ATT10.16

NUCLEAR MEDICINE QUALITY MANAGEMENT PROGRAM - 2.00

Approved By	**Orig. Date**	02-94
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Written By	**Review Date**	02-96
John Pfund, MS, Radiation Safety Officer, and Brent Colby, MS	**Revised Date**	05-01

PURPOSE

The Quality Management Program has been implemented in Nuclear Medicine to ensure quality care for those patients undergoing radiopharmaceutical therapy or receiving certain administrations of radioactive iodine.

POLICY

Diagnostic administrations of radioactive iodine may be used at the nuclear medicine departments at MeritCare Clinic Bemidji, MN or MeritCare Medical Center, Fargo, ND. A **written directive** is required prior to administration for every radiopharmaceutical administration of Iodine (125 or 131) greater than 30 μCi.

Radiopharmaceutical Therapy is performed only at MeritCare Medical Center, Fargo, ND. Written directives are required for all therapeutic administrations of radiopharmaceuticals. The following specific policies for Radiopharmaceutical Therapy incorporate the QMP requirements and have links to the specific written directive forms.

2.05 Procedure for Inpatient I-131 Therapy

2.10 Procedure for Outpatient Radiopharmaceutical Therapy

Staff shall follow the procedures below for any administration requiring a written directive.

PROCEDURES

Written Directives:

- 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. This oral revision will be documented immediately in the patient's record and a revised written directive will be dated and signed by the authorized user within 48 hours of the oral revision.

- 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. This oral directive will be documented immediately in the patient's record and a written directive will be prepared within 24 hours of the oral directive.

Prior to administration, the patient's identity as the individual named in the written directive will be verified by more than one method. The identification shall include the patient's name and at least one of the following from the patient's record: birth date, address, social security number, signature, the name on the patient's id bracelet or hospital id card or the name on the patient's medical insurance card.

Prior to administration, the technologist shall verify that the following are in accordance with the written directive: radiopharmaceutical, dosage (via dose calibrator) and route of administration.

In the event that the technologist does not understand how to carry out the written directive, they will ask a responsible individual (lead technologist, physician or physicist).

After the administration, a written record of the administered dosage will be dated and signed or initialed in the patient's record by an authorized user, technologist, physicist or physician.

DEVIATIONS FROM WRITTEN DIRECTIVES

An unintended deviation from a written directive resulting from any error will be evaluated according to the definitions of misadministrations and recordable events in the 10CFR Part 35 or ND Radiological Health Rules.

ANNUAL REVIEWS

The QMP shall be reviewed annually by the lead technologist and physicist or RSO. The review shall include a survey of all recordable events and misadministrations and a survey of all patients receiving a radiopharmaceutical dose. For each radiopharmaceutical therapy, the following shall be examined: the radiopharmaceutical, dosage and route of administration. These will be compared with the written directive.

The results of this review will be documented and presented to the Radiation Safety Committee. They will also be available to inspectors upon request.

REFERENCES

10CFR 35.32, 35.33

North Dakota Radiological Health Rules
Section 33-10-07-04, Subsection 7

MeritCare

Nuclear Medicine

Generic Outpatient Written Directive Form

Patient Name:_____ MR#:_____ DOB:_____

Diagnosis/Indication:_____

1. **WRITTEN DIRECTIVE**
(Must be completed by AU prior to administration. Required for I-131 or I-125 doses greater 30 microCi)

Planned Date of administration:_____ Radioisotope:_____

Chemical Form:_____ Dosage (mCi): _____

Planned Route of administration:_____

Authorized User Signature: _____Date:_____

2. **RECORD OF ADMINISTRATION** ___Breast Feeding/Pregnancy form completed and OK to proceed

ID of Patient checked by 2 methods: (indicate methods used below)

❑ Asked patient's name	❑ Checked patient ID
❑ Asked patient's birth date	❑ Asked patient's address

Actual Dose administered _____mCi Date:_____ Time:_____

Technologist Signature: _____

3. **RECORD OF PATIENT RELEASE** (complete both questions: A and B)

A. Was Dosage below the applicable limit for release stated in NRC Reg. Guide 8.39?

__Yes. Patient may be released with no further release documentation.
__No: __Patient released with attached specific release calculation*, or
__Evaluate survey results below:

Survey Meter: __Ludlum Model 14C, Ser. # with End-Window GM Probe Model 44-7, Ser. #
__Picker GM, Serial #655-186

Survey Result:_____mR/hr @ 1m

Surveyor:_____ Date:_____ Time:_____

Was Survey Result less than the applicable limit for release stated in NRC Reg. Guide 8.39?
__Yes. Patient may be released.

*Patient must comply with all guidelines in the written patient instruction handout for this method to be used.

B. Was the Dosage or Survey Result greater than the applicable limits for providing patient instructions stated in NRC Reg. Guide 8.39, or is the patient Breast Feeding?

__If Yes to any: __Written patient instruction handout must be given to patient.
"The instructions have been discussed with the patient. The patient understands and will comply." Staff Initials_____
__No. __Patient instructions not required.

Signature of person releasing patient: _____Date:_____Time:_____