McLaren
NORTHERN MICHIGAN

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5-25-2012

United States Nuclear Regulatory Commission
Region III, Division of Nuclear Materials Safety
2443 Warrenville Road
Suite 210
Lisle, IL 60532-4352
630-829-9650

RE: Violation found on Inspection 5-23-2012
McLaren Northern Michigan (Northern Michigan Regional Hospital)
License # 21-16732-01

Dear Mr. McCraw,

Violation:

Contrary to 10CFR 35.63(d), a dosage was administered to a patient that differed from the prescribed dosage by more than 20 percent. This dosage was not approved prior to administration by an Authorized User.

Corrective action taken:

All patient dosages not requiring a written directive will have a prescribed dosage entered into the pharmacy computer. The computer will be used as a secondary review. The computer will notify the technologist if the dosage falls outside of the range of 20 percent. A list of all radiopharmaceuticals and the range (+/- 20 percent from the prescribed dosage) will be posted in the hot lab.

For patient dosages that require a written directive, a second technologist, nurse or Authorized User will review the prescribed dosage and verify that the activity is within 20 percent of the prescribed dosage. The second signature will be recorded on the written directive.

Date full compliance was achieved: 5-25-2012

Dan Dryden, MS, RSO, DABR
Medical Physicist
McLaren-Northern Michigan

Mary Anne D. Ponti

Mary-Anne Ponti, RN, MS, MBA
Chief Operating Officer
McLaren-Northern Michigan

WRITTEN DIRECTIVE

Patients Name:_____Patient Id. Number:_____

RADIOPHARMACEUTICAL(Circle One)

^{131}I Sodium Iodide ^{89}Sr Chloride ^{153}Samarium Sodium ^{32}P Other:_____

DESIRED PROCEDURE

_____Na^{131}Iodine Whole Body Scan ____Na ^{131}Iodine Therapy for Hyperthyroidism

_____Na^{131}Iodine Substernal Thyroid Scan ____Na ^{131}Iodine Therapy-Thyroid CA Ablation

_____Na 131-Iodine Therapy for Metastatic Thyroid CA

Prescribed Dosage:_____ **Route:**_____

Signature of Authorized User:_____**Date:**_____

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PATIENT IDENTIFICATION (at least 2 methods)

Patient Spelled Name:_____Patient Stated Date of Birth:_____

Patient Stated S.S.N.:_____Patient Wrist ID Identified:_____

Patient Presented Driver License (Number and State):_____

Technologist Signature:_____Date:_____

PREGNANCY / BREAST FEEDING STATUS

Negative pregnancy confirmed by: _____PG Test _____LMP_____ ____N/A

Breast Feeding: _____Yes _____No _____N/A

DOSE DISPENSING RECORD

Radiopharmaceutical: _____Prescribed Dosage:_____

Dose Calibrator Assay:_____Time: _____

Verify Assayed Dosage is within 20% of the prescribed dose:_____ Yes _____ No

Written Revision to written directive needed*:___Yes ___No

***If yes, Written Revision must be completed prior to administration.**

****

Technologist Signature:_____Date:_____

Technologist Signature:_____Date:_____

Written Revision:

Prescribed Dosage:_____ **Route:**_____

Authorized User Signature:_____**Date:**_____

33 WRITTEN DIRECTIVE PROGRAM – RADIOPHARMACEUTICAL SECTION

Please note the following about your Written Directive Program:

- Reconfigured from previous Quality Management Program on 10/24/03 as required by the U.S. Nuclear Regulatory Commission (NRC) 10 CFR 35.40 and 35.41.

Impacts the usage of: ^{131}I as **Sodium Iodide only** in amounts greater than **30 μCi** for **either diagnostic or therapeutic uses**.

Any radiopharmaceutical used for therapeutic purposes such as ^{32}P, ^{89}S, ^{90}Y, ^{153}Sm, etc.

- A **"Written Directive"** (prescription) is required to be issued to the Nuclear Medicine technical staff from an authorized user (Nuclear Medicine Physician) as listed on your NRC License **prior** to the initiation of the procedure.

- The Written Directive for Iodine-131 must contain the following in a clear manner:

  1. Patient Name
  2. Activity to be administered
  3. Signature of Authorized User and Date

- The Written Directive for all other radiopharmaceuticals must contain the following in a clear manner:

  1. Patient Name
  2. The Radioactive Drug
  3. Activity to be administered
  4. The route of administration
  5. Signature of Authorized User and Date

  - If any of the above information is unclear or missing **STOP** and seek clarification.

  - The patient must be positively identified prior to administration.

- **Written procedures** must exist and be implemented for assurance that the written directive is followed and patient identification is made at a minimum.

- **MEDICAL EVENT** has been defined as follows and must be reported to the NRC within the next calendar day with a written report to follow in 15 days. Except in the case of patient intervention.

