UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

February 7, 2024

EA-23-124

Bradley Weast, Chief Operating Officer
CMSC, LLC
dba Great Falls Clinic Hospital
3010 15th Avenue South
Great Falls, MT 59405

SUBJECT: CMSC, LLC, dba GREAT FALLS CLINIC HOSPITAL - NRC INSPECTION REPORT 030-35944/2023-001

Dear Bradley Weast:

This letter refers to the unannounced inspection that was conducted on August 29, 2023, at your facility in Great Falls, Montana. The purpose of the inspection was to: (1) examine activities conducted under your license as they relate to public health and safety, to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules, and regulations and the conditions of your license; and (2) review your corrective actions related to violations previously cited by the NRC. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observation of activities, independent radiation measurements, and interviews with personnel. The inspectors continued in-office review through December 18, 2023. The enclosed inspection report presents the results of this inspection. The inspectors discussed the preliminary inspection findings with you and April Hammond, Director of Radiology, at the conclusion of the onsite portion of the inspection. On January 16, 2024, a final exit briefing was conducted via video conference with you and April Hammond.

As described in the enclosed NRC Inspection Report, the inspection reviewed your corrective actions to address two violations, collectively categorized as a Severity Level III problem, that were cited in a Notice of Violation (NOV) dated November 2, 2022 (Agencywide Document Access Management System (ADAMS) Accession No. ML22292A254). Based on the results of the current inspection, your corrective actions were adequate to address one of the previous violations, which involved the failure to ensure that written directives contained the required dosage.

However, this inspection identified that your corrective actions were not effective to address the other previous violation, which involved a written directive for an administration of sodium iodide iodine-131 (I-131) that was dated and signed by an individual who was not authorized under your license and did not meet the qualifications to perform the administration. The inspectors identified that there was a recurrence of the issue when a subsequent written directive was signed and dated by an individual who was not authorized under your license and did not meet the qualifications to perform the administration. Given the repeat nature of the issue, and the

corrective actions put in place to address the previous violation were not effective, the NRC is concerned that your radiation safety program lacks adequate oversight to effectively implement the program for administrations requiring written directives.

Based on the results of the inspection, two apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's website at http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations involve the failure to: (1) ensure that written directives were dated and signed by an authorized user; and (2) develop, implement, and maintain written procedures to provide high confidence that each administration is performed in accordance with written directives. The circumstances surrounding these apparent violations, the significance of the issues, and the need for lasting and effective corrective action were discussed with you and April Hammond during the videoconference exit meeting on January 16, 2024.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond in writing to the apparent violations addressed in the inspection report within 30 days of the date of this letter; (2) request a predecisional enforcement conference (PEC); or (3) request alternative dispute resolution (ADR). If a PEC is held, it will be open for public observation and the NRC may issue a press release to announce the time and date of the conference. Please contact Dr. Lizette Roldán-Otero, Chief, Materials Inspection Branch, at 817-200-1455 or Lizette.Roldan-Otero@nrc.gov within 10 days of the date of this letter to notify the NRC of your intended response to either provide a written response, participate in a PEC, or pursue ADR. A PEC should be held within 30 days and an ADR session within 45 days of the date of this letter.

If you choose to provide a written response, it should be clearly marked as a "Response to Apparent Violations in NRC Inspection Report 030-35944/2023-001; EA-23-124" and should include for each apparent violation: (1) the reason for the apparent violation or, if contested, the basis for disputing the apparent violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be (or has been) achieved. Your response may reference or include previously docketed correspondence if the correspondence adequately addresses the required response.

Your written response, should you choose to provide one, should be sent to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with identical copies mailed to the Director, Division of Nuclear Materials Safety, Region IV, 1600 East Lamar Boulevard, Arlington, TX 76011, and emailed to R4Enforcement@nrc.gov within 30 days of the date of this letter. If an adequate response is not received within the time specified or an extension of time has not been granted by the NRC, the NRC will proceed with its enforcement decision or schedule a PEC.

