UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

December 16, 1996

Barrett Memorial Hospital
ATTN: Bill R. Austin, M.D.
Radiation Safety Officer
1270 South Atlantic Street
Dillon, MT 59725

SUBJECT: QUALITY MANAGEMENT PROGRAM

Dear Dr. Austin:

This letter acknowledges receipt of your letter dated December 9, 1996 in response to our letter dated September 3, 1996 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
Jacqueline D. Burks

Jacqueline D. Burks
Health Physicist
Nuclear Materials Licensing Branch

Docket: 030-33800
License: 25-29088-01

ML40

bcc:
LJCallan
SJCollins
RAScarano
DBSpitzberg
LLHowell
FAWenslawski
MIS System

bcc w/incoming:
RIV Docket File
SLMerchant, NMSS/IMAB, MS:T-8 S5

DOCUMENT NAME: G:\NMLS\QMP\ACKNQMP.BMH

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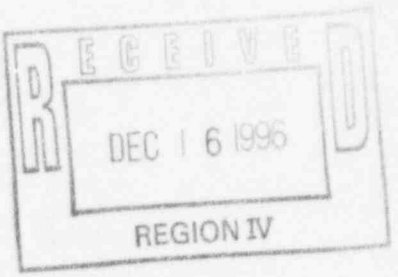
OFFICE	RIV:AO:NMLB	N						
NAME	JDBurks JDBurks							
DATE	12/16/96							

m/s#16 T9

December 9, 1996

Jacqueline D. Burks
Health Physicist
Nuclear Materials Licensing Branch
United States Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011-8064



RE: License: 25-29088-01
Docket: 030-33800

Dear Ms. Burks:

Concerning item 1. of your letter dated September 3, 1996:

I hereby certify that the Quality Management Program submitted to you and dated March 1996 has been implemented.

Jim Le Brun 12-9-1996

Jim Le Brun, CEO date

Concerning item 2. of your letter dated September 3, 1996:

We plan to use Iodine-131 in quantities greater than 30 microcuries to perform diagnostic imaging under the authority of 10 CFR 35.200. It is our understanding that our current license will allow us to possess quantities of Iodine-131 necessary to perform diagnostic imaging. Specifically, Iodine-131 will be administered to diagnose thyroid carcinoma metastisis in patients status post thyroidectomy and to determine presence of substernal or ectopic thyroid tissue in the chest or abdomen in patients where this condition is suspected.

I understand that the Quality Management Plan will not be a condition of the license. I appreciate you comments reminding us of the requirements in 10 CFR 35.32.

If you require additional information, please contact me.

Sincerely,

Jim Le Brun

Jim Le Brun, CEO

Bill Austin

Bill Austin, MD, RSO

46181

FILE COPY

BARRETT MEMORIAL HOSPITAL

1260 SOUTH ATLANTIC
DILLON, MONTANA 59725
406/683-2324

November 4, 1996

Jacqueline D. Burks
Nuclear Materials Licensing Branch
Nuclear Regulatory Commission, Reg. IV
611 Ryan Plaza Drive
Suite 400
Arlington, TX 76011-8064

Dear Ms. Burks:

In response to your letter of September 3, 1996 regarding our QMP, I would like to outline our course of action.

First, there will be no 131 Iodine used over 30 microcuries until the QMP is resolved.

Second, we have sent a copy of your recommendations to our consulting physicist from Health Physics Northwest. We expect his next visit to be in mid November and we will forward our changes after that time.

Third, we would like an extension of 90 days if possible as I would expect we could have our changes sent by the first of December after the physicist's visit.

Please let me know if you have any further questions or concerns at this time.

Sincerely,

Kevin Mackey

Kevin Mackey, CNMT
Radiology Manager

11/4/96:
Gave verbal authorization for 90 day extension.
12/5/96: Mr. Mackey unsure with patient; will call back Jacobs
12/6/96: Letter is ready, needs to be signed by the RSO; will fax letter Monday after signed by LSO.

