



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION IV
1600 EAST LAMAR BOULEVARD
ARLINGTON, TEXAS 76011-4511

November 2, 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 - NOTICE OF VIOLATION;
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 purpose of the inspection was 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. A final exit briefing was conducted by videoconference with you on August 16, 2022. Details of the inspection and two apparent violations were provided to you in the subject inspection report, dated August 22, 2022, Agencywide Documents Access and Management System (ADAMS) Accession No. ML22230D077.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violations by either attending a predecisional enforcement conference, requesting alternative dispute resolution, or providing a written response before we made our final enforcement decision. In a letter dated September 12, 2022 (ML22258A238), you provided a written response to the apparent violations.

Based on the information developed during the inspection and the information you provided in your September 12, 2022, written response to the inspection report, the NRC has determined that two violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice), and the circumstances surrounding them are described in detail in the subject inspection report. The violations involved the failures to ensure that written directives: (A) contained required dosage information as required by Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(b)(1), and (B) were signed and dated by an authorized user as required by 10 CFR 35.40(a).

The NRC considers violations A and B above to be significant violations because of the programmatic failures associated with the failure to prepare written directives in accordance with regulatory requirements. Therefore, these violations have been categorized collectively in accordance with the NRC Enforcement Policy as a Severity Level III problem. The

Enforcement Policy can be found on the NRC's website at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8,000 is considered for a Severity Level III problem.

Because your facility has not been the subject of an escalated enforcement action within the last two routine inspections, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the NRC Enforcement Policy. The NRC has determined that *Corrective Action* credit is warranted based on the prompt and comprehensive corrective actions you implemented. Your corrective actions to address the violation are documented in NRC Inspection Report 030-35944/2022-001 and in your letter dated September 12, 2022.

Therefore, to encourage prompt, and comprehensive correction of violations and in recognition of the absence of previous escalated enforcement action, I have been authorized, after consultation with the Director, Office of Enforcement, not to propose a civil penalty in this case. However, significant violations in the future could result in a civil penalty. In addition, issuance of this Severity Level III problem constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 030-35944/2022-001 and in your letter dated September 12, 2022. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter, the 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 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. The NRC also includes significant enforcement actions on its website at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions>.

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

Sincerely,



Monninger, John signing on behalf
of Morris, Scott
on 11/02/22

Scott A. Morris
Regional Administrator

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

Enclosure:
Notice of Violation

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 - NOTICE OF VIOLATION; NRC INSPECTION REPORT 030-35944/2022-001 - DATED NOVEMBER 02, 2022

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DOCUMENT NAME: [https://usnrc.sharepoint.com/teams/Region-IV-ACES/ACES S Drive/ENFORCEMENT/ _EA CASES-OPEN/Great Falls Hospital EA-22-052 directive/Final Action/NOV_EA-22-052 CMSC Great Falls Hospital.docx](https://usnrc.sharepoint.com/teams/Region-IV-ACES/ACES%20S%20Drive/ENFORCEMENT/_EA%20CASES-OPEN/Great%20Falls%20Hospital%20EA-22-052%20directive/Final%20Action/NOV_EA-22-052%20CMSC%20Great%20Falls%20Hospital.docx)

ADAMS: **ML22292A254**

SUNSI Review By: ACR		ADAMS <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<input checked="" type="checkbox"/> Publicly Available <input type="checkbox"/> Non-Publicly Available	<input checked="" type="checkbox"/> Non-Sensitive <input type="checkbox"/> Sensitive	Keyword: EA-22-052
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DATE	10/19/22	10/07/22	10/24/22	11/02/2022	

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

CMSC, LLC, dba Great Falls Clinic Hospital
Great Falls, Montana

Docket No. 030-35944
License No. 25-27721-01
EA-22-052

During an NRC inspection conducted on March 16, 2022, two violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 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.

- B. 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.

This is a Severity Level III problem (Enforcement Policy Sections 6.3.c.2 and 6.3.c.5).

The NRC has concluded that information regarding: (1) the reason for the violations; (2) the corrective actions that have been taken and the results achieved; and (3) the date when full compliance was achieved is already adequately addressed on the docket in NRC Inspection Report 030-35944/2022-001 and in your letter dated September 12, 2022.

However, if the description therein does not accurately reflect your position or your corrective actions, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 within 30 days of the date of the letter transmitting this Notice of Violation. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation; EA-22-052," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region IV, 1600 East Lamar Blvd., Arlington, Texas 76011-4511, and email it to R4Enforcement@nrc.gov.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

Enclosure

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, to the extent possible, the response should not include any personal privacy or proprietary information so that it can be made available to the public without redaction.

If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

Dated this 2nd day of November 2022