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GREAT FALLS CLINIC GREAT FALLS HOSPITAL

21 March 2024

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington DC 20555-0001

Tamara Bloomer
Director
Division of Radiological Safety & Security
U.S. Nuclear Regulatory Commission
Region IV
1600 East Lamar Boulevard
Arlington, Texas 76011-4511

U.S. Nuclear Regulatory Commission
R4Enforcment@nrc/gov

Via: Original Certified Mail and Email [8 Mar 24], and Supplemental via Email [20 Mar 24]

Re: Updated Response to Apparent Violations in NRC Inspection Report 030-35944/2023-001: EA-23-124

Dear U.S. Nuclear Regulatory Commission:

I am providing supplemental information related to achieving Full Compliance, which will be 23 May 24. We appreciate the NRC for taking the time to provide timely and thorough feedback 13 Mar 24, as related to our written response [submitted 8 Mar 24].

Based on the discussion we elected to do the following:

- Made changes to Policy, Written Directive Form and Procedure. The updated draft versions are attached.
- In addition to the changes made in processes in August 2022 and on-going compliance since that time, we have enhanced the action plan described in our initial Written Response. The refined compliance timeline:
  - The attached draft Policy, Forms and Procedure will be finalized and approved at the next Board of Directors meeting, scheduled for 23 May 24.
  - Existing Nuclear Medicine team members will be trained by this date.
  - Of note, if we can partner with qualified Authorized User(s) prior to 23 May 24, we will fast-track the process and seek an off-cycle review of these document by our Board, so these new items and education are in place prior to us performing any Iodine-131 Therapy Procedures.

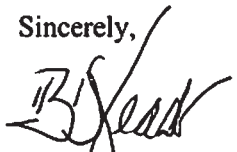
- We are also confirming any future change process enhancements in the Nuclear Medicine Department will employ the same diligent approach described in our original Response: collaboratively updating/creating applicable Procedures/Directives with key stakeholders; establishing training and competencies to ensure compliance; and after deploying said change(s), there will be routine monitoring and auditing to ensure Full Compliance.

8 March 2024 Original *Full Compliance Date* **paragraph**: We believe the 28 April 2022 episode of non-compliance was an isolated occurrence and that we have been fully compliant for the subsequent administration of sodium iodide 1-131 greater than 30 microcuries. The original 2022 written checklist and a safety time-out process were quickly re-implemented following the return of our prior lead nuclear medicine technologist in August 2022. Further enhancements to the action plan are underway, however the timing of the successful implementation of the Plan in its entirety is partially dependent on the resumption of the Nuclear Medicine Program via the addition of new qualified AUs.

GFH is committed to ensuring full compliance with applicable safety and regulatory standards that apply to our Nuclear Medicine Program on a consistent basis. We appreciate the expert guidance the NRC staff has provided us with to date as we seek to continually improve our Program. We hope the NRC recognizes this commitment as demonstrated by new organizational leadership and resources that are all focused on ensuring we have a comprehensive, robust, and sustainable approach to resolving the apparent violations, as well as seeking proactive NRC guidance as we evolve our Program. Thank you.

Please let me know if you have any questions. I can be reached at (406) 771-3126 or Bradley.Weast@gfclinic.com

Sincerely,



Bradley D. Weast, MHA, CMPE
Chief Operating Officer
Great Falls Hospital

Attachment: Nuclear Medicine Written Directive re: I-131

CC:
Mr. Ross Barnes
Director Radiation Control Program
Montana Department of Public Health and Human Services
2401 Colonial Drive
P.O. Box 202953
Helena, MT 59620 Ross.Barnes@mt.go

Policy Title: Iodine-131 Therapy Procedures

Effective Date: (insert) **Policy #:** GFH (insert)

DNV/Regulatory Reference: 10 CFR 35.13, 10 CFR 35.14, 10 CFR 35.300

Form Reference(s): Nuclear Medicine- Written Directive (Form# (insert))

Policy: Iodine-131 Therapy Procedures

Purpose: To ensure that therapeutic Iodine-131 ("I-131") procedures are performed in a safe and compliant manner.

