Hospital General Menonita, Inc.

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Toda correspondencia oficial deberá ser dirigida a la Oficina del Director Ejecutivo.

July 19, 1994

U.S. Nuclear Regulatory Commission
Region II
101 Marietta Street (N.W.)
Atlanta, Georgia 30323

RE: NRC LICENSE #52-25015-01

Dear Sir(s):

Please find enclosed copy of the revised Q.M. Program which will be implemented in our institution starting on July 15, 1994.

Sincerely yours,

Domingo Torres Zayas
Executive Director

DTZ:mc

Enc.

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Sirviendo con Amor Cristiano

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QUALITY MANAGEMENT (Q.M.) PROGRAM

INSTITUTION: MENNONITA GENERAL HOSPITAL

NRC LICENSE NO: 52-25019.01

In order to offer good quality services to satisfy the needs of the patients and physicians, it is mandatory to establish and closely follow an adequate quality assurance program. This program must include all the factors necessary to perform reliable and accurate Nuclear Medicine studies. Among these factors are: complete requests, appropriate laboratory records and evaluation of the cancelled or unsatisfactory studies. This Quality Management (QM) Program is part of the general quality assurance program of the Institution and is prepared in accordance with 10CFR 35.32 requirements with the main objective of avoiding misadministrations as defined in 10CFR 35.2.

1. **Policies and procedures for the therapeutic administration of radiopharmaceuticals.**

   1.1 Written order by an authorized user for therapeutic dosages:

   a. The authorized user will date and sign a written order prior to the administration of any therapeutic dosage of a radiopharmaceutical or any dosage of quantities over 30 µCi of I-125, I-131, Strontium 89, P-32 or any <u>other radiopharmaceutical</u> (Group 35.300) used for therapeutic purposes. The order will have: the radiopharmaceutical name, dosage, and route of administration.

   b. An oral revision to an existing written directive may be made if because of patient's medical condition a delay in the order to provide a written directive would jeopardize the patient's health. The oral revision should be documented immediately in the patient's record and a revised written directive must be dated and signed by the authorized user within 48 hours of the oral revision.

   c. 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 order is prepared within 24 hours of the oral directive.

   d. The radiopharmaceutical, dosage, and route of administration should be confirmed by the person administering the radiopharmaceutical to verify agreement with the written order. The dosage should be measured in the dose calibrator and the results compared with the prescribed dosage in the written order.

e. A record of each written directive for each radiopharmaceutical administered must be kept for three years after the date of administration as required in 10CFR 35.32 (d).

f. Unintended deviations from the written order shall be identified and evaluated. Appropriate action shall be taken under the direction of the authorized user as required by 10CFR 35.32 (a)(5).

1.2 All recordable events shall be evaluated and responded to within 30 days of the discovery of the event. The following action shall be taken:

a. Assemble all the facts, including the cause of the event.

b. Corrective action, if any, to prevent recurrence of the event.

c. A record of the above shall be maintained for a period of no less than three years.

1.3 Policies to verify the identity of the patients before administering any radiopharmaceutical dosage.

The technologist will verify the identity of the patient (Control Form-Item 3):

a. Ask the patient's name and at least one of the following: birth date, address or social security number.

b. Confirm the identity of the patient:

<u>For inpatients</u>:

- Comparison with corresponding information on the patient's bracelet.
- Comparison with corresponding information on patient's hospital record.
- Comparison with information on corresponding cards and insurance card.
- If possible, ask the patient to present an ID card with photograph.

<u>For outpatient</u>:

- Comparison with information on corresponding cards and insurance card.

- If possible, ask the patient to present an ID card with a photograph.

1.4 Policies to verify that the procedure is in accordance with the doctor's order before the administration of the radiopharmaceutical dosage (Control Form-Item 4).

The technologist will verify that the procedure (Control Form-Item 4) is in accordance with the doctor's order by reading the order in the patient's record (inpatient) or in the referral note (outpatients).

1.5 Policies to maintain written information of the procedure.

After verification of the identity of the patient and the verification of accordance with the doctor's order and the procedure, the technologist will administer the radiopharmaceutical and maintain a written record with:

a. Name of radiopharmaceutical (make)

b. Total dose injected. The dosage should be measured by the corresponding method.

c. Route of administration.

d. Date.

e. Initials of the technologist.

1.6 **Dose Verification:**

Prior to each administration of 131 Iodine or 25 Iodine greater than 30μCi and 89-Strontium or 32-Phosphorus the dose should be verified by the following methods:

a. Check the written dose in the chart against the dose received.

b. Verified the exact dose (131 Iodine and 125 Iodine or other gamma isotope) by measurement in the dose calibrator and check this against the written order.

c. Verification of 89-Strontium or 32-Phosphorus measurement will be done by decay factor method (Sr-89 Therapy form I and II).

2. <u>Policy for all workers</u>

2.1 It is required that any worker of the nuclear medicine

department who does not understand how to carry out any of the procedures described herein or does not understand the written doctor's order, seek guidance. He/she must ask the supervisor about what to do or how it should be done before continuing a procedure when there is any doubt.

