AUG 11 1994

Windham Community Memorial Hospital, Inc.
and Hatch Hospital Corporation
Attn: Robert B. Daly, M.D.
112 Mansfield Avenue
Willimantic, CT 06226

RE: License Number: 06-15203-01
Docket Number: 030-00728

Dear Dr. Daly:

This letter acknowledges receipt of your letter dated July 13, 1994, in response to our letter which addressed deficiencies in your Quality Management Program (QMP). Your implementation of the QMP and its adequacy will be reviewed as part of the next NRC inspection. This inspection will include a review of your letter referenced above and any resulting changes to your QMP.

This QMP will not be incorporated into your license by condition. You have the flexibility to make changes to your quality management program without obtaining prior NRC approval. However, modifications to your program must be submitted to this Office within 30 days as required by 10 CFR 35.32(e).

Thank you for your cooperation in this matter; no reply is required in response to this letter.

Sincerely,

Original Signed by
James P. Dwyer

James P. Dwyer
Quality Management Program Coordinator
Region I

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OFFICIAL RECORD COPY - D:\QM-ACK\WINDHAM.ACK - 07/21/94

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NOTE TO DMB:

THE ATTACHED DOCUMENTS ARE TO BE PROCESSED AS ONE QUALITY MANAGEMENT PACKAGE.

LICENSE NUMBER: 06-5203-01

DOCKET NUMBER: 030-02728

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

WINDHAM
HOSPITAL

030-00728

July 13, 1994

James P. Dwyer
Quality Management Program Coordinator
Region I
United States Nuclear Regulatory Commission
475 Allendale Road
King Of Prussia, Pennsylvania 19406-1415

RE: License Number: 06-15203-1

Dear Mr. Dwyer:

We appreciate your letter of 6/20/94 finding a number of deficiencies with the Quality Management Program (QMP) program submitted on January 24, 1992. The required program primarily deals with I-131 & I-125 of more then 30 microcuries, and all therapeutic radiopharmaceutical dosages of any isotope or quantity (e.g.SR-89). Therefore the QMP has been re-written to satisfy the requirements, as well as to document the procedures as they exist now at the hospital.

In order to document compliance with the program, a "Radiopharmaceutical Written Directive" form has been added (See last page of the program). This form is to be completed by the authorized radiologist prior to administration and by the person administering these radiopharmaceuticals prior to and after administering to the patient. This will be the primary documentation for showing compliance with the QM program and will be reviewed by NRC during inspections.

This new QMP is in place as of today. We feel you will find this acceptable. If not, we would appreciate you notifying us of any deficiencies or problems which you feel should be addressed.

Sincerely yours,

Robert B. Daly, MD
Radiation Safety Officer
Windham Community Memorial Hospital
112 Mansfield Avenue
Willimantic, CT 06226

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JUL 18 1994

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) 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.

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.

QUALITY MANAGEMENT PROGRAM

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

(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: N/A

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 N/A

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: N/A

QUALITY MANAGEMENT PROGRAM

GENERAL POLICIES AND PROCEDURES FOR MEDICAL USE OF ALL RADIOISOTOPES

(1) Prior to administration to a patient, 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 (N/A);
   (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) Workers involved in medical use of radioactive material will request clarification from an authorized user if any element of a diagnostic referral, a written directive, or any other written instruction or record is unclear, ambiguous or apparently erroneous.

(3) Workers will stop the medical use of radioactive material to a patient and seek guidance if there is an apparent discrepancy in records, observations or physical measurements that may result in a diagnostic or therapy misadministration. The workers may resume after resolving the discrepancy.

QUALITY MANAGEMENT PROGRAM

GENERAL POLICIES AND PROCEDURES FOR MEDICAL USE OF ALL RADIOISOTOPES

(4) Before medical use, the person administering the radioactive material will verify that the medical use is in accordance with the written directive or the diagnostic referral and clinical procedures manual.

(5) To avoid an inadvertent administration to a pregnant female, all female patients of child-bearing age should be explicitly questioned about the possibility of pregnancy. If the patient cannot verify that there is no practical possibility of a pregnancy (due to abstinence, medical condition, birth control practice or ten-days post-menses, etc.), the authorized user (or a physician under the supervision of an authorized user) should be contacted to verify that the requested procedure is nonetheless medically warranted or to postpone the procedure.

