AUG 29 1994

IMAGING ASSOCIATES, INC.
9 PATRICIA DRIVE
ABINGTON, MA 02351

ATTN: IRA MATLER, M.D.

RE: Docket Number: 030-31835
License Number: 20-28558-01

Dear Dr. Matler:

This letter acknowledges receipt of your letter dated August 1, 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

240093

OFFICIAL RECORD COPY - D:\QMP3-ACK\002938.ACK - 08/11/94

ML 10

NOTE TO DMB:

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

LICENSE NUMBER: 20-28555-01

DOCKET NUMBER: 030-31835

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

IMAGING associates INC
270 Centre St. • Unit F • Holbrook, Massachusetts 02343 • Tel: 617-767-5111 • FAX: 617-767-5191

030-31835

August 1, 1994

License No. 20-28558-01

Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards
475 Allendale Road
King of Prussia, PA 19406

Dear Reviewer:

Enclosed is a revised copy of our Quality Management Program. These revisions have been made in response to your review of our QM program submitted in January of 1992 and referenced in your letter dated July 19, 1993 as Docket Number 030-31835.

As Administrator for NRC License No. 20-28558-01, I certify that the enclosed program changes have been implemented.

Sincerely,

Charles E. McCarthy
Administrator

CEM/eam

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AUG - 5 1994

QUALITY MANAGEMENT PROGRAM FOR ADMINISTRATION OF DIAGNOSTIC DOSES OF I-125 AND I-131 GREATER THAN 30 uCi

NOTE: This program dated August 1, 1994 supersedes the program submitted Jan 27, 1994.

1. The objectives of the Quality Management Program are to assure that:

   a. A written directive is prepared before administration.
   b. The patient's identity is verified, by more than one method, as the individual named in the written directive, before each administration.
   c. Final plans for iodine diagnosis are in accordance with the respective written directive.
   d. Each administration is in accordance with the written directive.
   e. Any unintended deviation from the written directive is evaluated, and appropriate action is taken.

2. The Radiation Safety Officer and the License Administrator shall have the authority and responsibility to establish and implement the Quality Management Program. Directives contained herein remain responsive to the JCAHO and NRC.

3. Prior to administration, a written directive issued by an authorized user will be prepared, signed, and dated for any administration of Sodium Iodine I-125 or I-131 greater than 30 micro Curies.

A written directive is defined as an order, in writing, for a specific patient, dated and signed by an authorized user prior to the administration of the radiopharmaceutical, containing the following information:

   a. patient's name
   b. patient's identification number, if available
   c. radiopharmaceutical
   d. dosage
   e. route of administration
   f. any specific precautions

Except in emergent situations as defined in Part 17 below, no applicable radiopharmaceutical shall be administered by any personnel in the absence of a signed directive containing the above elements.

4. Prior to administration, the patient's identity is verified by more than one method as the patient named in the written directive. The person responsible for the administration of the radiophamaceutical will perform the verification.

Verification of identity must include at least two of the following methods coupled with a review of the patient's record:

a. the patient shall be asked to state and spell his/her name
b. the patient shall be asked to state his/her birth date
c. the patient shall be asked to state his/her Social Security Number
d. the patient shall be asked to state his/her address
e. the patient shall be asked for identification, i.e. driver's license

If the information obtained from any two of these methods dose not correspond to the information on the patient's record, the radiation dose shall not be administered until conclusive verification is obtained.

5. The person administering the applicable radiopharmaceutical shall read the written directive before administering the radiopharmaceutical. If any portion of the written directive is unclear to that person, he/she must contact the specific authorized user who provided the directive for clarification. The radiation dose shall not be administered until the intent of the written directive is thoroughly understood by the administering person. If the person preparing the dose is different from the person administering, both shall read and understand the written directive.

6. The individuals in Part 5 above shall verify that the specific details of the administration (radiopharmaceutical, dosage, and route of administration) are in accordance with the written directive. The actual dose calibrator assay shall be verified with the dosage listed on the written directive.

7. Revisions to written directives may be made for any applicable diagnostic procedure provided that the revision is dated and signed by an authorized user prior to the administration of the radiopharmaceutical and that all other above conditions are followed.

8. All written directives will be retained in an auditable form for a period of three years.

9. After administration of an applicable radiopharmaceutical dose, a responsible party shall make, date, sign or initial a written record that documents the administered dosage in an auditable form to be retained for three years.

10. Within 30 days after discovery of a recordable, the Radiation Safety Officer will evaluate and respond to each recordable event by: (a) assembling the relevant facts including cause, (b) identifying what, if any, corrective action is required to prevent reoccurrence and (c) retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action was taken.

11. All radiopharmaceutical administrations that require a written directive will be reviewed at intervals not to exceed 12 months. This review will include:

    (a) At least 20% of all cases if the number of cases performed is greater than 100, 20 cases it the number of cases is between 20 and 100, and all, if the number of cases is less than 20.
    (b) All recordable events
    (c) All misadministrations since the last review.

12. In the event of the discovery of a misadministration or a recordable event as a result of the periodic review, all radiopharmaceutical administrations that require a written directive will be reviewed.

