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

August 22, 2022

EA-22-052

April Hammond, Director of Radiology
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 030-35944/2022-001

Dear April Hammond:

This letter refers to the routine, announced inspection that was conducted on March 16, 2022, at your facility in Great Falls, Montana. The inspection was performed to examine activities conducted under your license as they relate to public health and safety and to confirm compliance with the U.S. Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license. 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 enclosed inspection report presents the results of this inspection. The inspector discussed the preliminary inspection findings with you and Kari Cann, Radiation Safety Officer, at the conclusion of the onsite portion of the inspection. On August 16, 2022, a final exit briefing was conducted via videoconference with you and Kari Cann.

Based on the results of this 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 contained required information; and (2) ensure that written directives were dated and signed by an authorized user.

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 Kari Cann during the videoconference exit meeting on August 16, 2022.

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 030-35944/2022-001; EA-22-052" 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. 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. 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 Mary Muessle, 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 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML061240509).

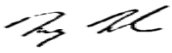
In lieu of a PEC, you may request ADR with the NRC in an attempt to resolve this issue. Alternative dispute resolution is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC employs is mediation. Mediation is a voluntary, informal 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.

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,



Signed by Muessle, Mary
on 08/22/22

Mary C. Muessle, Director
Division of Radiological Safety & Security

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

Enclosure:
NRC Inspection Report 030-35944/2022-001

cc w/Enclosure:
Carter Anderson, Administrator
Division of Quality Assurance
Department of Public Health and Human Services
2401 Colonial Drive
P.O. Box 202953
Helena, MT 59620

CMSC, LLC dba GREAT FALLS CLINIC HOSPITAL - NRC INSPECTION
REPORT 030-35944/2022-001 - DATED AUGUST 22, 2022

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ADAMS ACCESSION NUMBER: ML22230D077

X SUNSI Review by: **JFK**	ADAMS **X** Yes □ No	**X** Publicly Available □ Non-Publicly Available	**X** Non-Sensitive □ Sensitive	Keyword: NRC-002

OFFICE	RIV:MIB	BC:MIB	ACES:TL	RIV: RC	OE	NMSS	OGC	D: DRSS
NAME	JFKatanic	LRoldanOtero	JGroom	DCylkowski	LSreenivas	RSun	RCarpenter	MCMuessle
SIGNATURE	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/RA/ E	/NLO/ E	MCM
DATE	7/26/22	7/29/22	7/27/22	8/01/22	8/11/22	8/11/22	8/11/22	8/22/2022

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U.S. NUCLEAR REGULATORY COMMISSION
REGION IV

Docket No.:	030-35944
License No.:	25-27721-01
Inspection Report No.:	030-37399/2021-001
EA No.:	EA-22-052
Licensee:	CMSC, LLC dba Great Falls Clinic Hospital
Locations Inspected:	Great Falls Clinic Hospital 3010 15th Avenue South Great Falls, Montana 59405 Great Falls Clinic Surgery Center 1509 29th Street South Great Falls, Montana 59405 Great Falls Clinic Specialty Center 3000 15th Avenue South Great Falls, Montana 59405
Inspection Date:	March 16, 2022
Exit Meeting Date:	August 16, 2022
Inspector:	Janine F. Katanic, PhD, CHP Senior Health Physicist Materials Inspection Branch Division of Radiological Safety & 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 030-35944/2022-001

On March 16, 2022, the NRC performed an announced, routine inspection of GFCH. The inspector continued in-office review through July 26, 2022. The scope of the inspection was to examine the activities conducted under the NRC license issued to GFCH and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. 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 NRC license issued to GFCH authorizes uptake, dilution, and excretion studies under Title 10 of the *Code of Federal Regulations* (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.

Under 10 CFR 35.300, the inspection determined that two of the written directives for administrations of quantities greater than 30 microcuries of sodium iodide iodine-131 (I-131) did not contain the dosage. Specifically, the two written directives did not contain the units to indicate the prescribed dose. For prescribed activity, one of the written directives from December 2019 had the numerical value 15 without units of activity and the other written directive from October 2019 had the numerical value of 100 without units of activity.

The inspection also determined that the written directive that had the numerical value of 100 without units of activity was signed and dated by an individual that was not authorized on the NRC license issued to GFCH for either 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131. Accordingly, this individual was not authorized to sign and date the written directive.

Two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives for administrations of quantities greater than 30 microcuries of sodium iodide I-131 contained the dosage, and (2) ensure that written directives were dated and signed by an authorized user (AU) before the administration of sodium iodide I-131 greater than 30 microcuries.