(6) To avoid exposure to children of nursing mothers, all female patients of child-bearing age should be explicitly questioned if they are nursing. If the patient is nursing, the authorized user (or a physician under the supervision of an authorized user) should be contacted to verify that the requested procedure is nonetheless medically warranted or to postpone the procedure. If the study is performed, the patient will be given instructions concerning interruption of nursing until the radioactivity has subsided.

(7) Prior to each administration, radiopharmaceutical dosage will be measured in the dose calibrator and the measured value will be compared with the written directive or the diagnostic referral and clinical procedures manual.

(8) Prior to each administration, the patient's identity will be verified by more than one method as the individual named in the written directive. Any two of the following methods may be used:
(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.

(9) Any unintended deviation from the written directive that is identified will be evaluated, and appropriate actions will be taken. The actions may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work.

QUALITY MANAGEMENT PROGRAM

ADDITIONAL SPECIFIC PROCEDURES FOR RADIOPHARMACEUTICALS WHICH REQUIRE A WRITTEN DIRECTIVE PRIOR TO ADMINISTRATION (i.e. GREATER THAN 30 uCi I-125 OR I-131; OR ANY QUANTITY OF ANY THERAPY RADIOPHARMACEUTICAL)

(1) Prior to administration to a patient, a written directive must be prepared for a specific patient, dated & signed by an authorized user, and must include the type of radiopharmaceutical, the dosage, and route of administration. Each written directive, and a record of the associated administered radiation dose or radiopharmaceutical dosage will be maintained for a minimum of three years.

(2) Prior to each administration, the radiopharmaceutical dosage will be measured in the dose calibrator and the measured value will be compared with the written directive. (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). The radiopharmaceutical dosage as measured with the dose calibrator, should not differ from the prescribed dosage by more than 10%. When there is greater than 10% discrepancy, it must be brought to the attention of the authorized user prior to administration, to determine whether the planned study may be performed with the available dose.

(3) Prior to administration, the patient name and I.D.; the type of radiopharmaceutical and form; the dosage and route of administration will be confirmed by the person administering the radiopharmaceutical to match the signed and dated written directive.

(4) When in doubt, about any prescription or procedure, the worker shall not administer the radiopharmaceutical until understood. The worker shall contact the authorized user for clarification before proceeding with the administration.

(5) The person 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.

QUALITY MANAGEMENT PROGRAM

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. (The number of cases reviewed will be expanded if a recordable event or misadministration is uncovered during the periodic review.)
   (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 PROGRAM

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. FOR EACH PATIENT CASE REVIEWED, DEVIATIONS FROM THE WRITTEN DIRECTIVE, THE CAUSE OF EACH DEVIATION, AND THE ACTION REQUIRED TO PREVENT RECURRENCE SHOULD BE IDENTIFIED. THE ACTIONS MAY INCLUDE NEW OR REVISED POLICIES, NEW OR REVISED PROCEDURES, ADDITIONAL TRAINING, OR INCREASED SUPERVISORY REVIEW OF WORK.

PERIOD: FROM: _____ TO: _____

I. PROCEDURES WITH 30 MICROCURIES OR LESS OF I-131 OR I-125 RADIOPHARMACEUTICALS, OR ANY DIAGNOSTIC RADIOPHARMACEUTICAL.

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

_____

_____

_____

_____

_____

QUALITY MANAGEMENT PROGRAM

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

_____

_____

_____

_____

IV. EFFECTIVENESS OF THIS REVIEW

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

_____

_____

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

_____

_____

AUDITOR (RSO): _____ DATE: _____

QUALITY MANAGEMENT PROGRAM

RADIOPHARMACEUTICAL WRITTEN DIRECTIVE AND PATIENT VERIFICATION FORM
(MUST BE COMPLETED FOR ALL I-131 OR I-125 DOSAGES GREATER THAN 30 MICROCURIES, AND ALL THERAPEUTIC RADIOPHARMACEUTICAL DOSAGES)