4A6181

UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
611 RYAN PLAZA DRIVE, SUITE 400
ARLINGTON, TEXAS 76011-8064

September 3, 1996

Barrett Memorial Hospital
ATTN: Bill Austin, M.D.
Radiation Safety Officer
1260 South Atlantic Street
Dillon, MT 59725

SUBJECT: QUALITY MANAGEMENT PROGRAM

This refers to your Quality Management Program (QMP) for greater than 30 microcuries of sodium iodide (NaI) iodine-125 (I-125) or iodine-131 (I-131) dated August 5, 1996, which describes your written quality management program developed in accordance with 10 CFR 35.32. A review of the written QMP was performed to determine whether your described policies and procedures appear to meet the objectives of the rule. Based on the review of the above submission, there are questions regarding the potential for failure of your QMP to meet the objectives in 10 CFR 35.32. You should review your QMP with regard to these questions and determine if additions or modifications are necessary. Specifically,

For greater than 30 microcuries of NaI I-125 or I-131,

Each applicable 10 CFR part 35 licensee is required to submit written certification that their QMP has been implemented along with a copy of their plan, pursuant to 10 CFR 35.32.

Please provide written certification that your QMP has been implemented.

Currently, License No. 25-29088-01 authorizes the use of byproduct material identified in 10 CFR 35.100 and 35.200. If you plan to use byproduct material identified in 10 CFR 35.300, the license must be amended prior to possession and use of these radiopharmaceuticals.

Clarify that the license will be amended accordingly prior to using byproduct material identified in 10 CFR 35.300.

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 patent cases to be sampled should be based o 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 period 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 3 years.

2. <u>If there is a recordable event</u> (10 CFR 35.32(c)):

Please be reminded that within 30 days of the discovery of a recordable event, you must evaluate and 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 3 years, a record of items 1 and 2.

3. <u>Oral Directives and Oral Revisions to Written Directives:</u>

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, provide 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 procedures 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 817-860-8132.

Sincerely,

Jacqueline D. Burks
Health Physicist
Nuclear Materials Licensing Branch

License: 25-29088-01
Docket: 030-33800

10/7/96: should be submitting response sometime this week
10/15/96: Dr. Prosnitz stated that tech. is aware response is needed; requested a couple of days to get response to us. JaBurks
11/4/96: Spoke w/ Kevin; will request an extension in getting response to deficiency letter to us; also will not use I than 30 mCi of No. I I-125 or I-131 until deficiencies are resolved.

DOCUMENT NAME: P:\DEFICIEN\BARRETT.DEF

To receive a copy of this document, indicate in the box "C" - Copy without attachment/enclosure "E" - Copy with attachment/enclosure "N" - No Copy

RIV:NMLB	N						
JDBurks JDBurks							
08/21/96							

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: 20001231
Fee Comments: _____
Decom Fin Assur Reqd: N

LICENSE FEE TRANSMITTAL

A. REGION IV

1. APPLICATION ATTACHED
   Applicant/Licensee: BARRETT MEMORIAL HOSPITAL
   Received Date: 960821
   Docket No: 3033800
   Control No.: 466181
   License No.: 25-29088-01
   Action Type: QMP Submission

2. FEE ATTACHED
   Amount: 4
   Check No.: 4

3. COMMENTS

Signed Billie Gruszynski
Date 8/23/96

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

1. Fee Category and Amount: 1C

FEE NOT REQUIRED
Quality Management Program

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

3. OTHER _____

RECEIVED BY LFMS
Date 8/30/96
Log 96-111
By Ken
Date Completed 9/3/96

Signed Rita Massie
Date 9/3/96

BARRETT MEMORIAL HOSPITAL

1260 SOUTH ATLANTIC
DILLON, MONTANA 59725
406/683-2324

August 5, 1996

Nuclear Regulatory Commission
Region IV
611 Ryan Plaza Drive, Suite 400
Arlington, TX 76011

Reference: License #25-29088-01

Dear Sirs:

Enclosed is our Quality Management Program (QMP). This procedure is submitted in the eventuality that we choose to administer patient doses of greater than 30 microcuries of I-131 for *diagnostic* procedures, for the diagnosis of metastatic thyroid cancer by whole body imaging and detection of substernal thyroid tissue.