As corrective actions, the licensee provided sufficient information in a license amendment request to authorize the AU for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries.

REPORT DETAILS

1 Program Overview (Inspection Procedure (IP) 87131)

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

On March 16, 2022, the NRC performed an announced, routine inspection of GFCH. The inspector continued in-office review through July 26, 2022. The scope of the inspection was to examine the activities conducted under the NRC license issued to GFCH and to confirm compliance with the NRC's rules and regulations and with the conditions of the license. 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.

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, who is a consultant to GFCH and not a direct employee, is responsible for oversight and licensee compliance at the locations of use listed on the GFCH license.

2 Licensed Activities Requiring a Written Directive (IP 87131)

2.1 Inspection Scope

On March 16, 2022, the NRC performed an announced, routine inspection of GFCH. The inspection consisted of an examination of procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel.

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 May 2018, the only byproduct material utilized by GFCH for 10 CFR 35.300 administrations was sodium iodide iodine-131 (I-131). From May 2018 to March 16, 2022, GFCH had only performed six administrations of sodium iodide I-131 that required a written directive under 10 CFR 35.300. The last administration that required a written directive was performed in December 2019.

At the time of the inspection, there were eight authorized users (AUs) listed on the GFCH license, Amendment No. 20, dated November 25, 2020. Seven of the AUs were authorized for either 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131. As a result, any of these seven AUs could sign and date written directives for oral administrations of quantities greater than 30 microcuries of sodium iodide I-131. The remaining AU on the license, referred to hereafter as AU1, was only authorized on the GFCH license for 10 CFR 35.100 and 10 CFR 35.200 activities, which is for the use of unsealed licensed material for which a written directive is not required (i.e., diagnostic use). This individual, AU1, was therefore not authorized on the GFCH license for either 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131.

The inspector reviewed all six written directives that had been prepared for the administration of sodium iodide I-131. Title 10 CFR 35.40(b)(1) 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. Two of the written directives did not contain the units to indicate the prescribed dosage. In other words, the written directives only contained a numerical value for dosage without a corresponding unit of activity. One of the written directives from December 2019 had the numerical value 15 without units of activity and the other written directive from October 2019 had the numerical value of 100 without units of activity.

Units of activity, such as microcurie and millicurie, are critical to convey the amount or quantity prescribed by an AU. Units are necessary to prevent an administration of an incorrect quantity of byproduct material, which could result in a medical event. In both cases where the units of activity were missing from the written directives, the inspector was able to verify, through other information in the patient records, that the intended unit of activity was millicurie in each case, and that in each case, the patient received the intended prescribed dosage of sodium iodide I-131 and there were no resultant medical events.

The inspector also observed that the written directive that had the numerical value of 100 without units of activity was signed and dated by AU1. 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. As noted, AU1 was not authorized on the GFCH license for either 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131. This was discussed with the licensee, who stated that AU1 was also an AU on another NRC medical license. The licensee believed that AU1 was authorized for either 10 CFR 35.300 activities requiring a written directive or for oral administration of sodium iodide I-131 on the other NRC medical license. The inspector reviewed the other referenced NRC medical license (Benefis Hospitals, NRC license No. 25-12710-01, Docket No. 030-02404, Amendment No. 66, dated July 12, 2021). The inspector found that AU1 was indeed an AU on the license, but only for 10 CFR 35.100 and 10 CFR 35.200 activities.

The NRC inspector requested that the licensee provide information to support whether AU1 was qualified to perform administrations under 10 CFR 35.300 or for oral administration of sodium iodide I-131. The licensee provided this information in a non-publicly available amendment request dated May 13, 2022. Based on a review of the information provided, AU1 did have American Board of Radiology certification from March 2014. Although the certificate did not contain the words “AU Eligible” above the

seal, it was accompanied by a letter stating from the American Board of Radiology that AU1 was “AU eligible.” Therefore, the certification was considered to be adequate. However, AU1 was unable to demonstrate the required supervised clinical case experience from prior to October 2019 when the subject written directive as signed and dated by AU1. Although the information was requested by the inspector, AU1 was not able to produce documentation for the training or supervised case experience for administrations of sodium iodide I-131 they received during their residency or any point thereafter.

Two apparent violations were identified regarding the licensee’s failure to: (1) ensure that written directives contained required information as required by 10 CFR 35.40(b)(1); and (2) ensure that written directives were dated and signed by a qualified authorized user as required by 35.40(a).