WRITTEN DIRECTIVE (MUST BE COMPLETED & SIGNED BY THE AUTHORIZED PHYSICIAN PRIOR TO ADMINISTRATION OF RADIOACTIVE MATERIAL TO PATIENT)

PATIENT NAME & I.D.: _____

RADIOPHARMACEUTICAL: _____ FORM: _____

DOSAGE (mCi OR uCi): _____ ROUTE OF ADMINISTRATION: _____

AUTHORIZED M.D.: _____

SIGNATURE : _____ DATE: _____

MEASUREMENTS & PATIENT VERIFICATION
(COMPLETED BY PERSON ADMINISTERING RADIOISOTOPE TO PATIENT)

PRIOR TO ADMINISTRATION, MEASURE THE ACTUAL RADIOPHARMACEUTICAL DOSAGE IN THE DOSE CALIBRATOR, AND VERIFY EACH OF THE FOLLOWING WITH THE WRITTEN DIRECTIVE:

____ IS THE WRITTEN DIRECTIVE FOR A SPECIFIC PATIENT, DATED & SIGNED BY A PHYSICIAN AUTHORIZED ON THE RADIOACTIVE MATERIAL LICENSE TO PRESCRIBE THIS TYPE, FORM, QUANTITY & ROUTE OF ADMINISTRATION ?

____ DOES THE FORM, TYPE, AND QUANTITY OF RADIOISOTOPE ON THE CONTAINER AGREE WITH THE WRITTEN DIRECTIVE ?

____ DOES FEMALE PATIENT CONFIRM SHE IS NOT PREGNANT ?

____ DOES FEMALE PATIENT CONFIRM SHE IS NOT NURSING ?

____ PATIENT I.D. AGREES WITH WRITTEN DIRECTIVE BY AT LEAST 2 MEANS?.
VERBAL ?:_____ WRIST BAND ?:_____ OTHER ?:_____

____ DOES MEASURED DOSAGE AGREE WITH WRITTEN DIRECTIVE WITHIN 10% ?
MEASURED ACTIVITY: _____ DATE & TIME: _____

____ DO ALL ASPECTS OF THE WRITTEN DIRECTIVE AND PATIENT ADMINISTRATION AGREE ?

IF THE ANSWER TO ANY OF THE ABOVE IS NO, OR THERE ARE ANY QUESTIONS REGARDING THE WRITTEN DIRECTIVE OR ADMINISTRATION, THESE MUST BE CLARIFIED WITH THE AUTHORIZED USER PRIOR TO PATIENT ADMINISTRATION.

COMMENTS

_____

_____

RADIOISOTOPE ADMINISTERED TO PATIENT IN ACCORDANCE WITH THE WRITTEN DIRECTIVE AT DATE & TIME: _____

BY NAME: _____ SIGNATURE : _____

JUN 20 1994

Windham Community Memorial Hospital, Inc.
and Hatch Hospital Corporation
Attn: Robert B. Daly, M.D.
112 Mansfield Avenue
Willimantic, CT 06226

RE: License Number: 06-15203-01
Docket Number: 030-00728
Plan File Date: January 24, 1992
NRC Region: I

Dear Dr. Daly:

This refers to the review of your written Quality Management Program (QMP) submitted in accordance with 10 CFR 35.32. A review of the QMP was performed to determine whether policies and procedures have been developed to meet the objectives of the rule. Based on this submission, there appear to be significant weaknesses and potential substantial failure of your QMP to meet the objectives in 10 CFR 35.32 in that:

Regarding the Quality Management plan for I-125 and/or I-131 > 30 uCi,

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32(f)(2). Please provide written certification that your QMP has been implemented.

Revisions to written directives 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 radio pharmaceutical dosage. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

Your QMP for NaI I-125 or I-131 > 30 microCi must include policies/procedures to identify and evaluate any unintended deviations from a written directive as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radio pharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

According to guidance provided by Regulatory Guide 8.33, your QMP must include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

Regarding the QM plan for Therapeutic Radiopharmaceutical other than I-125 or I-131,

Each applicable Part 35 licensee is required to submit a written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32.f)(2). Please provide written certification that your QMP has been implemented.

Revisions to written directives 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. Your QMP must include a policy/procedure that requires that revisions to written directives will be made prior to administration.