I understand the QMP is not a condition of our license, therefore a license amendment is not required.

Sincerely,

Bill Austin, MD

Bill Austin, MD
Radiation Safety Officer

QUALITY MANAGEMENT PROGRAM

Requirements For Administration Of I^{131} And Therapy Radiopharmaceuticals

The quality management program requires that certain conditions be met to avoid the inadvertent administration of therapy levels of radioactive materials. This regulation applies to all uses of therapeutic radioactive materials, and to all uses of I^{131} or I^{125} as iodide in quantities greater than 30 uCi.

Note: Diagnostic procedures with I^{131} iodide may fall under this regulation.

1. A written directive (prescription), identifying the patient, intended dose, route of administration, and radiopharmaceutical, dated and signed by a physician authorized for this use by the license shall be prepared before the administration of *any applicable therapeutic radiopharmaceutical* or I^{131} or I^{125} as iodide *in quantities greater than 30 uCi.* The written directive must be retained for 3 years.

2. The patient must be positively identified by two means before the radiopharmaceutical is administered. The patient should be asked his name, and be asked to give his address, social security number, or phone number. Alternatively, the patient may be asked to show some form of identification.

3. The dose shall be assayed in the dose calibrator immediately before it is given to the patient. The written directive shall be referred to. The dose and route of administration must agree with the written directive.

4. *Stop and seek guidance* if you do not understand how to carry out any part of the written directive.

5. The actual assay shall be recorded, as well as the date and time of administration, and the initials of the person administering the dose. This record must be retained for 3 years.

6. After administration, the patient dose record and written directive will be reviewed by the authorized user, supervised user or supervised individual in order to identify unintended deviations from the written directive. Inadvertent deviations from written directives must be documented and investigated. These may be reportable.

7. If, because of the emergent nature of the patient's medical 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 revised written directive is signed by the authorized user within 24 hours of the oral revision.

   If, because of the patient's medical 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 dated and signed by the authorized user within 48 hours of the oral revision.

   Also, a written revision to an existing written directive 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.

QUALITY MANAGEMENT PROGRAM

Review Of Radiopharmaceutical Administrations

1. A review of the quality management program shall be conducted at intervals no greater than 12 months to verify compliance with all aspects of the quality management program. This review shall be conducted by the Radiation Safety Officer and shall include an identification and evaluation of:

   - A representative sample of patient administrations since the last review
   - All recordable events since the last review
   - All misadministrations since the last review

   A representative sample of all administrations consists of:

number of administrations	sample size
1 to 30	all
31-50	30
51-100	37
101-200	40

(10 CFR 32.110, table 6)

   For each patient's case, a comparison should be made between what was administered versus what was prescribed in the written directive (the radiopharmaceutical, dosage, and route of administration). If the difference between what was administrated and what was prescribed exceeds the criteria for either a recordable event or a misadministration, that comparison is unacceptable.

   If any deviations are discovered, the RSO shall identify the cause of each deviation, and suggest action required to prevent recurrence. The actions may include new or revised policies, new or revised procedures, additional training, or increased supervisory review of work.

   If a misadministration or recordable event is uncovered during the periodic review of the Quality Management Program the number of cases reviewed will be expanded by expanding the sampling size by 50%. If 30 cases or less are performed in one year an increase in the number of cases reviewed is impossible, since all cases will have been reviewed (10 CFR 32.110, table 6).

2. The Radiation Safety Committee shall:

   - Evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the objectives of the program.
   - Retain records of each review, including the evaluations and findings of the review, in an auditable form for three years.