If you choose to request a PEC, the conference will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The decision to hold a PEC does not mean that the NRC has determined that a violation has occurred or that enforcement action will be taken. This conference would be conducted to obtain information to assist the NRC in making an enforcement decision. The topics discussed during the conference may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned.

In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any civil penalty for the apparent violations. The guidance in NRC Information Notice 96-28, “Suggested Guidance Relating to Development and Implementation of Corrective Action,” may be helpful in preparing your response (ADAMS Accession No. ML061240509).

In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues.

Additional information concerning the NRC's ADR program can be obtained at http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html. The Institute on Conflict Resolution at Cornell University has agreed to facilitate the NRC's program as a neutral third party. Please contact the Institute on Conflict Resolution at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. Alternative dispute resolution sessions are not conducted with public observation, although the outcome of the ADR agreement is made public.

In addition, please be advised that the number and characterization of apparent violations described in the enclosed inspection report may change as a result of further NRC review. You will be advised by separate correspondence of the results on our deliberations in this matter.

In accordance with 10 CFR 2.390 of the NRC’s “Agency Rules of Practice and Procedure,” a copy of this letter, its enclosure, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or in the NRC’s ADAMS, accessible from the NRC’s website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If you have any questions concerning this matter, please contact Dr. Lizette Roldán-Otero of my staff at 817-200-1455.

Sincerely,

Tamara Bloomer Signed by Bloomer, Tamara on 02/07/24

Tamara Bloomer, Director
Division of Radiological Safety & Security

Docket No. 030-35944
License No. 25-27721-01

Enclosure:
NRC Inspection Report 030-35944/2023-001

cc w/Enclosure:
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.gov

CMSC, LLC dba GREAT FALLS CLINIC HOSPITAL - NRC INSPECTION
REPORT 030-35944/2023-001 - DATED FEBRUARY 7, 2024

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ADAMS ACCESSION NUMBER: ML24017A174

☒SUNSI Review:	ADAMS:	☐ Non-Publicly Available	☒Non-Sensitive	Keyword:
By: MHK	☒ Yes ☐ No	☒ Publicly Available	☐ Sensitive	

OFFICE	HP:MIB	SHP: MIB	BC:MIB	TL:ACES	RC
NAME	MKawasmi	JKatanic	LRoldanOtero	JGroom	DCylkowski
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E
DATE	01/18/24	01/18/24	01/18/24	01/19/24	01/18/24
OFFICE	OE	NMSS	OGC	D: DRSS	
NAME	CRiveraDiaz	MBurgess	RCarpenter	TBloomer	
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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.	030-35944
License No.	25-27721-01
Inspection Report No.	030-35944/2023-001
EA No.	EA-23-124
Licensee:	CMSC, LLC dba Great Falls Clinic Hospital
Location Inspected:	Great Falls Clinic Hospital 3010 15th Avenue South Great Falls, Montana 59405
Inspection Date:	August 29, 2023, with in-office review through December 18, 2023
Exit Meeting Date:	January 16, 2024
Inspectors:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Radiological Safety & Security, Region IV Mohanned Kawasmi Health Physicist Materials Inspection Branch Division of Radiological Safety and Security, Region IV
Approved by:	Lizette Roldán-Otero, PhD Chief, Materials Inspection Branch Division of Radiological Safety & Security, Region IV
Attachment:	Supplemental Inspection Information

Enclosure

EXECUTIVE SUMMARY

CMSC, LLC
dba Great Falls Clinic Hospital (GFCH)
NRC Inspection Report 030-35944/2023-001

On August 29, 2023, the NRC performed an unannounced inspection of GFCH. The inspectors continued in-office review through December 18, 2023. The purpose of the inspection was to: (1) examine activities conducted under the GFCH license as they relate to public health and safety, to confirm compliance with NRC rules and regulations and with the conditions of the GFCH license; and (2) review the licensee's corrective actions related to violations previously cited by the NRC. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

From March 16, 2022, to August 29, 2023, GFCH only performed two administrations of sodium iodide iodine-131 (I-131) that required a written directive under Title 10 of the *Code of Federal Regulations* (10 CFR) 35.300. The inspectors determined that both written directives contained the dosage in millicuries, as required. Accordingly, the previous violation regarding written directives not containing the required information is considered closed.