Your QMP for Therapeutic Radiopharmaceutical other than I-125 or I-131 must include policies/procedures to identify and evaluate any unintended deviations from a written directive as required by 10 CFR 35.32(a)(5). Please include such a provision in your QMP.

Your QMP review does not provide an evaluation of (i) an adequate representative sample of patient administrations (ii) all recordable events, and (iii) all misadministrations since the last review as required in 10 CFR 35.32(b)(1). The number of patient cases to be sampled should be based on the principles of statistical acceptance sampling and should represent each modality performed in the institution (e.g., radiopharmaceutical, teletherapy, brachytherapy, and gamma stereotactic radiosurgery). You may develop a sampling procedure of your own; use the chart provided in 10 CFR 32.110 (assuming an error rate of 2 percent); or a representative sample may be selected including (at a minimum): 20% if the number of cases performed is greater than 100, 20 cases if the number of cases is between 20 and 100, and all, if the number of cases is less than 20.) Provide a copy of your revised QMP to include this provision.

According to guidance provided by Regulatory Guide 8.33, your QMP should include a procedure to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP. Please include such a provision in your QMP.

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33 (enclosed), or submit procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procedures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that training and/or instruction of supervised individuals in your QMP is required by 10 CFR 35.25.

Due to the apparent failure of your written QMP to meet the objectives in 10 CFR 35.32, you must immediately modify your written QMP to address the items listed above, and provide those modifications to your NRC regional office within 30 days of the date of this letter. NRC will

review these matters during your next routine inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be take at that time for failure to meet the requirements of 10 CFR 35.32.

Please be advised that this QMP will not be incorporated into your license by condition. This allows you the flexibility to make changes to your Quality Management Program without obtaining prior NRC approval. When modifications are made to your program, you should submit any changes to your QMP to this office within 30 days as required by 10 CFR 35.32 (e).

Your QMP was reviewed by an NRC contractor following a standard review plan and related checklist provided by the NRC staff. This letter outlining the findings of that review was prepared by the contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management. If you have any questions about this review, you may call me at (610)337-5309. Thank you for your cooperation in this matter.

Sincerely,

Original Signed By:
James P. Dwyer

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

WINDHAM HOSPITAL

SECTION OF NUCLEAR MEDICINE

January 24, 1992

030-08728

06-15203-01

U.S. Nuclear Regulatory Commission
Quality Management Program 10CFR 35
Region I
475 Allendale Road
King of Prussia, PA 19406

Dear Sir:

Enclosed you will find the Quality Management Program required by the new regulations.

The hospital staff has been briefed on the record keeping requirements of this Program.

Sincerely,

Robert B. Daly, M.D.
Radiation Safety Officer

RBD:jaw

DRL 10

JAN 27 1992

LICENSE* ON-15023-01

NRC QUALITY MANAGEMENT PROGRAM

POLICIES AND PROCEDURES FOR ASSURING QUALITY IN NUCLEAR MEDICINE

HOSPITAL NAME: Windham Community Memorial Hospital

ADDRESS: 112 Mansfield Avenue
Willimantic, CT

EFFECTIVE DATE: January 27, 1992

Requirement: Title 10, Code of Federal Regulations, Part 35
Section 35.32

A. GENERAL REQUIRMENTS

1. Prior to the administration of:

a) Brachytherapy procedures
b) I-131 or I-125 in excess of 30 microcuries
c) Radiopharmaceutical therapy

a written directive that is signed by a facility's authorized user is required.

An oral directive is allowed if a delay in receiving the written directive would jeopardize the patient's health.

A written directive is required within 24 hours.

Revisions to the original written directive shall also be in writing. An oral revision to the written directive is allowed, if followed by a written confirmation within 48 hours.

2. The nuclear medicine technologist (NMT) shall not initiate a diagnostic or a therapeutic procedure outlined above without a written directive or an acceptable oral directive.

3. The NMT shall verify the patient's true identity prior to each administration requiring a written directive by more than one (1) method.

For inpatients:

a) correct name per the wrist identifiation band.
b) verbal request that the patient state his/her name. (NOTE: do not ask "... is your name Mr. Smith ..." , but rather ask "... what is your name...".

