April 6, 1998

Docket No. 030-34653 License No. 06-30432-01
Mail Control No. 125428

Dayton A. Rich
Manager
Whitney Imaging Center
2200 Whitney Avenue, Suite 120
Hamden, CT 06518

SUBJECT: Quality Management Program

Dear Mr. Rich:

This refers to your revised Quality Management Program (QMP) for administration of radiopharmaceuticals submitted with your letter dated March 18, 1998, that describes your written quality management program developed in accordance with 10 CFR 35.32. A review of your written QMP was performed to determine whether your described policies and procedures appear to meet the objectives of the rule. Based on that review, we have no questions regarding the objectives listed in 10 CFR 35.32.

Please be advised that the QMP will not be a condition of your license. 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 your modified QMP to this Office within 30 days after the modification is made, as required by 10 CFR 35.32(e).

Thank you for your cooperation in this matter. If you have any questions regarding this letter, please call me at (610) 337-5364.

Sincerely,

Original signed by Sattar Lodhi, Ph.D.

Sattar Lodhi, Ph.D.
Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

cc:
Vicente J. Caride, M.D., Radiation Safety Officer

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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	SLodhi							
DATE	04/06/98		04/ /98		04/ /98		04/ /98	

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RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM

A Quality Management Program will be established as a condition of our U S NRC License , as follows:

1. Written Directives. *Prior* to administration, a dated, written directive will be prepared for each specific patient, for any quantities of greater than 30 microCurie of either sodium iodide I-125, I-131, or other radiopharmaceuticals administered for therapeutic purposes. The directive will contain the identity of the radiopharmaceutical, the route of administration for radiopharmaceuticals other than iodine-125 or iodine-131, and be signed by an authorized user, for each individual patient.

2. Patient Identification. Prior to each administration mentioned above, the patient's identity will be verified by more than one method as the individual named in the written directive. Acceptable methods of identification include: a driver's license with photo, an employee identification badge with photo, affirmation of identification by a relative or friend accompanying the patient, or hospital identification band on the patient.

3. Dose Verification. Each radiopharmaceutical dose will be assayed twice, by two different individuals, to insure that the quantity of radiopharmaceutical is the amount specified on the written directive.

4. Dose Administration. Before administration, the person administering the radiopharmaceutical will verify that the specific details of the administration are in accordance with the written directive, with respect to radiopharmaceutical, dosage and route of administration.

5. Guidance for Questions. All workers are required to seek guidance if they do not understand how to carry out the written directive.

6. Quality Management. After each administration described above, the administration will be reviewed to determine that it was in accordance with the written directive. Unintended deviations from the written directive will be identified and evaluated, and appropriate action will be taken. Corrective action will include evaluation of the cause of unintended deviations, procedures for mitigation, and retraining if necessary.

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7. Quality Management Review. On an annual basis, a review of the quality management program will be carried out. This review will include:

a. A review of a representative sample of administrations.

b. A review of all recordable events, and all misadministrations to verify compliance with all aspects of the quality management program.

c. An evaluation of the review to determine the effectiveness of the quality management program and if required, modifications to meet the objectives of the program.

d. Recording and retaining for three years, in an auditable form, records of the annual review.

8. Reportable Events. We will 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, if any, was taken.

9. Records. We will retain, for a period of three years after the date of administration, in auditable form, the written directives described above, and the record of the administration itself.

Dayton A. Rich

Dayton A. Rich

Manager

March 18, 1998

Spring Glen Medical Center, 2200 Whitney Avenue, Hamden, CT 06518 • (203) 288-3068 • Fax (203) 288-3124

Affiliated with New Haven Radiology Associates, PC and Managed by Signal Medical Services, Inc.

February 27, 1998

Docket No. 030-34653
Control No. 125427

Vicente J. Caride, M.D.
Whitney Imaging Center
2200 Whitney Avenue
Hamden, CT 06518

Dear Dr. Caride:

This is in reference to your application dated February 5, 1998, applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. It appears from your application that Vicente J. Caride, M.D., is the applicant for the license to use licensed materials at Whitney Imaging Center's facilities. Please provide certification from the management of Whitney Imaging Center that they are aware of your application and that they will assume responsibility for the use of licensed material by you at their facility. If Whitney Imaging Center will be the licensee, then a management representative of this facility must sign the application, and if Dr. Caride is the management representative, then provide the title of his position (President, Owner, etc.) at the facility.

2. Please confirm that 2200 Whitney Avenue, Hamden, Connecticut, is not currently listed on another NRC license as an authorized location of use of licensed material.

3.. Your license will be written in a format that requires modification of possession limit for materials listed in 10 CFR 35.300. Please provide total possession limit (in millicuries) commensurate with your program for materials listed in 10 CFR 35.300. Please consider the maximum activity you will have on site at any one time including waste when setting the limit for these materials.

4. 10 CFR 35.972 states that the training and experience of a physician must have been obtained within the 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed. Dr. Malcom Friedman's certification, training and experience do not meet these criteria. Please submit documentation that demonstrates that Dr. Friedman has had related continuing education and experience during the last seven years.

5. Your application states that you will establish and implement the model training program that was published in Appendix A to Regulatory Guide 10.8, Revision 2. Please confirm that you will maintain records of worker training (initial and refresher) which include the

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date and duration of training, the topics covered, the name(s) of the individual(s) providing training and the names of attendees.