However, the inspectors determined that one of the written directives was signed and dated by an individual who was not an authorized user (AU) for any category of licensed activity on the GFCH license, and who did not meet the qualifications to perform administrations under 10 CFR 35.300 requiring a written directive or for oral administration of sodium iodide I-131.

Based on the results of the previous NRC inspection, the licensee received a Severity Level III violation regarding a written directive for an administration of sodium iodide I-131 that was dated and signed by an individual that was not authorized under the GFCH license as an AU for 10 CFR 35.300 or for oral administration of sodium iodide I-131. The inspectors concluded that the licensee's corrective actions to address the previous violation were not effective, as evidenced by a recurrence of the issue. Accordingly, the previous violation could not be closed.

Furthermore, the inspectors identified that the licensee did not have procedures to provide high confidence that each administration requiring a written directive is performed in accordance with the written directive.

As a result, two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries; and (2) develop, implement, and maintain procedures to provide high confidence that each administration is performed in accordance with written directives.

As corrective actions, at the conclusion of the onsite inspection, licensee senior management made commitments to the inspectors to improve the radiation safety program. The licensee informed the inspectors that it would revise its written directive form, as well as its policy and associated procedures for these types of administrations. The licensee has not provided the inspectors with the revised documents or any additional actions that it plans to take to correct the identified deficiencies.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87130)

1.1 Program Scope

CMSC, LLC, dba Great Falls Clinic Hospital (GFCH or licensee) is authorized under NRC Materials License No. 25-27721-01 to possess and use byproduct material for diagnostic and therapeutic medical use under Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35 at its facilities in Great Falls, Montana.

1.2 Observations and Findings

Great Falls Clinic Hospital is a short-term acute care facility that provides specialized medical services to Great Falls, Montana, and the surrounding geographic community. The NRC license issued to GFCH authorizes uptake, dilution, and excretion studies under 10 CFR 35.100; imaging and localization studies under 10 CFR 35.200; and the use of unsealed radioactive material for which a written directive is required under 10 CFR 35.300. The Radiation Safety Officer (RSO) listed on the GFCH license at the time of the inspection was a consultant to GFCH and not a direct employee. The RSO was responsible for oversight of licensed activities and licensee compliance at the locations of use listed on the GFCH license.

2 Licensed Activities Requiring a Written Directive (IP 87130)

2.1 Inspection Scope

On August 29, 2023, the NRC performed an unannounced inspection of GFCH. The purpose of the inspection was to: (1) examine activities conducted under the GFCH license as they relate to public health and safety, to confirm compliance with NRC rules, and regulations and the conditions the GFCH license; and (2) review the licensee's corrective actions related to violations previously cited by the NRC. Within these areas, the inspection consisted of a selected examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel. The inspectors continued in-office review through December 18, 2023.

The inspection reviewed the licensee's corrective actions to address a Severity Level III Problem involving two violations that were identified in the Notice of Violation (NOV), NRC Inspection Report 030-35944/2022-001, dated November 2, 2022 (ADAMS Accession No. ML22292A254)

2.2 Observations and Findings

The inspection determined that the 10 CFR 35.300 program at GFCH for administrations requiring a written directive was not very active. Through interviews and records reviews, it was determined that since the last NRC routine inspection in March 2022, the only byproduct material utilized by GFCH for 10 CFR 35.300 administrations was sodium iodide iodine-131 (I-131), and there were only two administrations performed under this authorization.