1. The radiation dose (mrem) delivered **DIFFERS** from the radiation dose that would have resulted from the prescribed dosage (mCi) by more than:

   5 rem (0.05 Sv) Effective Dose Equivalent (EDE) – Whole Body
   50 rem (0.5 Sv) to an organ or tissue or
   50 rem (0.5 Sv) Shallow Dose Equivalent (SDE) – Skin

   AND

   The total dosage (mCi) delivered differs from the prescribed dose by +/- 20% or more
   or
   The total dosage (mCi) delivered falls out of the prescribed dosage range.

2. A radiation dose exceeds -

   5 rem (0.05 Sv) Effective Dose Equivalent (EDE) – Whole Body
   50 rem (0.5 Sv) to an organ or tissue or
   50 rem (0.5 Sv) Shallow Dose Equivalent (SDE) – Skin

   from any of the following:

   Wrong Radioactive Drug
   Wrong Route of Administration
   Wrong Individual
   Delivered by Wrong Mode of Treatment
   Leaking Source

3. A radiation dose (mrem) to the skin or an organ or tissue other than the **treatment site** exceeds 50 rem (0.5 Sv) to an organ or tissue

   AND

   Exceeds 50% or more of the radiation dose expected from the administration as noted in the written directive.
   (This excludes permanent implants, seeds that were implanted correctly and migrated outside the treatment area.)

34 RADIOPHARMACEUTICAL PROCEDURES REQUIRING A WRITTEN DIRECTIVE -- ASSURANCE WRITTEN DIRECTIVE FOLLOWED

PURPOSE: To insure that the intent of the written directive was followed as required by 10 CFR 35.41.

SCOPE: Issuance of a written directive must be followed by confirmation that the explicit prescriptive directions of the written directive such as radiopharmaceutical, activity and route of administration were in agreement.

POLICY: The radiopharmaceutical, administered dose and route of administration must be verified by the individual administering the radiopharmaceutical for agreement with the written directive. Determine and record the activity of the radiopharmaceutical dosage or radiation dose before medical use. This can be done by dose calibrator assay or mathematical calculation.

* New 5-25-2012

A second Nuclear Medicine Technologist, Radiology Nurse, of an Authorized User must verify the dose amount by direct inspection of the dose calibrator reading.
Both personnel must sign and date the Dose dispensing Record on the Written Directive.
If the assay amount differs from the prescribed amount by + / – 20%, the Written Directive must be revised by an Authorized User prior to administration of the dose.

Each final container (i.e., syringe) must be properly labeled to identify the radiopharmaceutical and activity.

Written directives will contain the prescribed route of administration.

The sole responsibility for assurance that the patient was properly identified and the prescriptive instructions of the written directive were followed rests with the individual (Nuclear Medicine Technologist or physician authorized user) responsible for the direct administration of the radiopharmaceutical to the patient.

Verification must be established for:

- Patient identification by at least one of the following methods:
- Patient called by name
- Patient spells their name
- Patient states their Date of Birth

- Patient states their Social Security Number
- Patient provides positive (picture) identification
- In-patient identification verified by wrist band

- Route of administration by comparison to the written directive.
- Radiopharmaceutical and the dosage measurement noted on the final container label must be compared to the prescribed dosage on the written directive.

If any part of the written directive or patient identification process is unclear or not understood, do not proceed until you receive guidance to rectify any questions or concerns.

After the administration, the authorized user or qualified individual under the supervision of the authorized user, must record the administered dose, the date and their signature or initials in an auditable form, such as on the written directive itself.

35 RADIOPHARMACEUTICAL PROCEDURES REQUIRING A WRITTEN DIRECTIVE -- VERIFICATION OF PATIENT IDENTITY

PURPOSE: To provide a clear method of patient identification as directed by 10 CFR.35.41.

SCOPE: Verification of patient identity is a crucial facet in the prevention of medical events of radiopharmaceuticals such as:

- Sodium Iodide - 131 or in amounts greater than thirty (30) microcuries (μCi) for diagnostic or therapeutic purposes.
- Any radiopharmaceutical therapy, i.e., ^{32}P, ^{89}Sr, ^{153}Sm, ^{90}Y, etc.

POLICY: Each patient shall be properly identified prior to the administration of any radiopharmaceutical as noted in the scope of this policy.

The individual (Nuclear Medicine Technologist or physician authorized user) responsible for the direct administration of the radiopharmaceutical to the patient is solely responsible for securing the identity of the patient.

Each patient under this policy shall be identified by at least one of the following methods:

- Patient called by name
- Patient spells their name
- Patient states their Date of Birth
- Patient states their Social Security Number
- Patient provides positive (picture) identification
- In-patient identification verified by wristband

If the information obtained does not correspond to the information on the written directive, the radiopharmaceutical shall not be administered until conclusive evidence is obtained that this agent/procedure is intended for the patient in question.

200 dpm/ per 100 cm^2 for I-131, P-32

2000 dpm/ per 100 cm^2 for all other radionuclides.