3. Policy for review of these policies

3.1 The Quality Management Program will be reviewed every twelve months by the nuclear medicine technologist supervisor (the nuclear medicine portion), and the physicist (20% of the number of cases performed if greater that 100, 20 cases if the number of cases is between 20 and 100, and all, if the number is less than 20).

The review shall include all recordable events since the last review. A recordable event is:

a. An administration without a written order.

b. An administration dose that varies by more than 10% from the prescribed dose.

The review shall evaluate all misadministrations since the last review. A misadministration is:

a. The administration of a radiopharamaceutical agent to a wrong patient.

b. The use of a wrong isotope.

c. A measured dose that differs from the prescribed dose by more than 20%.

4. Notification of misadministrations will follow 10 CFR 35 directives in any event of a misadministration.

5. Modifications can be made at any time to this program to increase its effectiveness. Modifications cannot be made to decrease the effectiveness of this program. A copy of any modification will be forwarded to the NRC Region II Office within 30 days after implementing the medications as required by 10 CFR 35.32(e).

6. Availability of the program

6.1 Copy of the program will be available, in the administrative manual at the nuclear medicine office.

References:

1. Pilot Program to assess proposed Basic Quality Assurance requirements in the medical uses of by-product Material.

   NUREG/CR-5798

   BNL-NUREG 52303

2. NRC - Regulatory Guide 8.33

   Quality Management Program, October 1991.

3. 10-CFR Part 35, paragraph 35.32 (July 25, 1991).

   Quality Management Program.

4. NRC letter (Douglas M. Collins) June 21, 1994; Docket #030-31223.

REVISED BY:

Sandra C. Gracia-López, M.D.-R.S.O.

Santiago Gomez-Figueroa, R. Phy. Consultant

DATE: July 19, 1994

FORM
Q.M.-I

YEAR_____

MENNONITÉ GENERAL HOSPITAL

NUCLEAR MEDICINE LABORATORY

QUALITY MANAGEMENT (Q.M.) PROGRAM

CONTROL FORM

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1. PATIENT NAME:_____ S.S.#_____

2. DIAGNOSIS:_____

3. PATIENT IDENTIFICATION: Please confirm patient's name, verify identify by any two of the following:

   _____I.D. BRACELET _____SOCIAL SECURITY NO. ____SIGNATURE

4. DOSE ADMINISTRATION: DATE:_____ TIME:_____

   WRITTEN DIRECTIVE_____ORAL_____

   PROCEDURE REQUEST_____

   PREPARED BY:_____

   DOSE:_____ ADMINISTERED BY:_____

5. PHYSICIAN'S NAME: _____

   SIGNATURE:_____

6. REMARKS:_____

   _____

SR-89 THERAPY FORM II

MENNONITE GENERAL HOSPITAL
NUCLEAR MEDICINE LABORATORY

CHECK SHEET for eligibility for Metastron therapy:

Referring M.D.:_____ Tel: _____

YES	NO	
___	___	Patient has proven metastatic disease Primary is_____
___	___	Bone pain - Sites: 1) _____ 2)_____ 3)_____
___	___	Evidence of matching bone metastasis (check method of determination): ___ Positive bone scan - Date: _____ ___ Positive radiograph - Date: _____ ___ Positive CT or MRI - Date: _____
____	___	Prior chemotherapy date: _____
___	___	Prior Radiation Therapy - Date: _____
___	___	Radiotherapist Consulted - Date:_____
___	___	Hb:_____
___	___	WBC ()2400/µl):_____
___	___	Platelets()60,000/µL):_____
___	___	Crea (<2mg/dL):_____
___	___	Are you sure that this patient is not pregnant?
___	___	Is this patient at least 18 year of age?
___	___	Is patient under hospital care?
___	___	Does the patient have catheter?
___	___	If retreating with metastron, was the patient previously treated at least 3 months earlier.

A "NO" ANSWERS TO ANY OF THESE QUESTIONS COULD DISQUALIFY THIS PATIENT. PLEASE CONSULT THE PACKAGE INSERT, IF ANY ANSWERS ARE ANSWERED AS "NO".

I approve therapy for this patient.

_____ _____

Authorized User Date

Doc:METASTRON

MENNONITE GENERAL HOSPITAL
NUCLEAR MEDICINE LABORATORY

WORKSHEET FOR STRONTIUM-89 THERAPY

(Top section to be completed by Referring Physician)

Name:_____ Clinic #:_____ Date:_____
Primary cancer:_____ Positive bone scan date:_____
Bone pain locations:_____ CBC Date:_____
Patient Weight:_____kg WBCs :_____
HCG scheduled:_____ RBCs :_____
Platelets:_____

_____
REFERRING PHYSICIAN SIGNATURE

Dose of Sr-89 to be ordered_____mCi/GBq Treatment date:_____

_____
AUTHORIZED USER'S SIGNATURE

Date:_____

Patient identification verified by: Dose:_____mCi/GBq verified by:
Initials_____ Date:_____ Initials_____ Date:_____

DOSE CALCULATIONS:

I. Decay Method:

II. Dose Calibrator Measurement