2.2.1 Review of Previous Inspection Findings

The last routine inspection, on March 16, 2022, was documented in NRC Inspection Report 030-35944/2022-001, dated August 22, 2022 (ADAMS Accession No. ML22230D077). The inspection report identified two apparent violations (AVs) involving the licensee's program for the use of sodium iodide I-131 requiring written directives under 10 CFR 35.300. The apparent violations involved the failure to: (1) ensure that written directives contained all the information required by regulation; and (2) ensure that written directives were dated and signed by an Authorized User (AU).

In response to the NRC inspection report, the licensee chose to provide a response in writing, dated September 12, 2022 (ADAMS Accession No. ML22258A238). In its response, the licensee noted, in part, that as corrective actions, it had revised its written directive form to include the required information and trained its nuclear medicine personnel in the importance of verifying that the AU is authorized by the current license. The licensee noted that full compliance was achieved for both AVs on April 28, 2022, when GFCH performed an administration of sodium iodide I-131 requiring a written directive.

On November 2, 2022, the NRC issued an NOV that cited the two violations, categorized collectively as a Severity Level III problem (ADAMS Accession No. ML22292A254). As described in the November 2, 2022, letter, because GFCH had not been the subject of an NRC escalated enforcement action within the previous two routine inspections, and because the NRC determined that corrective action credit was warranted based on the prompt and comprehensive corrective actions described in the licensee's September 12, 2022, written response, the NRC did not propose a civil penalty in the case.

During the most recent inspection, the licensee's corrective actions for the two violations were reviewed.

The first violation (030-35944/2022-001-01) was related to 10 CFR 35.40(b)(1), which requires, in part, that the written directive must contain, for any administration of quantities greater than 30 microcuries of sodium iodide I-131, the dosage. The circumstances of the violation were that two written directives for administrations of quantities greater than 30 microcuries of sodium iodide I-131 did not indicate the units of activity to specify the dosage.

The inspectors determined that from March 16, 2022, to August 29, 2023, GFCH had only performed two administrations of sodium iodide I-131 that required a written directive under 10 CFR 35.300, one on April 28, 2022, and the other on December 7, 2022. The inspectors reviewed both written directives and observed that the licensee had revised its written directive form to include units of activity, in either unit of microcuries or millicuries, which could be circled on the form. The April 28, 2022, written directive prescribed a dosage of 18 millicuries, and the December 7, 2022, written directive prescribed a dosage of 20 millicuries. For both written directives, the units of activity in millicuries had been circled.

Accordingly, the inspectors determined that the licensee's corrective actions were sufficient to consider Violation 030-35944/2022-001-01 closed.

The second violation (030-35944/2022-001-02) was related to 10 CFR 35.40(a) which requires, in part, that a written directive must be dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries. The circumstances of the violation were that a written directive for an administration of 100 millicuries of sodium iodide I-131 was dated and signed by an individual that was not authorized under NRC License No. 25-27721-01 as an AU for 10 CFR 35.300 or for oral administration of sodium iodide I-131. The individual was an AU on the license for 10 CFR 35.100 and 10 CFR 35.200 diagnostic uses but was not authorized for 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131. Furthermore, the individual did not meet the qualifications to perform administrations under 10 CFR 35.300 requiring a written directive or for oral administration of sodium iodide I-131.

The inspectors reviewed the written directives for the April 28, 2022, and December 7, 2022, administrations.

For the April 28, 2022, written directive, the inspectors observed that in the space labeled “Authorized User,” the form had been dated and signed by a nuclear medicine technologist. The nuclear medicine technologist was not an AU listed on the GFCH license and did not meet the qualifications to perform administrations requiring written directives under 10 CFR 35.300 requiring a written directive or for oral administration of sodium iodide I-131. No AU listed in the GFCH license had signed or dated the written directive anywhere on the form for the April 28, 2022, administration.

For the December 7, 2022, written directive, the inspectors observed that in the space labeled “Authorized User,” the written directive was dated and signed by an AU listed on the license that was authorized to perform oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries.