6. The diagram for your hot lab does not appear to be consistent with typical dimensions of hot lab equipment (work area is indicated as only 19 inches wide). On a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-c) and describe the type, dimensions, and thickness of shielding that you will use. Exhibit 6 of the enclosed regulatory guide may be helpful in preparing your response and provides an example of a facility diagram that is acceptable to the NRC.

   a. Storage of radiopharmaceuticals (refrigerated and nonrefrigerated).

   b. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. This area should be large enough to handle an accumulation of all solid waste. If this area is not located within your main department, describe how you will secure the material.

   c. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

   In addition, identify adjacent areas across the walls from use and storage locations and show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301 (enclosed).

7. You have indicated that Appendix N Procedures and Table N-1 will be followed for area surveys. These procedures require a method for performing wipe tests that is sufficiently sensitive to detect 2000 disintegrations per minute per 100 square centimeters (dpm/100 cm^2) of removable contamination and 200 dpm/100 cm^2 if you are using iodine-131. Please describe the instrument you will use to perform these measurements and confirm that your instrumentation will be capable of detecting contamination below these limits.

8. Please confirm that backup instruments will be available to replace instruments off-site for calibration.

9 Your application states that you will establish and implement the model guidance for ordering and receiving licensed material that was published in Appendix K to Regulatory Guide 10.8, Revision 2. 10 CFR 20.1906, "Procedures for receiving and opening packages", states, in part, that each licensee shall monitor the surfaces of a labeled package for radioactive contamination within 3 hours of receipt if it is received during normal working hours or not later than 3 hours from the beginning of the next working day if it is received after working hours. Appendix K procedures do not address monitoring the surface of packages upon receipt. Please confirm that you will modify your package receipt procedures to comply with the requirements of 10 CFR 20.1906.

10. Your application should have been signed by a management representative rather than the Radiation Safety Officer. Please submit a letter signed by a management

representative indicating that management has reviewed the application and concurs with the statements and representations contained therein. Note also that a management representative should sign all future correspondence that requests a change in your license.

11. Please provide a written certification that your written quality management program (QMP) will be implemented.

12. Your quality management program (QMP) appears to be restatement of regulatory requirements only and does not include policies/procedures to ensure compliance with requirements of 10 CFR 35.32. Please submit a revised QMP that also addresses the following requirements::

- Your QMP does not require that a written directive for a specific patient, dated and signed by an authorized user will be prepared *prior* to administration of the dosage.

- The written directive must also include the name of radiopharmaceutical, the dosage, and for radiopharmaceuticals other than sodium iodide I-131, the route of administration.

- List of methods of verification of patient's identity must be included.

- Your QMP does not include procedures that will ensure that each administration is in accordance with the written directive. Examples of acceptable procedures include:

  a. verifying during preparation that the prepared dosage is as prescribed on the written directive.

  b. verifying, before administering the dosage, that the specific details of the administration are in accordance with the written directive. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written directive.

- Your QMP does not include procedures for instituting corrective actions after an unintended deviation has been identified.

- Your QMP must include a policy for instruction of all workers to seek guidance if they do not understand how to carry out the written directive.

We will continue our review upon receipt of this information. Please reply in duplicate to my attention at the Region I Office and refer to Mail Control No. 125427. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5364. If we do not

receive a reply from you within 30 calendar days from the date of this letter, we shall assume that you do not wish to pursue your application.

Sincerely,

Original signed by Sattar Lodhi

Sattar Lodhi, Ph.D.
Health Physicist
Nuclear Materials Safety Branch 2
Division of Nuclear Materials Safety

Enclosure:
10 CFR Parts 20, 35
Regulatory Guide 10.8, Rev. 2

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OFFICE	DNMS/RI	N	DNMS/R					
NAME	SLodhi							
DATE	02/27/98		02/ /98		02/ /98		02/ /98	

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This is to acknowledge the receipt of your letter/application dated

2/5/98, and to inform you that the initial processing which includes an administrative review has been performed.

NEW LICENSE APPLICATION / QMP

☑ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

_____.

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 125427.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

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NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader

WHITNEY IMAGING CENTER
3018 DIXWELL AVENUE
HAMDEN, CT 06514

030 - 34653
(NEW LICENSE
APPLICATION)

RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM

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c. retaining a record, in an auditable form, for three years, of the relevant facts and what corrective action, if any, was taken.

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BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 0C200
Status Code: 3
Fee Category: _____
Exp. Date: 0
Fee Comments: _____
Decom Fin Assur Reqd: _

LICENSE FEE TRANSMITTAL

A. REGION 1

1. APPLICATION ATTACHED
   Applicant/Licensee: WHITNEY IMAGING CENTER
   Received Date: 980209
   Docket No: 3034653
   Control No.: 125428
   License No.:
   Action Type: QMP Submission

2. FEE ATTACHED
   Amount: /
   Check No.: /

3. COMMENTS

Ref. 125427.

Signed M. A. Perkins
Date 2/10/98

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 08 is entered ✓)

1. Fee Category and Amount: 7C QMP Submission

2. Correct Fee Paid. Application may be processed for:
   Amendment _____
   Renewal _____
   License /

3. OTHER _____

Signed _____
Date _____

RECEIVED BY LFDCB
Date 2/27/98
Log Feb 10 I (98)
By BB
Log Completed 2/27/98

(Also on 125427)