FEES COPY

April 29, 1998

Docket No. 030-13596 License No. 06-17892-01
Control No. 125436

Yolanda Miller
Director Nuclear Medicine
New Milford Hospital
21 Elm Street
New Milford, CT 06776-3029

Dear Ms. Miller:

This refers to your Quality Management Program (QMP) for radiopharmaceutical dosages greater than 30 microcuries of either sodium iodide I-125 or I-131, included with the letter dated February 10, 1998, which 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.

You are reminded that, in addition to meeting the objectives listed in 10 CFR 35.32(a), you must also comply with the requirements described below. It is recognized that your QMP or operating procedures may have addressed the following requirements:

1. Periodic review of QMP (10 CFR 35.32(b)):

   You must conduct a periodic review of your QMP at intervals of no greater than 12 months. The review procedure must provide for:

   a. an adequate representative sample of patient administrations as required in 10 CFR 35.32(b)(1)(i). 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/or gamma stereotactic radiosurgery);

   b. identification and evaluation of all recordable events and misadministrations; and

   c. a provision to expand the number of cases reviewed when a misadministration or recordable event is uncovered during the periodic review of your QMP.

   To complete the review procedure, you must evaluate the effectiveness of your QMP, and, if necessary, make modifications to meet the objectives of the program as required by 10 CFR 35.32(b)(2). Records of each review and evaluation must be maintained for three years.

2. If there is a recordable event (10 CFR 35.32(c)):

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Please be reminded that within 30 days of the discovery of a recordable event, you must evaluate & respond to the event by:

a. assembling the relevant facts including the cause,

b. identifying what, if any, corrective action is necessary to prevent recurrence, and

c. retaining, in auditable form, for three years, a record of items 1 and 2.

3. Oral Directives and Oral Revisions to Written Directives:

A footnote to 10 CFR 35.32 provides the following guidance:

a. Oral directives:

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 contained 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.

b. Oral revisions to written directives:

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, an oral revision to an existing written directive will be acceptable, provided that the oral revision is documented immediately in the patient's record and a revised written directive is signed by the authorized user within 48 hours of the oral revision.

To meet the requirements in 10 CFR 35.32, you may choose to utilize the procedures described in Regulatory Guide 8.33 (copy enclosed), or develop procedures that are equivalent. If you choose to use Regulatory Guide 8.33, be certain that the procodures you select are adjusted to meet the specific needs of your program as necessary. Additionally, you are reminded that the training and/or instruction of supervised individuals for implementation of your QMP is required by 10 CFR 35.25.

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, please call me at (610)337-.6942

Sincerely,

Original signed by Michelle Beardsley

Michelle Beardsley
Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

cc:
Jules White, M.D., Radiation Safety Officer

April 29, 1998

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Sincerely,

Original signed by Michelle Beardsley

Michelle Beardsley
Health Physicist
Nuclear Materials Safety Branch 1
Division of Nuclear Materials Safety

cc:
Jules White, M.D., Radiation Safety Officer

DOCUMENT NAME: G:\DNMS\DOCWORK\LICLTR\L0617892.01 14287042

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OFFICE	DNMS/RI	N	DNMS/RI					
NAME	MBeardsley MB							
DATE	04/29/98		04/ /98		04/ /98		04/ /98	

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New Milford Hospital, Inc.
21 Elm Street
New Milford, CT 06776

06-17892-01
030-13596

QUALITY MANAGEMENT PROGRAM

A Quality Management Program will be established as a condition of our NRC License 06-17892-01, as follows:

1. Written Directives. Prior to administration, a written directive will be prepared for any quantities of greater than 30 microcurie of either sodium iodide I-125 or I-131. This written directive will be prepared specifically for each patient. It will contain the quantity of activity to be administered, and the date. The directive will be signed by an authorized user.

A written directive may be revised orally if, because of the patients condition, a delay in order to provide a written revision to an existing directive would jeopardize the patient's health. Oral revisions will be documented immediately in the patient's record, and a revised written directive will be signed and dated by an authorized user within 48 hours of the oral revision.

If because of the emergent nature of a patient's condition, a dely 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.

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 dose.

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.

3. Quality Management. Before each administration described above, the written directive will be reviewed to determine that it is in accordance with the intentions of the authorized user. This review will be undertaken by someone other than the authorized user, in his or her presence. Unintended deviations from the intentions will be identified and evaluated, and appropriate action will be taken.

The quantity of activity to be administered to the patient will be measured in the dose calibrator before administration, and the quantity cross-checked against the quantity specified in the written directive.

Workers will seek guidance if they do not understand how to carry out the written directive.

After each administration described above, the dose administration will be reviewed to determine that it is in accordance with the written

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directive. Unintended deviations from the written directive will be identified and evaluated, and appropriate action will be taken.

The written directive will be signed and dated by an authorized user after each administration of a radiopharmaceutical requiring a written directive. This document will be kept in the patient's medical record.

4. 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 all administrations.

b. a review of all recordable events, and all misadministrations since the last review, 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.

5. 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.

6. 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.

7. Other Therapeutic Radiopharmaceuticals. Other therapeutic radiopharmaceuticals are not used at this site.

RADIOPHARMACEUTICAL QUALITY MANAGEMENT PROGRAM
NEW MILFORD HOSPITAL
21 ELM STREET
NEW MILFORD, CT 06776

THERAPEUTIC ADMINISTRATION OF I-131

PATIENT NAME _____
PATIENT NUMBER _____
ADDRESS _____
_____

METHOD OF PATIENT IDENTIFICATION (TWO REQUIRED):
DRIVER'S LICENSE _____ SELF ID _____ ID BY
COMPANION____
OTHER (SPECIFY) _____

PRESCRIBED ACTIVITY OF I-131: _____mCi.
ADMINISTERED ACTIVITY OF I-131: _____mCi.

ADMINISTERED BY: _____
DATE: _____ TIME: _____

ADMINISTRATION REVIEWED BY: _____
DATE: _____

BETWEEN:

License Fee Management Branch, ARM
and
Regional Licensing Sections

(FOR LFMS USE)
INFORMATION FROM LTS

Program Code: 02120
Status Code: 0
Fee Category: 7C
Exp. Date: 20040228
Fee Comments: CODE 23
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
   Applicant/Licensee: NEW MILFORD HOSPITAL
   Received Date: 980212
   Docket No: 3013596
   Control No.: 125436
   License No.: 06-17892-01
   Action Type: QMP Submission

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

3. COMMENTS
   REF. 125405

Signed M. A. Cerbin
Date 2/17/98

B. LICENSE FEE MANAGEMENT BRANCH (Check when milestone 03 is entered ✓)

FEE NOT REQUIRED

1. Fee Category and Amount: 7C QMP SUBM

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

3. OTHER ________

Signed ________
Date ________

1998 FEB 23 AM 11:16

RECEIVED BY LFDCB
Date 3/13/98
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3/13/98