AUG 11 1994

NORWOOD HOSPITAL
800 WASHINGTON STREET
NORWOOD, MA 02062

ATTN: GEORGE EDEBURN, M.D.

RE: Docket Number: 030-01950
License Number: 20-12560-01

Dear Dr. Edeburn:

This letter acknowledges receipt of your letter dated July 18, 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

240207

OFFICIAL RECORD COPY - D:\QM-ACK\001797.ACK - 07/22/94

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NOTE TO DMB:

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

LICENSE NUMBER: 20-12560-01

DOCKET NUMBER: 030-01950

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

Norwood Hospital

800 Washington Street
Norwood, Massachusetts 02062
Telephone (617) 769-4000

July 18, 1994

United States Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

ATTN: JAMES P. DWYER, QUALITY MANAGEMENT PROGRAM COORDINATOR

RE: Docket Number: 3001950
License Number: 20-12560-01
Plan File Date: 24-JAN-92
Region Number: 1

Dear Mr. Dwyer:

Attached is an addition to our "Radiation Safety Program", whereby, we correct the previously specified weaknesses mentioned in your correspondence dated June 20, 1994.

Please call George O'Reilly at (617) 769-2950 x 2600 or x 2621 if this does not address all the weaknesses of our existing Q.M. Program. We will address any other areas of concern at once.

Thank you for calling these weaknesses to our attention. Please feel free to contact us should you require any additional information or if we can be of further service.

Sincerely,

Frank A. Niro
President

FJN/mhs

N.V.H.S. QUALITY MANAGEMENT CONTROL PROGRAM

Effective 06/28/94

N.R.C. requires a Quality Management Program to clearly communicate instructions to team members who deliver a treatment process. The administration of byproduct material or radiation can involve a number of treatment modalities. For each modality:

Policies to have an authorized user date and sign a written directive prior to the administration,

- Procedures to identify the patient by more than one method,
- Procedures to be sure the plans of treatment are in accordance with the written directive,
- Procedures to confirm that, prior to administration, the person responsible for the treatment modality will check the specific details of the written directive (e.g., in radiopharmaceutical therapy, verify the radiopharmaceutical, dosage, and route of administration; or in oncology, verify the treatment site, total dose, dose per fraction, and overall treatment period),
- Procedures to record the radiopharmaceutical dosage or radiation dose actually administered.

A. Nuclear Medicine & Radiation Therapy: "Therapeutic dosage" of a radiopharmaceutical or "any" dosage of quantities greater than 30 (uCi) microcuries of either Sodium I-125 or I-131.

1. "Written Directive" by an authorized user must be signed and dated by the user to authorize the exact dosage for the specific patient, prior to ordering the radiopharmaceutical.

2. The ordering physician will provide in writing, authorization for the patient to be treated, prior to administration of the radionuclide.

3. An oral revision to the written directive will be documented in the patient's record and a revised written directive will be signed and dated by the authorized user within 48 hours of the oral revision (the revised directive must be prepared within 24 hours) prior to the administration of the radiopharmaceutical.

4. The patients identity will be verified by the Hospital's registration desk and a requisition will be printed out prior to arrival in the treatment area. The Nuclear Technologist will verify the patient's identity and confirm the information on the requisition. The patient and the authorized user will both sign the consent form of the treatment, prior to administration. The Nuclear Technologist will confirm the written directive is filled out, with the patient's name, exact dosage, and authorized users signature are in hand, prior, to administration and attached to the signed consent sheet.

5. The Nuclear Technologist will confirm that the patient's physician has provided written instructions with pertinent history and attach it to the constent/written directive packet.

6. Any possible deviation will be documented in writing and signed by the Authorized user, prior to administration of the radiopharmaceutical. Corrective action will be undertaken **immediately** after any unintended deviation.

7. Immediately prior to administration of the radiopharmaceutical, the exact dosage will be verified by measuring in a dose calibrator. The measured dosage must agree with the written directive within +/- 10%. A signed "printout" must accompany the packet, prior to administration.

8. All paperwork will be kept under separate cover for three years.

9. A yearly inventory of all treatments will be reviewed. An audit will be prepared annually for review by the R.S.C. and kept on file for three years. The R.S.C. must approve of the effectiveness of Q.M. Program in Minutes of R.S.C. Meeting or recommended corrective action.

10. Any worker who does not understand any aspect of a written directive must seek guidance from the authorized user prior to continuing the procedures to administer the therapy.

11. Recordable events will be evaluated and reported within thirty days to the N.R.C. All facts and corrective action taken to prevent recurrence will be kept on file for three years. *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;

JUN 20 1994

NORWOOD HOSPITAL
800 WASHINGTON STREET
NORWOOD, MA 02062

ATTN: GEORGE EDEBURN, M.D.

RE: Docket Number: 3001950
License Number: 20-12560-01
Plan File Date: 24-JAN-92
Region Number: 1

Dear Dr. Edeburn:

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 I-125 and /or I-131 > 30 Microcuries

The written directive must be an order for a specific patient, dated and signed by an authorized user or physician under the supervision of an authorized user, and, for any administration of quantities greater than 30 microcuries of either I-125 or I-131, the dosage. Your QMP is missing procedures to require that the written directive for I-125 and/or I-131 > 30 microcuries:

- be an order for a specific patient

- contains the dosage to be administered

A footnote to 10 CFR 35.32(a)(1) provides that an oral revision to a written directive is acceptable 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. Oral revisions must be documented immediately in the patient's record and a revised written directive must be signed and dated by an authorized user or physician under the supervision of an authorized user within 48 hours of the oral revision. Please include such a policy in your QMP.

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 provided 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. Please include such a policy in your QMP.

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.

