

AUG 16 1994

NORTH JERSEY IMAGING CENTER
307 60TH STREET
WEST NEW YORK, NJ 07093

ATTN: ROBERT S. PORT M.D.

RE: Docket Number: 030-32732
License Number: 29-28747-01

Dear Dr. Port:

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

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PDR ADOCK 03032732
C PDR

OFFICIAL RECORD COPY - D:\QMP-ACK\002532.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: 29-28747-01

DOCKET NUMBER: 030-32732

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

070031

BIO MED ASSOCIATES, INC.
4 MAIN STREET FLEMINGTON, NEW JERSEY 08822

908-788-9440
FAX 788-6757

July 8, 1994

James P. Dwyer, Quality Management Coordinator
U.S. Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

RE: License No. 29-28747-01

Dear Mr. Dwyer:

I am writing in response to your letter received on June 23, 1994 concerning our Quality Management Program which was submitted to your office on June 22, 1993. Enclosed is a revised Q.M. program for radiopharmaceutical therapy.

There are still specific items listed as "significant weaknesses" in your letter which are not addressed in the revised program. The items not addressed, such as three year record retention, are licensing commitments or are identified in 10CFR35 as regulations. Once again we agree to follow all conditions and requirements of our Materials License.

Since our license was approved, no cases of radiopharmaceutical therapy have been performed and it is unlikely that administration of I-131 or other isotope requiring the Q.M. protocol will occur. In the unlikely incidence of a radiopharmaceutical procedure or other administration of I-131 we will follow the Q.M. program requirements.

If you require any additional information regarding this matter, do not hesitate to contact us.

Sincerely,



Michael Teters, M.S.
Radiological Physicist



Robert S. Port, M.D.
Radiation Safety Officer

ML 10

JUL 18 1994

QUALITY MANAGEMENT PROGRAM

- I. Diagnostic Procedures--Compare ordered procedure on request document to prescribed radiopharmaceutical, dosage, and route of administration listed on dose schedule. Dose schedule should be posted in dose preparation area.
- II. Verify the identity of the patient (for diagnostic or therapy procedures) by two methods before administration.

Check the patient's name orally and on a written document (eg. ID bracelet, chart, ID card, etc.). If the patient cannot speak, verify the patient's identity with a relative or guardian.

- III. A "Written Directive" must be received before each therapy or sodium I-131, I-125 ($>30\mu\text{Ci}$) procedure. It must contain the patient's name, the date of the order, the authorized user's signature, the radiopharmaceutical, and the dosage. For other radiopharmaceutical therapy, the route of administration must also be included. The administered dose must be checked and agree with the written directive. Complete all normally required information contained in the administration log, including assay of the dose.

The written directive for radiopharmaceutical therapy may be revised by an authorized user prior to administration, provided that the revision is signed and dated.

No one is authorized to administer a dose without a written directive (when required). Also, do not administer a dose when the written directive is unclear or incomplete.

- IV. "Recordable events" occur when any deviation from the written directive is identified, and include:
 - A. A missing or late written directive.
 - B. When an administered dose is not recorded.
 - C. When the prescribed dose differs from the administered dose by more than 10% and 30 μCi for sodium I-131, I-125 ($>30\mu\text{Ci}$).
 - D. When the prescribed dose differs from the administered dose by more than 10% for other radiopharmaceuticals in 35.300.

Recordable events must be evaluated and documentation must include the cause and relevant facts, and the corrective action to prevent future reoccurrence.

V. Misadministrations include:

- A. For sodium I-131, I-125 (>30 μ Ci):
 - 1. When an administered dose differs from the prescribed dose by > 20% and 30 μ Ci.
 - 2. The wrong patient.
 - 3. The wrong radiopharmaceutical.
- B. For other radiopharmaceuticals in 35.300:
 - 1. The wrong patient.
 - 2. The wrong radiopharmaceutical.
 - 3. The wrong route of administration.
 - 4. When the administered dose differs from the prescribed dose by > 20%.
- C. For diagnostic procedures:
 - 1. The wrong patient, or the wrong pharmaceutical, or the wrong route of administration, or the wrong dose, and
 - 2. The whole body dose equivalent is > 5 rems, or a organ dose is > 50 rems.

Misadministrations must be reported to the NRC, the referring physician, and the patient within 24 hours, and evaluated within 15 days.

VI. As part of the periodic Radiation Protection Audit, the Quality Management Program will be reviewed by the health physicist. This shall be performed at least annually, and should be performed quarterly when deemed necessary by the Radiation Safety Committee. The review will include:

- A. A representative sample of patient administrations including the written directive.
 - 1. All patients if less than 20 are performed.
 - 2. 20 patients if between 20 and 100 cases.
 - 3. 20 % of patient administrations if over 100 are performed.
- B. All recordable events.
- C. All misadministrations.

Additional cases may be audited if a misadministration or recordable event is discovered. The review also includes an evaluation of all procedures, commitments, and regulations regarding the quality management program.

The results of the audits will be presented to the Radiation Safety Committee and documented in the minutes. If a recordable event or misadministration occurs, the committee may institute corrective action and/or revise the program.

June 28, 1994

VII. Changes to the Quality Management Program may be made as approved by the Radiation Safety Committee. Notification of the changes must be submitted to the NRC.

June 28, 1994

NORTH JERSEY IMAGING CENTER
307 60TH STREET
WEST NEW YORK, NJ 07093

JUN 23 1994

ATTN: ROBERT S. PORT M.D.

RE: Docket Number: 030-32732
License Number: 29-28747-01
Plan File Date: 22-JUN-93
Region Number: 1

Dear Dr. Port:

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

- 1 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.
- 2 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.
- 3 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.