Responsibility: Nuclear Medicine Department, Nuclear Medicine Technologists, Authorized Users, Nuclear Medicine Radiation Safety Officer, Nuclear Medicine Physicist

Definitions:

Authorized User: A physician named as an authorized user on the current Great Falls Clinic Hospital's Nuclear Regulatory Commission's ("NRC") license who is responsible for ensuring that the prescribed radioactive materials are handled and used safely and in accordance with NRC regulations and the terms and conditions of the NRC license.

Nuclear Medicine Technologist: An employed or contracted Nuclear Medicine Technologist who has completed the required Great Fall Clinic Hospital's training on 1-131 procedures and has met the criteria and been deemed competent by the Radiology Department to perform I-131 procedures.

Procedure:

I. In accordance with the Great Falls Clinic Hospital's U.S. Nuclear Regulatory Commission License No.: 25-27721-01, therapeutic Iodine-131 ("I-131") dose administration greater than 30 microcurie will be performed in situations where:
   a. A valid and complete order is received from the patient's treating physician, including dose, radioisotope, and diagnosis,
   b. The patient has been screened and approved by a qualified Authorized User,
   c. The patient has been informed of the radiation safety considerations,
   d. The patient consents to the treatment,
   e. The Authorized User determines the appropriateness of the therapy, performs the necessary calculations, and fully completes the "Nuclear Medicine- Written Directive" (see Attachment 1), and
   f. The Nuclear Medicine Technologist completes the 1-131 procedure in accordance with the GFCH "1-131 Nuclear Medicine Technology Procedure" (see Attachment 2).

II. The GFCH Nuclear Medicine Radiation Safety Officer, in conjunction with the Program's Physicist, will perform periodic quality assurance reviews to determine if the documentation, approval, and procedural requirements are met.

References: GFCH Nuclear Medicine Department I-131 Nuclear Medicine Technologist Procedure

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Attachment 1

DRAFT NUCLEAR MEDICINE – WRITTEN DIRECTIVE

Patient Label	Diagnosis

DESIRED PROCEDURE: **Must be completed *before* the therapy event**

_____ ^{131}Iodine Whole-Body Scan

_____ ^{131}Iodine Therapy for Hyperthyroidism

_____ ^{131}Iodine Therapy for Thyroid Cancer

RADIOPHARMACEUTICAL ^{131}I Sodium Iodide (capsule)

Prescribed Dose: _____ **Route:** Oral Administration

Printed Name of Authorized User: _____ **Date:** _____

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

PATIENT IDENTIFICATION: ***Note: Patient must be identified by a minimum of two methods.***

_____Patient identifies self by name
_____Patient identifies correct date of birth
_____Patient provides valid driver's license
_____Patient provides valid State ID card
_____Positive identification by a relative or legal guardian
_____Other method _____

Name and signature of verifier:

Print Name: _____ Signature: _____ Date: _____

PREGNANCY / BREAST FEEDING STATUS:

Pregnancy Status: _____Post-menopausal female
_____Hysterectomy
_____Serum β-HCG obtained on _____ β-HCG: _____
(<4.9 milliUnits/ml is negative)

Breast Feeding Status: _____Yes _____No _____N/A

Timeout! Review Form for Completion and Accuracy Before Signing

Administered Dose: _____ _____% Error **Procedure Date:** _____

Printed name of Authorized User: _____

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

Post-Procedure Checklist -- to be Completed by Technologist	
Release Criteria	**Initial as Completed**
Prepared a patient release calculation utilizing the GFCH Patient Release Calculator.	
Confirmed the exposure to the maximally exposed individual remains below 0.5 rem.	
Patient Instructions	
Patient given copy of the Dose Specific Instruction sheet.	
Patient given copy of the Travel Letter.	
Retained Documents (Each Item is uploaded in PACS, sent to HIM, and filed in the I-131 Book)	
Written Directive	
Pregnancy status determination	
Signed Consent Form	
Travel Letter	
Signed Dose Specific Instruction sheet	
GFCH Patient Release Calculator print out	
Any additional documents	

DRAFT GFCH Nuclear Medicine Department
I-131 Nuclear Medicine Technologist Procedure

Step 1: Review of orders and further testing needed for clearance

- Is the ordering provider a GFC provider or outside provider?
  - If a GFC provider, check for the order in Athena.
  - If an outside provider – must have original order (can be electronic), labs, and last office notes describing reasons for exam.
- The order must include dose, radioisotope, and diagnosis.
- All female patients who are of childbearing age (have experienced an onset of menses) and up to 70 years old must have a serum pregnancy test within 72 hours of the scheduled therapy.
  - A history of a tubal ligation procedure does not negate this.
  - A reported history of hysterectomy must be documented with a signed provider note.

