



March 8, 2024

U.S. Nuclear Regulatory Commission  
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Washington DC 20555-0001

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U.S. Nuclear Regulatory Commission  
R4Enforcement@nrc.gov

Via: Certified Mail and Email

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

Dear U.S. Nuclear Regulatory Commission:

I am writing in response to the Inspection Report that CSMC, LLC d/b/a Great Falls Hospital ("GFH") received from the U.S. Nuclear Regulatory Commission ("NRC") dated 6 February 2024. As I previously communicated to Dr. Lizette Roldán-Otero on 15 February 2024, we have elected to submit a written response to the findings.

Background:

During the NRC's on-site inspection on 29 August 2023, the following two (2) apparent violations were identified:

- (1) 030-35944/2023-001-01 AV: Failure to ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries (10 CFR 35.40(a)).
- (2) 030-35944/2023-001-02 AV: Failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive (10 CFR 35.41(a)(2)).

For each apparent violation, we will provide:

- (1) The reason for the apparent violation.
- (2) The corrective steps that have been taken and the results achieved.
- (3) Further corrective steps will be taken.
- (4) The date when full compliance has been achieved.

*Please note, we have combined our response for both apparent violations in a consolidated format so as not to be repetitive for the reader.*

**Apparent Violation #1: 030-35944/2023-001-01 AV: Failure to ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries (10 CFR 35.40(a)).**

**Apparent Violation #2: 030-35944/2023-001-02 AV: Failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive (10 CFR 35.41(a)(2)).**

**Findings:** As noted in the NRC's Inspection Report, our program has historically performed a low volume of sodium iodide 1-131 greater than thirty (30) microcuries administration. From 16 March 2022 to 29 August 2023, GFH performed only two (2) administrations that required a written directive. The first was performed on 28 April 2022, and the second was administered on 7 December 2022.

The NRC found that the 7 December 2022 administration of sodium iodide 1-131 was in full compliance of these requirements as the written directive was dated and signed by an appropriate Authorized User ("AU").

The NRC also found that for the 28 April 2022 administration of sodium iodide 1-131 the written directive was dated and signed by a nuclear medicine technologist rather than an appropriate AU. We do not refute that the 28 April 2022 administration does not contain a signature of an AU.

**Reason:** Following the submission of our NRC Inspection Report Response in March 2022, GFH's lead nuclear medicine technologist, along with the then Radiation Safety Officer, developed a written checklist and a safety time-out process to ensure the proper procedures were followed for the administration of sodium iodide 1-131. The lead technologist retired from her position on 23 January 2022; however, the expectation was all staff going forward would follow the checklist and time-out procedures for all sodium iodide 1-131 greater than thirty (30) microcurie administrations.

The nuclear medicine technologist who performed the 28 April 2022 procedure and accidentally dated/signed the written directive in lieu of an AU, had limited hands-on experience with this procedure. In addition, she was employed by us for less than one (1) year from 2 August 2021, through 8 July 2022. We have not been able to interview the performing technologist to understand the root cause of this error. We do believe the low frequency of the procedure, staff inexperience, and staff transitions may have contributed to this error; however, we are not able to fully understand why this error occurred.

**Corrective Steps Taken to Date and the Results Achieved:** The following corrective action steps have been taken in response to the NRC Inspection in August 2023:

- Our well-experienced lead nuclear medicine technologist, who was part of our initial corrective action plan, returned to the GFH on a full-time basis on 29 August 2022, and actively partners with our current Radiation Safety Officer, AUs, and Administration to ensure our quality, safety, and clinical procedures are followed.
- The original 2022 written checklist and a safety time-out process for sodium iodide 1-131 administrations were quickly re-implemented in August 2022.
- An internal record review was conducted of any sodium iodide 1-131 greater than thirty (30) microcuries performed after the NRC's August 2023 inspection to the present time. This review found we performed one (1) procedure on 25 October 2023. The Authorized User and Dose Administered Fields of the Written Directive for this procedure were signed by the AU. The AU was on the NRC license as of the date of service and had been approved for the specific material and use ordered for this administration.

