Mercy Memorial
Medical Center
Lakeland Regional Health System, Inc.

Weber

May 10, 1994

John D. Jones, Acting Chief
Nuclear Materials Inspection Section 2
United States Nuclear Regulatory Commission
801 Warrenville Road
Lisle, IL 60532-4351

RE: License No. 21-04177-01

Dear Mr. Jones:

Enclosed you will find a copy of our revised QM program. Revisions were made to incorporate the administration of all Radionuclide Therapies.

If you have any questions or require additional information please feel free to contact Cheryl Weise at (616) 983-8868.

Sincerely,

Robert P. Harrison
COO Mercy Memorial Medical Center

Alex Bogda
RSO

CC: Mike Weber

1234 Napier Avenue, St. Joseph, MI 49085-2158 • 616/983-8300

QUALITY MANAGEMENT PROGRAM
NUCLEAR MEDICINE DEPARTMENT
MERCY MEMORIAL MEDICAL CENTER
LAKELAND REGIONAL HEALTH SYSTEM

Implemented 1/27/92
Revised 4/22/94

1. OBJECTIVE

To provide high confidence that byproduct material will be administered as directed by the authorized user.

2. RESPONSIBILITY, AUTHORITY AND AUDIT

The responsibility and authority to establish and implement the Quality Management Program (QMP) shall be given to Cheryl Weise, CNMT.

3. Elements for Medical Use- Radiopharmaceuticals Therapies

A. Prior to administration, a written directive will be prepared for:

Any administration of quantities greater than 30 microcuries (>30uCi) of either sodium iodide I-125 or I-131; or

Any therapeutic administration of a radiopharmaceutical, other than sodium iodide, I-125 or I-131;

With regard to diagnostic and therapeutic radiopharmaceutical, A Written Directive means an order in writing for a specific patient, dated and signed by an authorized user prior to the administration of a radiopharmaceutical or radiation, containing the following information:

Patient Name
Radiopharmaceutical
Dosage
Route of administration
Type of procedure desired

B. Authorized Users on License number 21-041FF-01 include the following:

A. Henry J. Klos, M.D.
B. Gene E. Maddock, M.D.
C. John T. McLelland, M.D.
D. William F. Leahey, M.D.
E. Walter M. Decker, M.D.
F. M. Blanche T. Lim, M.D.
G. Anwar Ahmad, M.D.
H. Muhammad Z. Iqbal
I. Roman Hyszczak, M.D.
J. Dan Kreider, M.D.
K. Kent Lancaster, M.D.
L. Kathleen Gafarian, M.D.
M. Brad Bastow, M.D.
N. Don Brooks, M.D.
O. Dilip Arora, M.D.

C. Prior to the administration, the patient's identity is verified by more than one method as the individual named in the written directive by the person administering the radiopharmaceutical.

1. The patient shall be called by name.
2. The patient shall be asked to spell their name.
3. Tne patient shall be asked to state their birthdate.
4. The inpatient's wrist band shall be checked.

If the information obtained from both of any two of these methods do not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive verification that this procedure is intended for the patient is obtained.

D. Each administration is in accordance with the written directive.

The technologist shall read the written directive before preparing or administering the radiopharmaceutical. If any portion of the written directive is unclear to the technologist, they shall contact an authorized user for clarification. The radiopharmaceutical shall not be administered until the intent of a written directive is thoroughly understood by the technologist. If the technologist preparing the dose is different from the technologist administering the dose, both technologists shall read and understand the written directive.

The technologist 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 listedo the written directive and/or in the permanent patient record.

A procedure manual shall be available and shall contain protocols for all radiopharmaceutical procedures performed which require written directives. A procedure which requires a written directive shall not be initiated until a written protocol approved by an authorized user is available.

The technologist shall be familiar with the contents of the manual. They shall be instructed to refer to the manual before proceeding with non-routine procedures or in any case where the protocol is not completely familiar to them.

The protocols shall contain the following elements:

-pharmaceutical
-radionuclide
-routine dosage
-route of administration
-indications
-contraindications

Each change in protocol shall be approved by an authorized user before the change is implemented and before the change is incorporated into the procedure manual. Each technologist shall be instructed in the change before it is implemented or incorporated into the procedure manual.

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

Upon identification of an unintended deviation, 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 part 35.

REVIEW

The licensee shall develop procedures for and conduct a review of the quality management program including, since the last review, an evaluation:

1. A representative sample of patient administrations.
2. All recordable events, and
3. All misadministrations to verify compliance with all aspects of the quality management program at intervals no greater than 12 months.

The licensee shall evaluate each of these reviews to determine the effectiveness of the quality management program and, if required, make modifications to meet the stated objectives.

The licensee shall retain records of each review, including evaluations and findings of the review, in an auditable form for three years.

MODIFICATIONS

The licensee may make modifications to the quality management program to increase the program's efficiency provided the program's effectiveness is not decreased. The licensee shall furnish the modification to the appropriate NRC Regional office within 30 days after the modification has been made.

ANNUAL REVIEW

The annual review shall be conducted by a member of management and the consulting medical physicist. The review shall be conducted at intervals not to exceed 12 months. The review shall determine the effectiveness of the program. Areas identified as inadequate shall be modified to meet the objectives of 35.32(a).

Reports of each review, including the evaluations and findings in an auditable form must be kept for three years.

AUDIT

Frequency: An audit of the quality management program shall be conducted at twelve (12) month intervals.

Responsibility: The audit shall be conducted by the designee of the licensed department and consulting medical physicist. If the audit is performed by the consulting physicist alone, management shall be briefed in writing of the findings.

Scope: The audit shall evaluate the following items:

1. The compliance rate of having written directives prior to the ordering of and administration of a radiopharmaceutical or radiation in those cases where written directives are required.
2. The content of the written directive is as required.
3. The instruction of the supervised individual(s) in the licensee's written quality management program and requirement of following the quthorized user's instructions.
4. The methods of verifying the patient's identity by more than one method is performed as stated in the QM program.
5. The compliance rate of verifying the patient's identity by more than one method.
6. Radiopharmaceutical or radiation administrations are in accordance with the written directives.
7. The compliance of the staff in identifying, evaluating, and taking appropriate corrective actions for unintended deviations from the written directives.

8. The compliance with the requirement to respond to each recordable event.
9. The compliance with the requirements to notify and report misadministrations.
10. To evaluate the effectiveness of the QMP if/when and make any necessary revisions.