- 4 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.
- 5 Your submittal for I-125 and/or I-131 > 30 microcuries administration does not include policies/procedures that ensure before administration that each administration is in accordance with the written directive as required by 10 CFR 35.32(a)(4). Describe your policy/procedure to verify, before administering the by-product material, that the specific details of the administration are in accordance with the written directive.
- 6 The dosage 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 written directive. Please provide such (or similar) procedures in your QMP.
- 7 Your QMP should include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive. Please include such a provision in your QMP.
- 8 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.
- 9 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.
- 10 Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.
- 11 As required in 10 CFR 35.32(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.

- 12 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.
- 13 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).
- 14 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).
- 15 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:
Francis M. Costello

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

NORTH JERSEY
IMAGING
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CENTER

307 60th Street • West New York, NJ 07093
(201) 854-1200 • FAX (201) 854-3333



030-32732

JUNE 16, 1993

MS. JUDITH A. JOUSTRA
U. S. NUCLEAR REGULATORY COMMISSION
REGION 1
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406-1415

RE: LICENSE NO. 29-28747-01; DOCKET NO. 030-32732; EA 93-156

DEAR MS. JOUSTRA:

ENCLOSED IS THE QUALITY MANAGEMENT PROGRAM FOR IODINE I-131 ADMINISTRATION AT NORTH JERSEY IMAGING CENTER. THE AUTHORIZED USERS AT NORTH JERSEY IMAGING CENTER MAY TREAT PATIENTS WITH IODINE I-131 FOR HYPERTHYROIDISM OR CARDIAC DYSFUNCTION. THIS WOULD BE THE ONLY USE OF IODINE I-131 AT OUR FACILITY.

ALSO, PLEASE NOTE THAT NO PATIENTS HAVE BEEN TREATED WITH IODINE I-131 FOR THERAPY OR DIAGNOSTIC SCANNING SINCE OUR LICENSE WAS APPROVED.

IF YOU REQUIRE ANY ADDITIONAL INFORMATION REGARDING THIS MATTER, PLEASE CONTACT US AT (201) 854-1200.

VERY TRULY YOURS,


ROBERT S. PORT, M. D.

RSP:BD

ENC

CERTIFIED MAIL
RETURN RECEIPT
#P349 041 179

ML 10

JUN 22 1993



QUALITY MANAGEMENT PROGRAM

- I. Diagnostic Procedures--Compare ordered procedure on request document to prescribed radiopharmaceutical, dosage, and route of administration listed on dose schedule. Dose schedule should be posted in dose preparation area.
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Check patient's name orally and on a written document (e.g. ID bracelet, chart, ID card, etc.). If the patient cannot speak, verify the patient orally with a relative or guardian.

- III. A "Written Directive" must be received before each therapy or sodium I-131, I-125 ($>30\mu\text{Ci}$) procedure. It must contain the patient's name, the date of the order, the authorized user's signature, the radiopharmaceutical, and the dosage. For P-32 therapy, the route of administration must also be included. The administered dose must be reviewed and agree with the written directive. This review should be noted on the written directive. Complete all normally required information contained in the administration log, including assay of the dose.

No one is authorized to administer a dose without a written directive (when required). Also, do not administer a dose when the written directive is unclear or incomplete.

- IV. "Recordable events" occur when any deviation from the written directive is identified, and include:
 - A. A missing or late written directive.
 - B. When an administered dose is not recorded.
 - C. When the prescribed dose differs from the administered dose by more than 10% and $15\mu\text{Ci}$ for sodium I-131, I-125 ($>30\mu\text{Ci}$).
 - D. When the prescribed dose differs from the administered dose by more than 10% for P-32.

Recordable events must be evaluated and documentation must include the cause and relevant facts, and the corrective action to prevent future reoccurrence.

V. Misadministrations include:

- A. For sodium I-131, I-125 (>30 μ Ci):
 - 1. When an administered dose differs from the prescribed dose by > 20% and 30 μ Ci.
 - 2. The wrong patient.
 - 3. The wrong radiopharmaceutical.
- B. For P-32:
 - 1. The wrong patient.
 - 2. The wrong radiopharmaceutical.
 - 3. The wrong route of administration.
 - 4. When the administered dose differs from the prescribed dose by > 20%.
- C. For diagnostic procedures:
 - 1. The wrong patient, or the wrong pharmaceutical, or the wrong route of administration, or the wrong dosage, and
 - 2. The whole body dose equivalent is > 5 rems, or a organ dose is > 50 rems.

Misadministrations must be reported to the NRC, the referring physician, and the patient within 24 hours, and evaluated within 15 days.

- VI. As part of the periodic Radiation Protection Audit, the Quality Management Program will be reviewed by the health physicist. This shall be performed at least annually, and should be performed quarterly when deemed necessary by the Radiation Safety Committee. The review will include:
- A. A representative sample of patient administrations.
 - B. All recordable events.
 - C. All misadministrations.

The results of the audits will be evaluated to determine the program's effectiveness, and will be presented to the Radiation Safety Committee and documented in the minutes.

- VII. Changes to the Quality Management Program may be made as approved by the Radiation Safety Committee. Notification of the changes must be submitted to the NRC.

IODINE - 131 RADIOPHARMACEUTICAL THERAPY

Written Directive

Patients Name _____ IP/OP
Prescribed Dose _____
Route of Administration _____
Authorized User _____ Date _____

Dose Measurement

Dose _____ Time _____ Date _____

Comments:

Signature _____

Verification Post - Administration

Does written directive agree with administered dose ? YES ____ NO ____

Signature _____