Apparent violation of 10 CFR 35.40(b)(1)

Title 10 CFR 35.40(b)(1) 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.

Contrary to the above, in October 2019 and December 2019, the licensee failed to ensure that written directives for administrations of quantities greater than 30 microcuries of sodium iodide I-131 contained the dosage. Specifically, two written directives for administrations of quantities greater than 30 microcuries of sodium iodide I-131 did not contain the dosage, in that the written directives did not indicate the units of activity to specify the dosage.

The licensee’s failure to ensure that written directives contained required information was identified as an apparent violation of 10 CFR 35.40(b)(1). (030-35944/2022-001-01)

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 authorized user before the administration of sodium iodide I-131 greater than 30 microcuries.

Contrary to the above, in October 2019, the licensee failed to prepare written directives that that were dated and signed by an authorized user before the administration of sodium iodide I-131 greater than 30 microcuries. Specifically, 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 authorized user 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 authorized user before the administration of sodium iodide I-131 greater than 30 microcuries was identified as an apparent violation of 10 CFR 10 CFR 35.40(a). (030-35944/2022-001-02)

2.3 Causal Evaluation

A formal root cause analysis was not performed as it was beyond the scope of the inspection. General inspection observations indicated that in recent years, GFCH had a decline in the number of administrations requiring written directives under 10 CFR 35.300. Additionally, the nuclear medicine staff experienced significant turnover during recent years. At the time of the inspection, the nuclear medicine program was staffed by only one nuclear medicine technologist. This nuclear medicine technologist had started in August 2021 and had not yet performed any administrations requiring written directives at GFCH. As a result, the individual was not able to provide insight on the program deficiencies. The previous nuclear medicine technologists who no longer worked at GFCH were unavailable for interview. However, it appeared that the previous nuclear medicine technologists were passive in their approach to written directives, relying on the knowledge and expertise of the AUs, rather than independently verifying information on written directives or verifying AU authorizations in the license.

Although the RSO regularly reviewed written directives as part of routine radiation safety program audits, these audits were not effective to identify the deficiencies associated with the written directives.

2.4 Corrective Actions

On May 13, 2022, the licensee submitted a non-publicly available amendment request regarding AU1. The request was to authorize AU1 for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries. Note that the written directive that AU1 signed and dated in October 2019 prescribed a dose of 100 millicuries of sodium iodide I-131, which is greater than the 33 millicuries that would be authorized if the NRC granted the license amendment. The licensee provided AU1's American Board of Radiology certification from March 2014. Since GFCH does not perform many administrations requiring a written directive, AU1 also provided a preceptor attestation form from an AU at Benefis Hospitals. The preceptor attestation stated that on February 2, 2022, April 14, 2022, and May 11, 2022, AU1 participated in supervised clinical cases involving the oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries. Based on the information provided by the licensee, the GFCH NRC license was amended on June 29, 2022, Amendment No. 21, to authorize AU1 for oral administration of sodium iodide I-131 requiring a written directive in quantities less than or equal to 33 millicuries (ML22180A304).

The licensee has not provided other corrective actions to address such matters as retraining of personnel in preparing written directives, or in the verification of AUs signing and dating written directives against the GFCH license authorizations.

2.5 Conclusions

Two apparent violations were identified regarding the licensee's failure to: (1) ensure that written directives for administrations of quantities greater than 30 microcuries of sodium iodide I-131 contained the dosage, and (2) ensure that written directives were dated and signed by an AU before the administration of sodium iodide I-131 greater than 30 microcuries.

3 Exit Meeting Summary

On August 16, 2022, a final videoconference exit meeting was conducted with April Hammond, Director of Radiology, and Kari Cann, Radiation Safety Officer, 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

April Hammond, Director of Radiology
Jeremy Pack, Executive Director of Ancillary Services
Kari Cann, MS, DABR, Radiation Safety Officer
Blessing Odusola, Nuclear Medicine Technologist

INSPECTION PROCEDURES USED

IP 87131 Nuclear Medicine Programs, Written Directive Required

ITEMS OPENED, CLOSED, AND DISCUSSED

Opened

030-35944/2022-001-01	AV	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))
030-35944/2022-001-02	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))

Closed

None

Discussed

None

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
NRC	U.S. Nuclear Regulatory Commission
PEC	Predecisional Enforcement Conference
RSO	Radiation Safety Officer