MISADMINISTRATIONS, RECORDABLE EVENTS

Misadministrations are reportable

Misadministrations are defined as:

- Involving the wrong patient,
- wrong radiopharmaceutical,
- wrong route of administration, or
- wrong diagnostic dosage,
- *when the dose to the patient is 5 rem whole body or 50 rem to any organ.*

The wrong I^{131} dosage, when the dosage is greater than 30 uCi and the error exceeds 20% of the intended dose and the difference between the intended dose and the actual dose exceeds 30 uCi is a misadministration.

The wrong therapy dosage, when the error exceeds 20% of the intended dosage, is a misadministration.

Certain other errors are considered to be "recordable" events which must be documented.

If a misadministration or recordable event is suspected:

1. Inform the RSO immediately.

2. Assemble all relevant facts, including the caused. Preserve all documentary and physical evidence, such as labels and the actual syringe and vial.

3. The RSO will determine what, if any, corrective action is necessary to prevent recurrence.

4. The RSO will determine if the incident is a misadministration or recordable event

If the event is a reportable misadministration,

1. The NRC must be informed by telephone no later than the next calendar day.

2. Inform the referring physician.

3. Inform the patient within 24 hours unless the referring physician agrees to inform the patient or advises that it is likely to be harmful to the patient.

4. Written reports must be filed within 15 days.

5. Retain records of reportable misadministrations, in auditable form, for 3 years.

Recordable Events:

"Recordable event" means the administration of:

- A radiopharmaceutical or radiation without a written directive where a written directive is required;
- A radiopharmaceutical or radiation where a written directive is required without daily recording of each administered radiopharmaceutical dosage or radiation dose in the appropriate record;
- A radiopharmaceutical dosage greater than 30 microcuries of either sodium iodide I^{125} or I^{131} when both: The administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage, and the difference between the administered dosage and prescribed dosage exceeds 15 microcuries;
- A therapeutic radiopharmaceutical dosage, other than sodium iodide I^{125} or I^{131}, when the administered dosage differs from the prescribed dosage by more than 10 percent of the prescribed dosage;

Documentation of recordable events must be completed with 30 days and must include a description of the circumstances, the consequences, and the corrective action taken.

Records of recordable events must be retained, in auditable form, for 3 years.

TRAINING

Training and/or instruction of supervised individuals (technologists) is required prior to implementation of the Quality Management Program.

Some events may not fit the definition of either misadministration or recordable event, but action may be called for. Mislabeled drugs may be a violation of FDA regulations but not NRC regulations. Radiopharmaceuticals and kit products which have unusual biodistribution, poor labeling efficiency, or free pertechnetate are not reportable or recordable under the regulations. Problems with radiopharmaceuticals may be reported through the USP/SNM drug product problem reporting program at (800) 638-6725. Documentation should follow hospital policy for incident reports.

Written Directive For Radiopharmaceutical Therapy

(I-131, Sr-89, P-32)

Patient Name:_____ ID Number:_____

Therapy procedure:_____ Radiopharmaceutical:_____

Prescribed dose:_____ Route of Administration:_____

Physician Signature:_____ Date:_____

Note: physician must be an authorized user listed on the license

Technologist Flow Record

Patient ID by two methods: 1._____

2._____

Pregnancy/nursing status: _____

Radiopharmaceutical:_____ Form (liquid or capsule)_____

Dose Assay: _____mCi

Time of Assay _____ Date of Assay _____

Initials of person assaying the dose:_____

Dose Assay must correlate with written directive. Any revision to the dose must be documented and signed by the authorized user within 48 hours.

Time of administration: _____

Date of administration: _____

Route of administration: _____

Initials of person administering the radiopharmaceutical:_____

Notes: Additional written prescriptions, copies of radiopharmacy dispensing forms, documentation of patient ID should be attached to this sheet.

This record must be retained for NRC inspection for 3 years.