AUG 22 1994

CHILDREN'S NATIONAL MEDICAL CENTER
111 MICHIGAN AVENUE, N.W.
WASHINGTON, DC 20010

ATTN: THOMAS FEARON, PH.D

RE: Docket Number: 030-01323
License Number: 08-03309-01

Dear Dr. Fearon:

This letter acknowledges receipt of your letter dated July 14, 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

OFFICIAL RECORD COPY - D:\QM-ACK\002400.ACK - 08/09/94

ML 10

Children's
National Medical Center

Department of
Diagnostic Imaging and
Radiology
Children's Hospital
111 Michigan Avenue, N.W.
Washington, D.C. 20010-2970
(202) 884-5080

030-01323

July 14, 1994

US NRC
Region I - Attention: Mr. James Dwyer
475 Allendale Road
King of Prussia, Pennsylvania 19406-1415

Dear Mr. Dwyer:

This is in response to your recent letter regarding Children's National Medical Centers Quality Management Program for the use of ^{131}I. Reference is made to Docket #: 3001323, License #: 08-03309-01. Please find enclosed a revised QMP that reflects the addition of required elements noted in your review submitted in accordance with 10 CFR 35.32(c). Please note that only ^{131}I are used for therapy and are covered by our QMP. I believe our revised QMP brings us into compliance.

If you have any questions please call at (202) 884-5075.

Thank you.

Sincerely,

Thomas Fearon

Thomas Fearon, Ph.D.
Radiation Safety Officer

TF:jmc

Department of Pediatrics
Department of Radiology
The George Washington University
Medical Center

ML 10

JUL 22 1994

Quality Management Program for Use of ^{131}I for Diagnostic and Therapeutic Purposes

Nuclear Medicine Section
Department of Diagnostic Imaging & Radiology
Children's National Medical Center

1. The Nuclear Medicine Physician performing the study shall date and sign the requisition for the study prior to administration of doses of ^{131}I greater than 30 uCi.

2. Before administration of the radiopharmaceutical the Nuclear Medicine Physician or his designee (Nuclear Medicine technologist) shall verify by more than one method the identity of the patient as the individual named in the requisition. 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: birth date, 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 because of the patient's medical 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 dated and 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 or the therapy dosage.

   If, because of the emergent nature of the patient's medical 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 patient's record and a written directive is prepared within 24 hours of the oral directive.

4. The radiopharmaceutical, dosage and route of administration should 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 requisition or the dosage prescribed by the Nuclear Medicine Physician.

5. Nuclear Medicine Technologists will seek guidance from the Nuclear Medicine Physician if there are any questions about the written requisition.

6. An authorized user or qualified individual under the supervision of an authorized user (e.g., nuclear medicine physician or technologist), after administering a radiopharmaceutical shall initial or sign and date the written record that documents the administered dosage. This written record and the original requisition for each administered radiopharmaceutical dosage will be retained for three years after the date of the administration.

7. The Radiopharmaceutical Quality Management Program will be reviewed by the Radiation Safety Committee annually as part of the review of the Radiation Safety Program.

   Unintended deviations from the written requisitions for radiopharmaceuticals labeled with ^{131}I greater than 30 micro Curies will be identified and evaluated during an annual review of the QMP for diagnostic as well as for therapeutic use of ^{131}I. No other isotopes are used for therapy at Children's National Medical Center. A sample of 20 requisitions for diagnostic use and 100% for therapeutic use will be reviewed, (these are appropriate sample sizes noting that 100 diagnostic cases using ^{131}I-MIBG are seen annually and only one therapeutic case in the last 15 years). Recordable deviations and misadministrations will be documented and reported within 30 days after discovery of the recordable event as required by 10 CFR 35.32 (c). The report shall include relevant facts and causes of the event as well as any corrective actions taken to prevent future recurrence if such actions are deemed appropriate by the Radiation Safety Committee. Corrective actions may include new or revised policies and procedures, additional training, or increased supervision. Upon discovery of a misadministration or significant deviation from the ordered and administered dosage a 100% sample will be reviewed.

NOTE TO DMB:

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

LICENSE NUMBER: 08-03309-01

DOCKET NUMBER: 030-01323

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

CHILDREN'S NATIONAL MEDICAL CENTER
111 MICHIGAN AVENUE, N.W.
WASHINGTON, DC 20010

JUN 17 1994

ATTN: THOMAS FEARON, PH.D

RE: Docket Number: 3001323
License Number: 08-03309-01
Plan File Date: 10-MAY-93
Region Number: 1

Dear Dr. Fearon:

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

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

Children's
National Medical Center

Department of
Diagnostic Imaging and
Radiology
Children's Hospital
111 Michigan Avenue, N.W.
Washington, D.C. 20010-2970
(202) 745-5079

08-03309-01
030-01323

May 7, 1993

James P. Dwyer, Acting Chief
Medical Inspection Section
Div. Radiation Safety & Safeguards
US Nuclear Regulatory Commission
Region I
475 Allendale Rd.
King of Prussia, PA 19406-1415

Dear Mr. Dwyer:

This is in reply to your letter of April 27, 1993, pursuant to the item of noncompliance with NRC regulations and requirements of Children's National Medical Center's license at the time of inspection on April 6, 1993.

In accordance with 10CFR 30.6 Children's National Medical Center certifies that a quality management program has been implemented for the use of mIBG-^{131}I for diagnostic purposes. A copy of our program is enclosed. We believe that full compliance has been achieved.

We found the NRC inspection of April 6, 1993 to be thorough and an informative contribution to the Radiation Safety Program at Children's National Medical Center. In particular, we would like to commend Mr. Davidson for the inspection he performed. It is hoped that this constitutes a satisfactory reply to your recent letter and Notice of Violation.

Sincerely,

Andrea R. Price

Andrea R. Price
Vice President, Professional Services

ARP/dkj
Enclosure
c: Radiation Safety Committee

Department of Pediatrics
Department of Radiology
The George Washington University
Medical Center

ML 10

(FAX RECD MAY 7, 1993)

MAY 10 1993

Quality Management Program for Use of mIBG-^{131}I for Diagnostic Purposes

Nuclear Medicine Section
Department of Diagnostic Imaging & Radiology
Children's National Medical Center

1. The Nuclear Medicine Physician performing the study shall date and sign the requisition for the study prior to administration of doses of mIBG-^{131}I greater than 30 uCi.

2. Before administration of the radiopharmaceutical the Nuclear Medicine Physician or his designee (Nuclear Medicine technologist) shall verify by more than one method the identity of the patient as the individual named in the requisition. 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: birth date, 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.

3. The radiopharmaceutical, dosage, and route of administration should 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 requisition or the dosage prescribed by the Nuclear Medicine Physician.

4. Nuclear Medicine Technologists will seek guidance from the Nuclear Medicine Physician if there are any questions about the written requisition.

5. The Nuclear Medicine Technologists shall document the administered dose, date and sign or initial the written record.

6. The Radiopharmaceutical Quality Management Program will be reviewed by the Radiation Safety Committee annually as part of the review of the Radiation Safety Program.