**Further Corrective Steps:** As the NRC is aware, due to a contracting change in our Radiology Groups, we have currently paused our Nuclear Medicine Program pending the identification of new AUs. We continue to work on ensuring our NRC action plan in response to this finding is robust and are currently taking the following additional corrective actions steps:

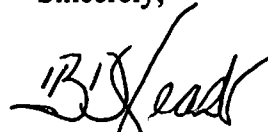
- Revamping the “*Nuclear Medicine Written Directive*” form regarding the sodium iodide 1-131 thyroid procedures greater than thirty (30) microcuries. This document is currently undergoing formal review and approval (See attached draft that is part of the umbrella policy and procedure).
- Revamping the “*I-131 Nuclear Medicine Technologist Procedure*” regarding the sodium iodide 1-131 thyroid procedures greater than thirty (30) microcuries. This document is currently undergoing formal review and approval (See attached draft that is part of the umbrella policy and procedure).
- Created a new draft formal umbrella policy and procedure titled “*Iodine-131 Therapy Procedures*”, which references the Written Directive and Procedure described above. Following approval, this policy and procedure will be reviewed, and updated at least every two (2) years and more often as needed.
- When the new formal policy, procedure and forms are finalized, we will provide formal education to all nuclear medicine technologists, the RSO, and applicable AUs upon approval, upon joining GFH, and on an annual basis thereafter.
- Existing technologists will be required to demonstrate competency prior to performing any procedures.
- Any new technologist who joins the organization will be required to demonstrate competency with sign-off during their orientation period.
- The recently appointed Radiation Safety Officer, in conjunction with the Program's Physicist, will perform a 100% quality assurance review to determine if documentation and approval requirements are met. All findings shall be promptly shared with GFH's Administration and the newly appointed full-time Compliance Officer.
- The GFH's Compliance Officer will complete monthly compliance audits to ensure the training, documentation, and approval requirements are met. These monthly audits will be performed until there is a large enough volume to evaluate on-going compliance with the requirements. The frequency of the compliance audits will then be ramped down over time to ensure sustained compliance.
- The conformance to this corrective action plan will be overseen operationally by the GFH Compliance Committee and reported to the GFH Governing Board on a periodic basis.

**Full Compliance Date:** 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](mailto:Bradley.Weast@gfclinic.com)

Sincerely,



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

Attachment: Draft "Iodine-131 Therapy Procedures" policy and procedure, includes the draft "Nuclear Medicine- Written Directive" and "I-131 Nuclear Medicine Technologist Procedure".

CC:  
Mr. Ross Barnes  
Director Radiation Control Program  
Montana Department of Public Health and Human Services  
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P.O. Box 202953  
Helena, MT 59620 [Ross.Barnes@mt.go](mailto: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))

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**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 I-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 30mCi 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 I-131 procedure in accordance with the GFCH "I-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.

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

DRAFT

**DRAFT NUCLEAR MEDICINE – WRITTEN DIRECTIVE**

Patient Label

Diagnosis

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

\_\_\_\_\_ <sup>131</sup>Iodine Whole-Body Scan

\_\_\_\_\_ <sup>131</sup>Iodine Therapy for Hyperthyroidism

\_\_\_\_\_ <sup>131</sup>Iodine Therapy for Thyroid Cancer

**RADIOPHARMACEUTICAL**      <sup>131</sup>I Sodium Iodide (capsule)

Prescribed Dose: \_\_\_\_\_ mCi      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

Administered Dose: \_\_\_\_\_ mCi    \_\_\_\_\_ % Error      Procedure Date: \_\_\_\_\_

Printed name of Authorized User: \_\_\_\_\_

Signature of Authorized User: \_\_\_\_\_ Date: \_\_\_\_\_

**Post-Procedure Checklist**

<b>Release Criteria</b>	<b>Initial as Completed</b>
Prepared a patient release calculation utilizing the GFCH Patient Release Calculator.	
Confirmed the exposure to the maximally exposed individual remains below 0.5 rem.	
<b>Patient Instructions</b>	
Patient given copy of the Dose Specific Instruction sheet.	
Patient given copy of the Travel Letter.	
<b>Retained Documents (Each Item is uploaded in PACS, sent to HIM, and filed in the I-131 Book)</b>	
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)



***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  $\pm 10\%$  of the prescribed dose identified on the written directive. If the dose is  $> \pm 10\%$ , 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.

Approved by: (insert)

Date Last Approved/Reviewed: (insert)