A commitment to retain each written directive and a record of each administered radiopharmaceutical dosage for three years after the date of administration is required in 10 CFR 35.32(d). Describe the procedure for an authorized user or a qualified individual under the supervision of an authorized user (e.g., a nuclear medicine physician, physicist or technologist), after administering a radiopharmaceutical, to make, date, sign or initial a written record that documents the administered dosage in an auditable form.

Your QMP for NaI I-125 or I-131 >30 microcuries 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 must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

As required in 10 CFR35.32(c), the licensee shall evaluate and respond, within 30 days after discovery of the recordable event, to each recordable event by: (a) assembling the relevant facts including the cause, (b) identifying what, if any, corrective action is required to prevent recurrence, and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken. Please include such a provision in your QMP.

Your QMP review procedure does not provide an evaluation of:(a) an adequate representative sample of patient administrations, (b) all recordable events, and (c) 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.

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.

Describe your procedures to evaluate the effectiveness of the QMP, and, if necessary, to make modifications to meet the objectives of the program as required by 10 CFR 35.32 (b)(2).

Please provide assurance that modifications to your QMP will be submitted to the NRC within 30 days after the modification has been made as required by 10CFR 35.32(e).

Please provide assurance that records of each QMP review and evaluation will be maintained for three years as required in 10 CFR 35.32 (b)(3).

Regarding Therapeutic Radiopharmaceutical other than I-125 and/or I-131

A written QMP must be established and maintained for use of Radiopharmaceuticals for therapy other than I-125 and I-131 as required in 10 CFR35.32(f)(1). Please submit your QMP for your Radiopharmaceutical therapy.

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 NRC inspection to determine whether violations of NRC requirements have occurred. Enforcement action may be taken 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

QUALITY MANAGEMENT PROGRAM

For NORWOOD Hospital

This Program will be implemented by January 27, 1992.

NORWOOD HOSPITAL
NRC License 20-12560-01
DOCKET #030-01950

ALL 10

George F. Edeburn, M.D.

Jan. 24, 1992

DATED FAX JAN 27 1992

NORWOOD HOSPITAL

NUCLEAR MEDICINE QUALITY MANAGEMENT PROGRAM

The Nuclear Medicine Department uses 131I for diagnostic and therapeutic treatment.

1.1 All administrations of 131I (diagnostic or therapeutic) shall have an authorized user date and sign a written directive prior to administration of any therapeutic dose or any dose of quantities greater than 30 microcuries of sodium iodide 131. The Nuclear Medicine Department does not use 125I.

1.2 Before administering a radiopharmaceutical dosage, the licensee shall verify the patient's identity by asking the patient what their name is and their date of birth. Patients receiving 131I therapy doses are also required to sign an informed consent form.

1.3 Before administering the by product material, the specific details of the administration must be in accordance with the written directive. The radiopharmaceuticals must be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive, that is, the dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written directive.

1.4 All workers who do not understand how to carry out the written directive should ask the Chief Technologist, , if they have any questions about what to do or how it should be done rather than continuing a procedure when there is any doubt.

1.5 The Chief Nuclear Medicine Technologist after administering a radiopharmaceutical will make, date and sign or initial a written record that documents the administered dosage in the patient's chart.

1.6 See attached QMP review form

NORWOOD HOSPITAL

QUALITY MANAGEMENT PROGRAM

Annual Audit of Quality Management Program

An annual review of the quality management program will be conducted by the Radiation Safety Officer at the time of the annual ALARA audit.

NCR License No._____

Date of Audit: _____

Audit Conducted by:_____

Audit Findings:

The scope of the audit consisted of a review of the quality management program and supporting documentation, interview with appropriate personnel, and direct observations of certain procedures. The following findings resulted from this audit:

A. Patient Records

1. Prior to administration a written directive was prepared for:

   a. Any administration of radioactive sodium iodide in quantities greater than 30 microcuries (uCi).

      Yes_____ No_____ N/A_____

   b. Any therapeutic administration of a radiopharmaceutical other than sodium iodide.

      Yes_____ No_____ N/A_____

2. Each written directive was maintained in an auditable form for three years.

   Yes_____ No_____

3. A record of each administered radiopharmaceutical dosage where a written directive is required is maintained for three years.

   Yes_____ No_____

4. Prior to dosing, the patient's identity was verified by more than one method as the individual named on the written directive.

   Yes_____ No_____

5. Each administration of a radiopharmaceutical was in accordance with the written directive when a written directive was required.

Yes_____ No_____

6. Any unintended deviation from a written directive was identified and evaluated.

Yes_____ No_____ N/A_____

7. Have recordable events been evaluated within thirty (30) days after discovery? (10 CFR 35.32 (c)).

Yes_____ No_____ N/A_____

8. Have records of recordable events been retained for three (3) years? (10 CFR 35.32 (c) (3)).

Yes_____ No_____ N/A_____

9. Has the NCR been informed of any misadministrations?

Yes_____ No_____ N/A_____

10. Have the reporting requirements of 10 CFR 35.33 (a) (3) and (a) (4) been completed for each misadministration?

Yes_____ No_____ N/A_____

11. Have records of misadministrations been maintained for ten (10) years? (10 CFR 35.33 (b))

Yes_____ No_____ N/A_____

12. Has the Radiation Safety Committee reviewed previous audits to determine the effectiveness of the quality management program and made modifications as necessary? (10 CFR 35.32 (b) (2))

Yes_____ No_____ N/A_____

13. Has the Hospital retained records of the audit for three (3) years? (10 CFR 35.32 (b) (3))

Yes_____ No_____ N/A_____

Reviewed by Radiation Safety Officer

Signature:_____ Date:_____

Review by Radiation Safety Committee

Signature of Chairman:_____ Date:_____