For outpatients:

a) ask the patient to state his/her name
b) ask for written identification (ie: drivers license; birth certificate; social security card; etc)

The application of radiation or a radiation dose shall not occur unless positive identification of the patient is made.

4. Prior to the administration of diagnostic quantities of I-131 or I-125 in excess of 30 microcuries, the NMT that is assigned to the "hot lab" shall verify the prepared dosage with that of the written directive.

Any deviation shall be brought to the attention of the chief NMT and the radiation safety officer (RSO).

The "hot lab" NMT shall seek guidance from the chief NMT or the RSO if the written directive is confusing, ambiguous or not understood. DO NOT ASSUME.

The NMT is to sign or initial the patient's dose record and insure that the administration date; radiopharmaceutical; and radiation dose are properly recorded and conform to those specified in the written directive.

5. Prior to the adminsitration of any therapeutic dose of I-131 or I-125 in excess of 30 microcuries but less than 30 millicuries, the NMT assigned to the "hot lab" shall verify the prepared dosage with that of the written directive.

Any deviation shall be brought to the attention of the chief NMT and the radiation safety officer (RSO).

The "hot lab" NMT shall seek guidance from the chief NMT or the RSO if the written directive is confusing, ambiguous or not understood. DO NOT ASSUME.

The NMT is to sign or initial the patient's dose record and insure that the administration date; radiopharmaceutical; and radiation dose are properly recorded and conform to those specified in the written directive.

6. Prior to the administration of any radiopharmaceutical therapy, the chief NMT shall verify the dosage with that of the written directive.

Any deviation shall be brought to the attention of the radiation safety officer (RSO).

The chief NMT shall seek guidance from the RSO if the written directive is confusing, ambiguous or not understood. DO NOT ASSUME.

The NMT is to sign or initial the patient's dose record and insure that the administration date; radiopharmaceutical;

and radiation dose are properly recorded and conform to those specified in the written directive.

Only an authorized user may administer a therapeutic dose of a radiopharmaceutical.

7. Any unintended deviation from the physician's written directive, as outlined above, will be brought to the attention of the RSO.

The RSO shall,

a) Confer with the physician who prepared the written directive ; the NMT or RTT involved; and, the facility's health physicist to confirm that a deviation from the written directive did in fact occur.

b) With the assistance of the health physicist, evaluate the underlying causes of the deviation.

c) Make recommendations and/or changes in departmental procedure to attempt to prevent the cause of this deviation in the future.

d) Report this occurance to the radiation safety committee and the quality assurance committee of the facility.

B. PROGRAM REVIEW

1. Under the direction of the facility's RSO, the health physicist shall conduct a review of the effectiveness of the quality management program.

2. Since the time of the last quality management program review, a listing of the patient procedures requiring a physician written directive will be obtained from the nuclear medicine department of the radiation therapy department.

3. A random sample of patient folders will be reviewed by the health physicist for compliance with the requirements of the quality management program. This sample shall be no less than 10% nor greater than 50% of procedures requiring a written directive.

4. In addition, the health physicist will review all cases of misadministration - as defined by 10 CFR 35.2 - and all cases of recordable events - as defined by 10 CFR 35.2 - to determine the underlying cause of the event.

5. This review and evaluation will occur quarterly for the period of time 1/27/92 thru 1/26/93 (ie: first year of the program) and at a frequency of at least once per twelve (12) months thereafter.

6. Records of the quality managements program review, evaluation and recommendations for corrective action will be presented to the radiation safety committee and the quality assurance committee of the facility.

   Separate department records will be kept for a period of time equal to three (3) years.

C. IMMEDIATE PROGRAM EVALUATION

1. In the event of a misadministration or the occurance of a recordable event, the RSO shall direct an immediate program evaluation.

2. The RSO and or the health physicist shall assemble the relevant facts concerning the misadministration or recordable event,

3. The causes of the event shall be identified.

4. The necessary corrective actions shall be determined.

5. The staff involved shall be briefed concerning the causes of the event and corrective actions required.

6. A formal report shall be prepared of the event for the NRC (if required); the radiation safety committee; and the quality assurance committee of the facility.