Although there were only two written directives to review since the previous NRC inspection, the licensee’s corrective actions to address the previous violation were not effective. The previous violation was related to an AU that had dated and signed a written directive but was not authorized for 10 CFR 35.300 administrations requiring a written directive or for oral administration of sodium iodide I-131. The April 28, 2022, written directive was dated and signed by an individual who was not an AU for any category of licensed activity on the GFCH license, and who did not meet the qualifications to perform administrations under 10 CFR 35.300 requiring a written directive or for oral administration of sodium iodide I-131. The licensee’s stated corrective actions to train nuclear medicine personnel in the importance of verifying that the AU is listed on the current license were not effective in this case, because a nuclear medicine technologist, who was not an AU listed in the GFCH license, signed a written directive as if they were an AU, and the sodium iodide I-131 was administered to the patient based on this written directive.

Accordingly, the inspectors determined that the licensee’s corrective actions were insufficient to consider Violation 030-35944/2022-001-02 closed. The violation remains open.

2.2.2 Current Inspection Findings

Based on the inspectors' review of licensed activities, two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries; and (2) develop, implement, and maintain procedures to provide high confidence that each administration is performed in accordance with written directives.

As described in Section 2.2.1, the April 28, 2022, written directive for an administration of 18 millicuries of sodium iodide I-131 was dated and signed by an individual who was not an AU for any category of licensed activity on the GFCH license and did not meet the qualifications to perform administrations under 10 CFR 35.300 requiring a written directive or for oral administration of sodium iodide I-131.

Licensees authorized to perform administrations requiring written directives are required to develop, maintain, and implement procedures for administrations to provide high confidence that each administration is in accordance with the written directive. To provide high confidence, procedures should include steps to verify that individuals signing and dating written directives are authorized on the GFCH license for the type of administration described in the written directive. The inspectors identified that GFCH did not develop, maintain, or implement procedures for administrations requiring a written directive to provide high confidence that each administration is in accordance with the written directive. Licensee personnel informed the inspectors that there had been procedures used in the past, but that were apparently discontinued. When the inspectors requested to review the procedures, GFCH was unable to locate or produce them.

Apparent violation of 10 CFR 35.40(a)

Title 10 CFR 35.40(a) requires, in part, that a written directive must be dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries.

Contrary to the above, on April 28, 2022, the licensee failed to prepare written directives that were dated and signed by an AU before the administration of greater than 30 microcuries of sodium iodide iodine-131. Specifically, a written directive for an administration of 18 millicuries of sodium iodide I-131 was dated and signed by an individual that was not authorized under NRC License No. 25-27721-01 as an AU for 10 CFR 35.300 or for oral administration of sodium iodide I-131.

The licensee's 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 was identified as an apparent violation of 10 CFR 35.40(a). (030-35944/2023-001-01)

Apparent violation of 10 CFR 35.41(a)(2)

Title 10 CFR 35.41(a)(2) requires, in part, that for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive.

Contrary to the above, from March 16, 2022, to August 29, 2023, for administrations requiring a written directive, the licensee failed to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive. Specifically, the licensee failed to develop, implement, and maintain written procedures for the administration of sodium iodine I-131, that provided high confidence that written directives would be properly prepared, and dated and signed by an AU listed in the license prior to the administration.

The licensee's failure to develop, implement, and maintain written procedures to provide high confidence that each administration is in accordance with the written directive was identified as an apparent violation of 10 CFR 10 CFR 35.41(a)(2). (030-35944/2023-001-02)

2.3 Causal Evaluation

A formal root cause analysis was not performed by the inspectors as it was beyond the scope of the inspection. General inspection observations indicated that over the past two inspection cycles, GFCH has performed very few administrations requiring written directives under 10 CFR 35.300. Similar to the previous NRC inspection, the nuclear medicine staff experienced turnover. The one full time nuclear medicine technologist during the previous inspection left GFCH employment. The licensee brought back a full-time nuclear medicine technologist who had retired from the position at GFCH several years prior and added one contract nuclear medicine technologist to provide additional support. Due to very few administrations requiring written directives performed, and repeated staff turnover over the past two inspection cycles, the staff have not developed or maintained the baseline of experience for these types of administrations. This was compounded by the licensee not having formal procedures to provide high confidence that written directives would be properly prepared, dated, and signed by an AU listed on the GFCH license prior to administration.

