AUG 11 1994

BOWER, BRUCE F. (M.D., P.C.)
100 RETREAT AVENUE
HARTFORD, CT 06106

ATTN: BRUCE F. BOWER, M.D.

RE: Docket Number: 030-08163
License Number: 06-14854-01

Dear Dr. Bower:
This letter acknowledges receipt of your letter dated July 8, 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\001648.ACK - 07/20/94

ML 10

NOTE TO DMB:

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

LICENSE NUMBER: 06-14854-01

DOCKET NUMBER: 030-08163

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

280068

030-08163

ENDOCRINE ASSOCIATES, P.C.

ADULT AND PEDIATRIC
ENDOCRINOLOGY
METABOLISM
DIABETES
NEUROENDOCRINOLOGY
PSYCHOENDOCRINOLOGY
REPRODUCTIVE ENDOCRINOLOGY
NUCLEAR MEDICINE

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BRUCE F. BOWER, M.D., F.A.C.P., P.C.
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July 8, 1994

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

re: Bruce F. Bower, M.D.
Docket Number: 3008163
License No. 06-14854-01
Plan File Date 31-Aug-94
Region No. I

To whom it may concern:

I am in receipt of your communication of June 21, 1994 raising questions with respect to the Quality Management Program (QMP).

Each patient chart contains a written physician users statement specifying the therapeutic administration of I-131 for therapy of Grave's Disease (I-131 > 30 microcuries) as well as a specific dose. Each chart is patient specific and identified and includes the dose to be administered.

The charts are in general retained indefinitely and are never discarded before seven years. In addition an independent User Log identifying each patient and administered dose is retained indefinitely.

Each chart contains a signed written directive by an identified physician user specifying dose and date of administration.

The therapeutic log is completed by each physician at the time of administration. The log documents both the ordered and administered dose of therapeutic I-131. Any potential deviations are noted in the patient chart.

Only individual physician users are involved in therapeutic administration. No unrecorded unintended administrations have occurred or could occur under these circumstances.

A new log will be created to identify and document any recordable events and corrective actions. A written report will be provided to the NRC within 30 days of any recordable event. The records will be maintained for three years.

All (100 %) of all therapeutic administrations are reviewed by the licensee and are initialled in the Administration log. Expansion of monitoring following a recordable event is irrelevant since all therapeutic administrations are reviewed in any event.

ML 10

JUL 12 1994

The administration of therapeutic I-131 to established patients in an Endocrinology practice inherently provides clinical and patient continuity as well chart documentation of these specifics.

I trust that this response adequately addresses the specifics of your computer based request. If I can be of further help please feel free call upon me.

Yours very truly,

, M.D.

Bruce F. Bower, M.D.

BFB/jcf

BOWER, BRUCE F. (M.D., P.C.)
100 RETREAT AVENUE
HARTFORD, CT 06106

JUN 21 1994

ATTN: BRUCE F. BOWER, M.D.

RE: Docket Number: 3008163
License Number: 06-14854-01
Plan File Date: 31-AUG-94
Region Number: 1

Dear Dr. Bower:

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 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.

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).

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

ENDOCRINE ASSOCIATES

CONSULTING ENDOCRINOLOGISTS
ENDOCRINE ASSOCIATES LABORATORY

030-08163

ADULT AND PEDIATRIC
ENDOCRINOLOGY
METABOLISM
DIABETES
NEUROENDOCRINOLOGY
PSYCHOENDOCRINOLOGY
REPRODUCTIVE ENDOCRINOLOGY
NUCLEAR MEDICINE

January 30, 1992

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100 RETREAT AVENUE
SUITE 605
HARTFORD, CT 06106

United States Nuclear Regulatory Commission
Materials Licensing Safety Branch
475 Allendale Road
King of Prussia, PA 19406

re: Quality Management Program
NRC License 06-14854-01

Dear sirs:

Enclosed please find a copy of the Quality Management Program that has been implemented in our office.

Submission of these documents to your agency is required according to 10 CFR 35.32.

If there are any questions or if you desire further information, please contact me at (203) 547-1278.

Respectfully submitted,

Bruce F. Bower, M.D.

BFB/jcf

MLIO

JAN 31 1992

BRUCE F. BOWER, M. D.
QUALITY MANAGEMENT PROGRAM

THERAPEUTIC USE OF RADIOPHARMACEUTICALS & OF > 30 MICROCURIES OF NaI-125, OR, NaI-131

I. POLICY STATEMENTS

A. Written Directive*

An authorized user will date and sign a written directive prior to the administration of any therapeutic amount of radiopharmaceutical, or, of greater than 30 microCuries of sodium iodide prepared with I-125 or I-131.

Authorized users are listed on the NRC By-product Materials License for these specific uses of radioactive material.

B. Procedural Guidance

In the event that an employee is not entirely knowledgeable in the procedures required to satisfy a written directive, or, has any questions regarding those procedures, then he/she must seek the appropriate guidance rather than continue with the procedures.

* Interpret as: written prescription, written physician's orders.

II. PROCEDURES

A. Pre-administration of the Radiopharmaceutical

1. Identify the patient by more than one method.
    a. Ask the patient for their name and confirm with the patient's record, and,
    b. Also confirm information such as birth date, social security number, or, ID bracelet with the patient's record.
2. Verify the details for the administration.
    a. The radiopharmaceutical should be measured in the dose calibrator and the result compared to the prescribed dose in the written directive.
    b. The person administering the radiopharmaceutical should verify the radiopharmaceutical, the dosage and the route of administration for agreement with the written directive.

B. Post-administration of the Radiopharmaceutical

1. After administering a radiopharmaceutical an authorized user, physicist, or, nuclear medicine technologist will prepare, date and sign a written record that documents the administered dosage. This written record may go into the patient's chart or other appropriate record.

III. ORAL DIRECTIVES & REVISIONS TO WRITTEN DIRECTIVES

A. Emergent Condition of Patient

If a delay would jeopardize the patient's health, then:

1. An oral directive is acceptable if said information is documented immediately in the patient's record and a written directive is prepared within 24 hours.
2. An oral revision to an existing written directive is acceptable if said information is documented immediately in the patient's record and a revised written directive is dated and signed by an authorized user within 48 hours.

B. A written revision to an existing written directive may be made if the revision is dated and signed prior to the administration of the radiopharmaceutical.

IV. PERIODIC REVIEWS

A. Reviews of the Quality Management Program

A review of the Quality Management Program will be conducted at least annually. The review should include a representative sample of patient administrations, all recordable events and misadministrations. Patients are to be selected at random, and, a statistical acceptance sampling table can be found in 10 CFR 32.110. For each patient reviewed:

1. The written directive should be compared to the radiopharmaceutical used, dosage and route of administration.
2. Identify deviations from the written directive, the cause of the deviation and the action taken to prevent a recurrence.

B. Assessment of Policies and Procedures

The program's policies and procedures should be reevaluated to ensure or enhance the program's effectivity, and, any corrective actions implemented within a reasonable period of time. The program review results will be distributed to the management and presented.