7. Records of this review and subsequent report shall be retained for a period of three (3) years.

8. This investigation and review will be completed within thirty (30) days of occurance of the event.

D. QUALITY MANAGEMENT PROGRAM RECORDKEEPING

1. The facility nuclear medicine department or radiation therapy department will keep the following records for three (3) years:

   a) each written directive

   b) review of each administered radaition dose or radio-pharmaceutical where a written directive is required.

   c) all formal reports of the effectiveness of the quality management program including:

      - routine reports
      - special reports due to misadministration or recordable event.

2. Any modifications to the quality management program developed to increase the program effectiveness will be filed with the NRC within thirty (30) days of the effective date of the change.

E. PROGRAM DEFINITIONS

1. written directive: an order, in writing, for a specific patient, dated and signed by an authorized user of the facility prior to the administration of a radiopharmaceutical or radiation which contains the following information:

   - for any administration of I-131 or I-125 in excess of 30 microcuries: the dosage.

   - for a therapeutic administration of a radiopharmaceutical: the radiopharmaceutical; the dosage and the route of administration.

   - for Co-60 teletherapy: the total dose; the dose per fraction; and the overall treatment period.

   - for brachtherapy:
     - prior to implantation: the radioisotope, number of sources, and the source strength

     - after implantation but prior to completion of the procedure: the radioisotope, treatment site, and total source strength (or equivalently, the total dose).

2. prescribed dose: the quantity of a radiopharmaceutical activity as documented in either the written directive or the diagnsotic clincial procedure manual and shall include:

   - for Co-60 teletherapy: the toal dose and dose per fraction as documented in the written directive.

   - for brachytherapy: either the total source strength and exposure time or the total dose as documented in the written directive.

3. recordable event: the administration of:

   - a radiopharmaceutical or radiation dose without a written directive when one was required.

   - a radiopharmaceutical or radiation dose where a written directive was required without daily recording of each administered radiopharmaceutical dose or radiation dose in the appropriate record.

   - a radiopharmaceutical dosage of I-125 or I-131 greater than 30 uCi when both:
     - the administered dose differs from the prescribed dose by more than 10%; and,
     - the difference between the administered dose and the prescribed dose exceeds 15 uCi.

   - a therapeutic radiopharmaceutical dose when the administered dose differed from the prescribed dose by more than 10%.

   - a teletherapy dose when the calculated weekly administered

dose is 15% greater than the weekly prescribed dose.

- a brachytherapy dose when the calculated administered dose differs from the prescribed dose by more than 10% of the prescribed dose.

4. misadministration: means the administration of:

- a radiopharmaceutical dose of I-131 or I-125 that is greater than 30 uCi that:
  - involves the wrong patient.
  - when both the administered dose differs from the prescribed dose by more than 20% of the prescribed dose and the difference exceeds 30 uCi.

- a therapeutic radiopharmaceutical dose other then I-131 or I-125 that:
  - involves the wrong patient, wrong radiopharmaceutical, or route of administration.
  - when the administered dose differs from the prescribed dose by more than 20%.

- a teletherapy dose that:
  - involves the wrong patient, wrong mode of treatment, or the wrong treatment site.
  - when the treatment consists of three or fewer fractions and the calculated total administered dose differs from the prescribed dose by more than 10%.
  - when the calculated weekly administered dose is 30% greater than the weekly prescribed dose.
  - when the calculated total administered dose differs from the total prescribed dose by more than 20%.

- a brachytherapy dose that:
  - involves the wrong patient, wrong radioisotope, or wrong treatment site (excluding permanent implant, seeds that were implanted in the correct site but migrated outside of the treatment site).
  - involves a leaking sealed source.
  - when for a temporary implant, one or more sealed sources are not removed upon the completion of the procedure
  - when the calcualted administered dose differs from the the prescribed dose by more than 20%.

- a diagnositc radiopharmaceutical dose, other than quantities greater than 30 uCi of I-131 and I-125 that:
  - involves the wrong patient, wrong radiopharmaceutical wrong route of administration or when the administered dose differs from the prescribed dose; and,
  - when the dose to the patient exceeds 5 rem effective dose equivalent or 50 rem dose equivalent to any individual organ.

Approved by:

Radiation Safety Officer

1/17/92
Date