SUPERVISION

The licensee is responsible for the acts and omissions of the individuals within the institution who are permitted to receive, possess, use, or transfer radioactive material under the supervision of an authorized user. Supervision of these individuals shall include:

(1) The supervised individual will be instructed in the principles of radiation safety appropriate to that individual's use of radioactive material

(2) The supervised individual will be required to follow the instructions of the supervising authorized user, follow the institution's written radiation safety and quality management procedures, and comply with the applicable license regulations and license conditions with respect to radioactive material; and

(3) Periodic review of the supervised individual's use of radioactive material and the records kept to reflect this use.

SPECIFIC OBJECTIVES, POLICIES AND PROCEDURES

(1) Prior to administration, a written directive* must be prepared for:
  (i) Any teletherapy radiation dose (N/A);
  (ii) Any gamma stereotactic radiosurgery radiation dose (N/A);
  (iii) Any brachytherapy radiation dose;
  (iv) Any administration of quantities greater than 30 microcuries of either sodium iodide I-125 or I-131; or
  (v) Any therapeutic administration of a radiopharmaceutical, other than sodium iodide I-125 or I-131;

The written directive must include the type of isotope or radiopharmaceutical, dosage or dose, route of administration, and must be signed and dated by an authorized user. Each written directive, and a record of the associated administered radiation dose or radiopharmaceutical dosage will be maintained for a minimum of three years.

* If, because of the patient's condition, a delay in order to provide a written revision to an existing written directive would jeopardize the patient's health, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

Also a written revision to an existing written directive may be made for any diagnostic or therapeutic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical dosage, the brachytherapy dose, the gamma stereotactic radiosurgery dose, the teletherapy dose, or the next teletherapy fractional dose.

If, because of the emergent nature of the patient's condition, a delay in order to provide a written directive would jeopardize the patient's health, an oral directive will be acceptable, provided that the information contained in the oral directive is documented immediately in the patient's record and a written directive is prepared within 24 hours of the oral directive.

(2) Prior to each administration, the patient's identity is verified by more than one method as the individual named in the written directive.
   (i) verbally ask patient's name & compare with hospital chart.
   (ii) compare patient provided ID with hospital chart for one of the following: birth date, address, social security number, signature, the name on patient's ID bracelet, the name on the hospital ID card, or the name on the patient's medical insurance card.
   (iii) obtain patient's signature on the hospital consent form.

(3) That each administration is in accordance with the written directive.

(4) That any unintended deviation from the written directive is identified and evaluated, and appropriate action is taken.

(5) Specific Radiopharmaceutical Procedures
   (i) The dosage to be administered shall be measured in the dose calibrator and the measured value shall be compared with the written prescription prior to administration. (For Sr-89, an approximate dose calibrator correction factor is determined, by comparison with quoted supplier dosage, and the relative reading on the facility dose calibrator).
   (ii) The radiopharmaceutical, dosage and route of administration shall be confirmed by the person administering the radiopharmaceutical to match the written prescription.
   (iii) When in doubt, about any prescription or procedure, the technologist shall not administer the radiopharmaceutical until understood. The technologist shall contact the Nuclear Medicine Physician for clarification before proceeding with the administration.
   (iv) The technologist administering the radiopharmaceutical shall make, date and sign or initial a written record of the administration by logging the radiopharmaceutical, dose, date and time and technologist's initials, immediately after each therapeutic administration.

(6) Specific Brachytherapy Procedures

(i) Prior to implantation, the written directive must include the treatment site, the radioisotope, the intended number of sources, and source strengths.

(ii) After implantation but prior to completion of the procedure, the written directive must include the total source strength and exposure time (or equivalently, the total dose).

(iii) Prior to loading temporary implants, the dosimetrist will check each source's isotope, strength, number, serial number and loading sequence as applicable and will log this information in the sealed source log-out book.

(iv) When in doubt about any brachytherapy prescription or procedure, the dosimetrist shall not load the active sources until every aspect of the prescription and procedure are clearly understood. The dosimetrist shall contact the Radiation Oncologist for clarification before loading the active sources.

(v) After insertion of the active brachytherapy sources, but prior to completion of the procedure, the authorized user must sign and date a written record in the patient's chart. The written record must include the administered radioisotope, treatment site, and total source strength and exposure time (or equivalently, the total dose).

(vi) After insertion of the active brachytherapy sources, and before the total prescribed dose delivery, a second check by a qualified individual shall be performed. This check should look for arithmetic errors, data transfer errors, nomogram use errors, and appropriate use of all pertinent data.

(vii) Procedure for Acceptance Testing of Computer Planning. Acceptance testing and QC testing of the computerized treatment planning system used for brachytherapy planning shall be performed by a qualified user for new or upgraded hardware of software. Such testing shall be completed before the first clinical use of the computerized calculation system.

REVIEW OF QUALITY MANAGEMENT PROGRAM

The Quality Management Program will be reviewed by the institution at least every 12 months.

(1) The review shall include, since the last review, an evaluation of:
   (i) A representative sample of patient administrations.
   (ii) All recordable events, and
   (iii) All misadministrations to verify compliance with all aspects of the quality management program.
(2) An evaluation of each of these reviews will be performed to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of the Quality Management Program.
(3) Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

RESPONSE TO A RECORDABLE EVENT

The institution will evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by:

(1) Assembling the relevant facts including the cause;
(2) Identifying what, if and, corrective action is required to prevent recurrence; and
(3) Retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

MISADMINISTRATION NOTIFICATIONS, REPORTS, AND RECORDS

For a misadministration:

(1) The licensee shall notify by telephone the NRC Operations Center (301-951-0550) not later than the next calendar day after discovery of the misadministration.

(2) The licensee shall submit a written report to the NRC Regional Office I within 15 days after discovery of the misadministration. The written report must include the licensee's name; a brief description of the event; why the event occurred; the effect on the patient; what improvements are needed to prevent recurrence; actions taken to prevent recurrence; whether the licensee notified the patient, or the patient's responsible relative or guardian (this person will be subsequently referred to as the patient in this section), and if not , why not, and if the patient was notified, what information was provided to the patient. The report must not include the patient's name or other information that could lead to identification of the patient.

(3) The institution shall notify the referring physician and also notify the patient of the misadministration no later than 24 hours after its discovery, unless the referring physician personally informs the licensee either that he will inform the patient or that, based on medical judgment, telling the patient would be harmful. The licensee is not required to notify the patient without first consulting the referring physician. If the referring physician or patient cannot be reached within 24 hours, the licensee shall notify the patient as soon as possible thereafter. The licensee may not delay any appropriate medical care for the patient, including any necessary remedial care as a result of the misadministration, because of any delay in notification.

(4) If the patient was notified, the licensee shall also furnish, within 15 days after discovery of the misadministration, a written report to the patient by sending either:

(i) A copy of the report that was submitted to the NRC; or

(ii) A brief description of both the event and the consequences as they may affect the patient, provided a statement is included that the report submitted to the NRC can be obtained from the licensee.

Misadministration records shall be maintained for a minimum of five years. The record must contain the names of all individuals involved (including the prescribing physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number if one has been assigned, a brief description of the misadministration, why it occurred, the effect on the patient, what improvements are needed to prevent recurrence, and the actions taken to prevent recurrence.

QUALITY MANAGEMENT REVIEW AUDIT

PURPOSE
TO REVIEW THE EFFECTIVENESS OF THE QUALITY MANAGEMENT PROGRAM IN PROVIDING A HIGH CONFIDENCE THAT BYPRODUCT MATERIAL OR THE RADIATION FROM BYPRODUCT MATERIAL IS ADMINISTERED AS DIRECTED BY THE AUTHORIZED PHYSICIAN USER.

PERIOD: FROM: _____ TO: _____

I. DIAGNOSTIC CLINICAL NUCLEAR MEDICINE PROCEDURES
(Includes all I-125 and I-131 dosage of less than 30 microcuries)

1. TOTAL NUMBER OF PROCEDURES PERFORMED _____

2. NUMBER OF PROCEDURES INVOLVING ADMINISTRATION ERRORS:
   A. WRONG PATIENT _____
   B. WRONG PHARMACEUTICAL _____
   C. WRONG ROUTE OF ADMINISTRATION _____
   D. ADMINISTERED DOSAGE DIFFERS FROM PRESCRIBED DOSAGE BY MORE THAN 50 % _____

3. NUMBER OF MISADMINISTRATIONS
   (i.e. Patients involved in administration errors and the dose to the patient exceeds either 5 rem effective dose equivalent or 50 rem dose equivalent to any organ) _____

4. COMMENTS

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II. PROCEDURES WITH GREATER THAN 30 MICROCURIES OF I-131 OR I-125 RADIOPHARMACEUTICALS, OR ANY THERAPEUTIC RADIOPHARMACEUTICAL.

1. TOTAL NUMBER OF PROCEDURES PERFORMED _____

2. NUMBER OF PROCEDURES INVOLVING A MISADMINISTRATION:
   A. WRONG PATIENT _____
   B. WRONG PHARMACEUTICAL _____
   C. ADMINISTERED DOSAGE DIFFERS FROM PRESCRIBED DOSAGE BY MORE THAN 20% AND THE DIFFERENCE EXCEEDS 30 MICROCURIES _____

3. NUMBER OF PROCEDURES INVOLVING A RECORDABLE EVENT.
   A. NO WRITTEN DIRECTIVE
      (i.e. No authorized physician's written order specifying the prescribed dosage) _____
   B. NO RECORDING OF THE ADMINISTERED DOSAGE IN THE APPROPRIATE LOG _____
   C. ADMINISTERED DOSAGE DIFFERS FROM PRESCRIBED DOSAGE BY MORE THAN 10% AND THE DIFFERENCE EXCEEDS 15 MICROCURIES _____

4. COMMENTS

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III. BRACHYTHERAPY PROCEDURES

1. TOTAL NUMBER OF PROCEDURES PERFORMED _____

2. NUMBER OF PROCEDURES INVOLVING A MISADMINISTRATION:
   A. WRONG PATIENT _____
   B. WRONG ISOTOPE _____
   C. WRONG TREATMENT SITE _____
   D. TREATMENT INVOLVED A LEAKING SOURCE _____
   E. FOR A TEMPORARY IMPLANT, A SOURCE NOT REMOVED AT COMPLETION OF PROCEDURE _____
   F. CALCULATED ADMINISTERED DOSE DIFFERS FROM THE PRESCRIBED DOSE BY MORE THAN 20%. _____

3. NUMBER OF PROCEDURES INVOLVING A RECORDABLE EVENT.
   A. NO WRITTEN DIRECTIVE _____
   B. NO RECORDING OF THE ADMINISTERED DOSE IN THE APPROPRIATE LOG _____
   C. CALCULATED ADMINISTERED DOSE DIFFERS FROM THE PRESCRIBED DOSE BY MORE THAN 10% _____

4. COMMENTS

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IV. EFFECTIVENESS OF THIS REVIEW

1. BASED ON THIS REVIEW, ANY RECOMMENDED CHANGES TO ROUTINE PROCEDURES?

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_____

2. ANY RECOMMENDATIONS TO MODIFY QUALITY MANAGEMENT PROGRAM ? (QM PROGRAM CHANGES MUST BE SUBMITTED TO NRC WITHIN 30 DAYS)

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AUDITOR _____