The licensee's corrective actions to address NRC's previous inspection findings in Inspection Report 030-35944/2022-001 were not effective. The licensee's September 12, 2022, written response regarding those violations stated that full compliance had been achieved with the administration performed on April 28, 2022 (ADAMS ML22258A238). However, in its written response, the licensee failed to identify that the April 28, 2022, administration was not in compliance, in that the written directive was not dated and signed by an AU listed on the GFCH license to perform administrations under 10 CFR 35.300 requiring a written directive or to perform oral administration of sodium iodide I-131.

In December 2022, the licensee missed a second opportunity to identify the April 28, 2022, noncompliance. Prior to their retirement, the former RSO performed an audit of the licensee's radiation safety program. The former RSO noted that GFCH had only performed one administration requiring a written directive in calendar year 2022, and that it was in accordance with the regulations. Although there actually were two administrations requiring written directives in calendar year 2022, it was clear from the RSO's audit notes that the one reviewed was the April 28, 2022, administration: "nuclear medicine technologist successfully completed an 18 millicurie dose of I-131 with proper documentation on the written directive." However, as observed by the inspectors, the written directive was not properly documented.

2.4 Corrective Actions

At the conclusion of the onsite inspection, the inspectors met with licensee senior management and discussed the repetitive nature of the issues and stressed the importance of developing lasting corrective actions that will prevent recurrence of the issues. The licensee's Chief Operating Officer, who had only come on board a few days prior to the inspection, made commitments to the inspectors to improve the program.

The licensee informed the inspectors that it would revise its written directive form, as well as its policy and associated procedures for these types of administrations. The licensee has not provided the inspectors with the revised documents or any additional actions that it plans to take to correct the identified deficiencies.

The licensee's previous RSO retired at the end of December 2022, and a new RSO was named on the license with Amendment No. 22, issued on January 6, 2023. However, during the inspection, the inspectors were informed that the licensee planned to transition the RSO position to a different individual. On September 29, 2023, the licensee submitted an amendment request to NRC to change the RSO. This amendment request is currently under review by the NRC.

2.5 Conclusions

Two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries; and (2) develop, implement, and maintain procedures to provide high confidence that each administration is performed in accordance with written directives.

3 Exit Meeting Summary

On January 16, 2024, a final videoconference exit meeting was conducted with the licensee's Chief Operating Officer and the Director of Radiology to discuss the inspection findings. The NRC representatives discussed the content of the inspection report, described the NRC's enforcement process, and described the options for the licensee to: (1) respond in writing to the apparent violations described in the inspection report; (2) request a predecisional enforcement conference; or (3) request alternative dispute resolution. The licensee did not identify any proprietary information.

Supplemental Inspection Information

PARTIAL LIST OF PERSONS CONTACTED

Bradley Weast, Chief Operating Officer
April Hammond, Director of Radiology
Angie Korte, Nuclear Medicine Technologist
Gibson Duversonne, Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

IP 87130 Nuclear Medicine Programs

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

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))
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))

Closed

030-35944/2022-001-01	NOV	Failure to ensure that written directives for administrations of quantities greater than 30 microcuries of sodium iodide I-131 contained the dosage. (10 CFR 35.40(b)(1))

Discussed

030-35944/2022-001-02	NOV	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))

LIST OF ACRONYMS AND ABBREVIATIONS USED

10 CFR	Title 10 of the *Code of Federal Regulations*
ADAMS	Agencywide Documents Access and Management System
ADR	Alternative Dispute Resolution
AU	Authorized User
AV	Apparent Violation
GFCH	Great Falls Clinic Hospital
I-131	iodine-131
IP	Inspection Procedure
NOV	Notice of Violation
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer