SEP 15 1994

MEDICAL COLLEGE HOSPITALS
BUCKS COUNTY CAMPUS
225 NEWTOWN ROAD
WARMINSTER, PA 18974

ATTN: S. WARREN GROSS, M.D.

RE: Docket Number: 030-14750
License Number: 37-18263-01

Dear Dr. Gross:

This letter acknowledges receipt of your letter dated July 15, 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

240073

OFFICIAL RECORD COPY - C:\D\QM-ACK\002334.ACK - 08/29/94

ML 10

NOTE TO DMB:

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

LICENSE NUMBER: 37-18263-01

DOCKET NUMBER: 030-14750

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

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Telephone (215) 441-6600

July 15, 1994

Mr. James P. Dwyer
Quality Management Program Coordinator
U.S. Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, PA 19406

Re: License No. 37-18263-01
Docket No. 3014750

Dear Mr. Dwyer:

We have enclosed the latest revision of our quality management program incorporating the revisions you requested in your June 17 letter. This plan was implemented on the date of this letter.

Sincerely,

S. Warren Gross, M.D.
Radiation Safety Officer

ML 10

AUG 26 1994

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QUALITY MANAGEMENT PROGRAM

JULY 1994

Janice Vandolsen
Administrator
Department of Radiology

S. Warren Gross, M.D.
Radiation Safety Officer

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PURPOSE: To provide high confidence that the byproduct material or the radiation from the byproduct material will be administered as directed by the authorized user.

PROCEDURE: The technologist is to confirm the physician's order for the procedure.

The authorized user will initiate a written directive for all administrations which involve greater than 30 microcurie of either I-125 or I-131 and for all administrations of a therapeutic radiopharmaceutical other than I-125 or I-131, e.g. Sr-89, P-32, etc.

All completed written directives shall

1. be an order for a specific patient;
2. have the date and signature of an authorized user;
3. contain the radiopharmaceutical and the dosage to be administered;
4. specify the route of administration if other than by mouth;
5. document confirmation of the patient's identification;
6. contain the results of the dosage assay from the dose calibrator.

If the authorized user decides to modify the prescribed dose or if the assayed dose deviates from the prescribed dose by more than $\pm$ 10% (because, for example, a delay in patient treatment occurs), then the authorized user **must** complete the change in written directive portion of the written directive form **prior** to administration. The authorized user has to enter the new dose, date, and his/her signature.

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 the authorized user within 48 hours of the oral revision.

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

Prior to administration of the byproduct material, the authorized user or a qualified individual under the supervision of an authorized user (e.g., nuclear medicine technologist or physicist) will review the written directive for inclusion of the six (6) items listed above. If any of the information is missing, the administration will be delayed or postponed until the necessary information is obtained and entered on the written directive.

After administering the radiopharmaceutical, the authorized user or qualified individual will make, date, and sign the written directive.

All written directives will be retained for at least three (3) years after the date of administration.

PROGRAM REVIEW:

Because of the limited number of cases we perform, i.e. less than 20, we plan to review **all** written directives. If the number of cases exceeds 20 in a given calendar year than we will develop a procedure which we feel adequately evaluates the effectiveness of our quality management program.

A review of written directives will occur on **semi-annual** basis. These reviews will be done by the radiation safety officer and at least one other member of the department, i.e. chief technologist, nurse, etc., and can include the consulting radiation physicist. The review will examine the completeness of the directive with specific regard to inclusion of items 1-6 stated previously on page 1.

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After analyzing the results of the review, the radiation safety officer will determine the corrective action, if any. The corrective action undertaken will depend on the inconsistencies , inaccuracies, or lack of information uncovered.

Each review as well as the corrective action will be reported to the radiation safety committee at its next scheduled meeting. The committee can recommend further action to supplement that of the radiation safety officer.

Records of each quality management program review and evaluation will be maintained for at least three (3) years.

If the review uncovers a recordable event, the following procedure will be performed within 30 days after discovery: (a) the relevant facts, including the cause, will be assembled; (b) identifying any corrective action necessary to prevent reoccurrence. Documentation on each recordable event will be kept for at least three (3) years.

Lastly, modifications to the quality management program will be submitted to the U.S. Nuclear Regulatory Commission within 30 days after the modification has been made.

MN:kdc/purpro

MEDICAL COLLEGE HOSPITALS
BUCKS COUNTY CAMPUS
225 NEWTOWN ROAD
WARMINSTER, PA 18974

JUN 17 1994

ATTN: S. WARREN GROSS, M.D.

RE: Docket Number: 3014750
License Number: 37-18263-01
Plan File Date: 27-MAY-92
Region Number: 1

Dear Dr. Gross:

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

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.

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

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May 27, 1992

030-14750

U. S. Nuclear Regulatory Commission
Region I
Office of Medical Licensing Assistance
475 Allendale Road
King of Prussia, PA 19406

RE: License No. 37-18263-01

Dear Sir:

We are submitting a copy of our Quality Management Program as required by current regulation.

After your review we would appreciate any comments you may have.

Sincerely,

Janice Van Dolsen

Janice Vandolsen
Administrator
Radiology Department

cc: S. Warren Gross, M. D.
Radiation Safety Officer

MLL 10

JUN 03 1992

MEDICAL COLLEGE HOSPITALS

BUCKS COUNTY CAMPUS

225 Newtown Road

Warminster, PA 18974

NRC Quality Management Program

May 1992

Janice Van Dolsen

Janice Vandolsen
Administrator
Radiology Department

S. Warren Gross

S. Warren Gross, M. D.
Radiation Safety Officer

Policy: NRC Quality Management Program for Nuclear Medicine

Purpose: To delineate a method for compliance with the requirements of the U. S. Nuclear Regulatory Commission for quality management of programs related to a (n)

1. Greater than 30 microcurie administration of I-131 for diagnostic purposes in a patient who is known to have thyroid cancer and is being evaluated for residual functioning thyroid tissue;
2. I-131 administration in millicurie amounts for therapy of hyper thyroidism.

Responsibility: Radiation Safety Officer, NRC Authorized Users

Procedure:

1. A nuclear medicine physician's consult regarding the appropriateness of a requested I-131 diagnostic study or of a requested I-131 treatment.

2. The completion of a "Radionuclide Therapy Prescription" by the nuclear medicine physician. The prescription must be dated and signed, and must specify the radionuclide, total activity to be administered, patient's name, and route of administration.

3. Before administering a therapeutic dosage of a radiopharmaceutical, the identity of the patient must be verified using more than one method. The procedure used to identify the patient should be to ask the patient's name and confirm the name and at least one of the following by comparison with corresponding information in the patient's record: birthdate, address, social security number, signature, the name on the patient's ID bracelet or hospital ID card, or the name on the patient's medical insurance card.

   If, at any time, the technologist or physician is not completely convinced of the patient's identity prior to the administration of radioactive material they must STOP and immediately contact the attending or referring physician before proceeding further.

4. Prior to administration, the person administering a therapeutic dosage of a radiopharmaceutical shall verify that the details of the administration are in accordance with the written directive. This shall include confirmation that the radiopharmaceutical, dosage, and route of administration are in agreement with the written directive. Confirmation of the correct dosage shall include assay of the dosage in the dose calibrator and comparison of this result with the prescribed dosage in the written directive, including application of decay corrections, as appropriate. The administered dose should not vary by more than $\pm$ 10% from the prescribed dose.

No radioactive material will be administered to any patient until the nuclear medicine physician communicates to the technologist that they have reviewed all written directives and the patient is ready to receive their prescribed therapy dose.

If at any time, the technologist has any question about the administration, he or she should seek guidance from the nuclear medicine physician before proceeding.

5. After therapeutic administration of a radiopharmaceutical, the authorized user or technologist shall make, date, and sign the written treatment record to document the administered dosage.

Written treatment records will be permanently retained by the hospital or until the Nuclear Regulatory Commission grants approval upon petitioning to destroy such records.

Program Review: At 6 month intervals, all radionuclide therapy procedures will be scrutinized for compliance with the directives listed in the departmental QM (Quality Management) program. The results will be summarized and made available to the Radiation Safety Officer with subsequent reporting to the hospital Radiation Safety Committee and Quality Assurance Department.

The following parameters will be monitored:

1. Radionuclide therapy prescriptions.
2. Quality control of dose calibrator.
3. Verification of prescribed dose.
4. Confirmation of informed consent.
5. Confirmation of written directives.
6. Confirmation of patient identification.
7. Pregnancy test results prior to radionuclide therapy.
8. Documentation of administered dose.