Step 2: Chart Prep/Validation of Authorized User

- Assemble the following paperwork (can be copied from procedure manual or printed from K-drive):
  - Nuclear Medicine- Written Directive – properly completed, signed, and dated by an AU so listed on the license.
  - Prepare a patient release calculation utilizing the GFCH Patient Release Calculator, selecting either the hyperthyroidism or thyroid cancer disease states. Confirm the exposure to the maximally exposed individual remains below 0.5 rem.
  - Patient instruction sheet – use the one with the appropriate dosage. (ex: 15-33 mCi vs 33-100)
  - Print Labs and office visit notes from Athena.
  - Print Pregnancy test results document on written directive and add to paperwork in I-131 book behind written directive.
  - Travel Letter
  - Patient Information Sheet explaining the procedure.
  - Nuclear Medicine Consent to Treat form.
  - If ordered by an outside provider, all historical information must be sent to us.
- Fill out the Nuclear Medicine- Written Directive & Consent as much as possible.
  - Insert the performing provider/Authorized User's name on the written directive and consent form as indicated.
  - Verify that the Provider you are listing as the performing provider/Authorized User is listed as an Authorized User on the current NRC license. The NRC License is posted on the wall in Nuclear Medicine and in the NRC manual.
  - Verify that the designated performing provider/Authorized User is currently credentialed for the appropriate material, use and dose amount ordered.
    - 35.300.
    - Or it must state oral administration of sodium iodide 131.
    - It might list a specific quantity. Ex: only in quantities less than or equal to 33 millicuries.
    - **If a radiologist who is not an appropriate Authorized User is scheduled for this procedure, you must talk to the radiologists and have them trade with each other to dose the patient. NO EXCEPTIONS!!!**

Approved by: (insert)
Date Last Approved/Reviewed: (insert)

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Step 3: Deliver Chart to Authorized User on Day of Procedure

- On the morning of the exam take assembled paperwork to the designated performing provider/Authorized User for their review.

Step 4: Upon Patient Arrival

- Retrieve paperwork from the designated performing provider/Authorized User
- Bring patient into Nuclear Medicine
- Verify patient identity with two forms of identification as listed on the Written Directive.
  - Check off the type of identification used on the Written Directive.
- Call the performing provider/Authorized User and to come talk to the patient, explain the procedure, and verbally obtain the patient's informed consent.
  - Obtain consent form signed by patient.
- Review the Dose Specific Instruction sheet with the patient.
  - Obtain the patient's signature on the sheet,
  - Copy the sheet. Keep the original for the medical record.
- Place dose in dose calibrator and verify that the dose is within ±10% of the prescribed dose identified on the written directive. If the dose is > ±10%, do not proceed with the administration and contact the AU.
- After the performing provider/Authorized User approves proceeding with the procedure, have them sign and date the written directive as indicated for the AU.
- Tell the performing provider/Authorized User what the dose measures. Ask if it is ok to dose the patient.
- If the performing provider/Authorized User says its ok to proceed, take the dose to the patient with a bottle of water.
- Have the patient take the pill.
- Give the patient:
  - A copy of the Dose Specific Instruction sheet that they signed.
  - A travel letter. Instruct the patient to carry the travel letter for 2 months.
- Instruct the patient to contact us at the number on the travel letter if they get sick and vomit within the next week.
- Walk the patient out of the department.

Step 5: File the Paperwork

- File the written directive, pregnancy status documentation, the GFCH Patient Release Calculator print out, and the original copy of the instruction sheet in the I-131 book. If an outside provider is ordering the procedure, file the original order with the paperwork.
- File the written directive, pregnancy status documentation, signed consent form, travel letter provided, instruction sheet, GFCH Patient Release Calculator print out, and any additional patient documentation in the medical record.
  - Upload into PACS AND
  - Send via interoffice mail (yellow envelope) to "HIM Hospital" for scanning into the electronic medical record.