13. The effectiveness of this plan will be evaluated by looking at the total number of misadministrations and/or recordable events versus the total number of administrations performed. Any increase in the occurrence rate will prompt the Radiation Safety Officer and the License Administrator to make modifications to meet the objectives of the program.

14. All modification to this QM program will be submitted to the NRC within 30 days after the modification has been made.

15. All reviews of this program will be retained in an auditable form for a period of three years.

16. Training will be conducted for all employees involved in the quality management program.

17. Oral directives or amendments are permissible when a patient's medical condition is such that his/her health would be jeopardized by the delay needed for originating or revising a written directive. When oral directives or amendments are employed, the information contained in the oral directive is immediately documented in the patient's record and the original written directive is prepared within 24 hours of the oral issue. In the situation of an oral revision of an existing written directive, it must be revised, dated, and signed by the authorized user within 48 hours of the oral revision.

18. Following administration of the radiopharmaceutical, a dated and signed written note is entered into the patient's record documenting the administration and dosage.

19. If any unintended deviation from the written directive is identified, it is evaluated, and appropriate action taken. Upon identification of an unintended deviation, whether a recordable event or a misadministration, an investigation of the

incident shall be made. The cause of the incident shall be determined and, if appropriate, corrective procedures will be implemented. Documenting and reporting of the unintended deviation shall be in accordance with the reporting rules of 10 CFR Part 35.

IMAGING ASSOCIATES, INC.
9 PATRICIA DRIVE
ABINGTON, MA 02351

[JUL 19 1993]

ATTN: IRA MATLER, M.D.

RE: Docket Number: 030-31835
License Number: 20-28558-01
Plan File Date: 27-JAN-92
Region Number: 1

Dear Dr. Matler:

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 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:

- is dated and signed by the authorized user

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 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.

6 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.

7 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.

8 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.

9 Your QMP must include policies/procedures to institute corrective actions to be taken after an unintended deviation has been identified.

10 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.

11 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.

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 NRC contractor utilizing standard paragraphs previously reviewed and approved by NRC headquarters and regional management.

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

IMAGING associates INC

030-31835

January 22, 1992

License No. 20-28558-01

Nuclear Materials Safety Section A
Division of Radiation Safety
and Safeguards
475 Allendale Road
King of Prussia, PA 19406

Dear Reviewer:

Enclosed is a copy of our Quality Management Program.

As Administrator for NRC License No. 20-28558-01, I certify that the enclosed program has been implemented.

Sincerely,

Charles E. McCarthy
Administrator

CEM/eam

ML 10

JAN 27 1992.

91 Patricia Drive • Abington, Massachusetts 02351-1052 • (617) 871-4010

QUALITY MANAGEMENT PROGRAM REGARDING

1. Administration of greater than 30 microcuries of I-125 or I-131.

REFERENCE: FEDERAL REGISTER NOTICE PUBLISHED 7/25/91 AND 10 CFR 35.32

A quality management program is hereby established in order to meet the directives of 10 CFR 35.32 as published in the Federal Register of July 1991.

The objectives of the quality management program are to assure that:

1. A written directive is prepared before administration;

2. The patient's identity is verified, by more than one method, as the individual named in the written directive, before each administration;

3. Final plans for diagnosis involving radioiodine are in accordance with respective written directives;

4. Each administration is in accordance with the written directive, and

5. Any unintended deviation from the written directive is evaluated, and appropriate action is taken.

IMPLEMENTATION

1. In regard to a written directive for a diagnostic procedure involving greater than 30 μCi of iodine, the referring physician consults with the nuclear physician in regard to appropriate dosage for procedure and prescribes the desired dose. The consulting nuclear physician will write a prescription for the patient with the desired dose, and arrange for the radiopharmaceutical to be ordered. When the prescription for the procedure arrives from the referring physician, it will be attached to the prescription written by the nuclear physician for comparison.

2. The patient's identity must be verified by more than one method. Following are suggested methods of identification:

   asking the patient to spell his/her name
   checking the patient's ID bracelet, if present
   asking for photo ID or other ID

3. Each such administration must be within 10% of the written directive.

4. Any unintended deviation from the written directive must be evaluated and appropriate action taken.

5. Each recordable event must be fully recorded, evaluated, and corrective action taken within 30 days by the RSO.

6. Each misadministration must be reported by the RSO to the appropriate authorities in accordance with the regulations.

ADMINISTRATIVE PROCEDURES RELATIVE TO THIS PROGRAM:

1. A copy of this management program shall be submitted to NRC prior to January 27, 1992.

2. Accompanying that submission, written certification shall be made to the NRC indicating that the quality management program has been implemented.

3. This quality management program will be reviewed at intervals of no greater than 12 months.

4. Records of review of the quality management program, each written directive, each administered radiopharmaceutical dosage of greater than 30 μCi of Iodines 131 or 125, each recordable event, and each misadministration will be retained.

5. The written prescriptions for administration of such radiopharmaceutical will be attached to the medical records copy of the patient record and sent to Medical Records for permanent filing.