

AUG 29 1994

LAWRENCE MEMORIAL HOSPITAL
170 GOVERNORS AVENUE
MEDFORD, MA 02155

ATTN: GWENDOLYN B. NICHOLS, MD.

RE: Docket Number: 030-08404
License Number: 20-15007-01

Dear Dr. Nichols:

This letter acknowledges receipt of your letter dated July 22, 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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NOTE TO DMB:

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

LICENSE NUMBER: 20-15007-01

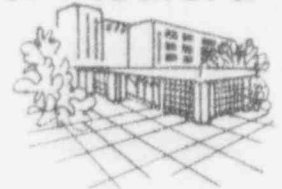
DOCKET NUMBER: 030-08404

THIS SHEET MAY BE DISCARDED AFTER PROCESSING.

THANK YOU!

CHARLES F. JOHNSON
PRESIDENT

Lawrence Memorial Hospital of Medford



170 Governors Avenue
Medford, Massachusetts
02155
(617) 396-9250

July 22, 1994

Nuclear Regulatory Commission
Region I
475 Allendale Road
King of Prussia, Pennsylvania 1906-1415

ATTENTION: James P. Dwyer
Quality Management Program Coordinator
Region I

Dear Mr. Dwyer:

We are in receipt of your letter in regards to our Quality Management Program. Thank-you for your comments. According to your directives, our Quality Management Program has been ammended. I have included with this document a copy of our Quality Management Program. All changes to the Quality Management Program will be instituted as of August 1, 1994.

I hope you will find this in order. Should you have any further comments, I would more than happy to address them.

Thank-you for ur interest in our program.

Sincerely,

Guenevieve B. Nichols, M.D.

G. B. Nichols M.L.
Chief, Department of Radiology

DOCKET # 303-08404
License # 20-15007-01

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AUG - 8 1994

LAWRENCE MEMORIAL HOSPITAL

NUCLEAR MEDICINE DEPARTMENT

QUALITY MANAGEMENT PROGRAM FOR
ADMINISTRATION OF THERAPEUTIC AND DIAGNOSTIC DOSES
OF CERTAIN PHARMACEUTICALS

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 or for treatment 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 Nuclear Medicine Department 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:
 - a. Any therapeutic administration of a radiopharmaceutical.
 - b. Any administration of Sodium Iodine I-125 or I-131 greater than 30 microcuries.

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 a radiopharmaceutical containing the following information:

- a. patient's name
- b. patient identification number, if available
- c. radiopharmaceutical
- d. dosage
- e. route of administration
- f. the type of procedure desired
- g. any special precautions

Except in emergent situations as defined in Part 17 below, no 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 radiopharmaceutical will perform the verification.

Verification of indentity 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 date of birth.
- 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.
- f. the inpatient's wrist identification band shall be checked for name and patient number (SSN).

If the information obtained from any two of these methods does 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 radiation dose shall read the written directive before administering the radiopharmaceutical. If any portion of the written directive is unclear to that person, (s he 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 or therapeutic 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 event the Radiation Safety Officer will evaluate and respond 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.
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 if 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 radiopharmaceuticals 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 Radiation Safety Committee to make modifications to meet the objectives of the program.
14. All modifications 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 in the contents of this program will be conducted for all employees evolved 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 18 hours of the oral revision.

18. Following administration of the radiopharmaceutical dose, a dated and signed written note is entered into the patient's record documenting the administration and dosage. Any therapeutic administration, including dosimetric estimates, must be recorded into the patient's permanent medical record.
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 all the unintended deviation shall be in accordance with the reporting rules of 10CFR Part 35.

JUL 19 1993

LAWRENCE MEMORIAL HOSPITAL
170 GOVERNORS AVENUE
MEDFORD, MA 02155

ATTN: GWENDOLYN B. NICHOLS, MD.

RE: Docket Number: 030-08404
License Number: 20-15007-01
Plan File Date: 30-DEC-93
Region Number: 1

Dear Dr. Nichols:

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 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
- 3 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.

- 4 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.
- 5 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.
- 6 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.
- 7 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.
- 8 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.
- 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 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.

- 12 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.
- 13 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.
- 14 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).
- 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,

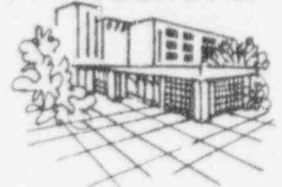
Original Signed By:
James P. Dwyer

James P. Dwyer
Quality Management Program Coordinator
Region I

Enclosure: As stated

CHARLES J. HANSON
PRESIDENT

Lawrence Memorial Hospital of Medford



170 Governors Avenue
Medford, Massachusetts
02155
617-396-9250

030-08404

December 27, 1993

Nuclear Regulatory Commission
Region 1
475 Allendale Road
King of Prussia, PA 19406-1415

Gentlemen,

Our license #20-15007-01 has recently been amended to allow us to use Metastron as a therapeutic radiopharmaceutical. Accordingly, I am today submitting an amendment to the quality management program to reflect the usage of Metastron in a therapeutic manner. The quality management program for the Lawrence Memorial Hospital is appended to this letter.

Thank you for your consideration and assistance.

Sincerely,

Gwendolyn B. Nichols, M.D.

Gwendolyn B. Nichols, M.D.
Radiation Safety Officer

GBN/k
Encl.

DEC 30

DEC 30 1993

Lawrence Memorial Hospital of Medford



170 Governors Avenue
Medford, Massachusetts
02155
617-396-9250

QUALITY MANAGEMENT PROGRAM REGARDING

1. Administration of greater than 30 microcuries of ^{125}I or ^{131}I .
2. Administration of outpatient radiopharmaceutical therapy under 35.300.

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 identify 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 or radiopharmaceutical therapy are in accordance with the 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 $30\ \mu\text{Ci}$ of iodine or any radiopharmaceutical therapy procedure, 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.

LAWRENCE MEMORIAL HOSPITAL, MEDFORD, MA
Quality Management Program

2. The patient's identify 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 the original management program shall be submitted to NRC prior to January 27, 1992. Any change in the program will be submitted to NRC within 30 days of the change.
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 μ Ci of Iodines 131 or 125 or radiopharmaceuticals for treatment, 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.

20-15207-01
030-08404

LAWRENCE MEMORIAL HOSPITAL MEDFORD, MA

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 μ Ci 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.

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FAX RECD MAY 20 1993

LAWRENCE MEMORIAL HOSPITAL MEDFORD, MA

Quality Management Program
Page 2

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 μ Ci 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.