



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
REGION III  
2443 WARRENVILLE ROAD, SUITE 210  
LISLE, ILLINOIS 60532-4352

EA-22-111

February 22, 2023

Dareld LaBeau II  
Manager of Imaging  
Barnes-Jewish St. Peters Hospital  
10 Hospital Dr.  
St. Peters, MO 63376

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO.  
03017414/2022001(DRSS) - BARNES-JEWISH ST. PETERS HOSPITAL

Dear Dareld LaBeau II:

This letter refers to the US Nuclear Regulatory Commission (NRC) inspection conducted on August 3, 2022, at Barnes-Jewish St. Peters Hospital with continued in-office review through November 17, 2022. The purpose of the inspection was to review activities performed under your NRC license to ensure that activities were being performed in accordance with NRC requirements. An exit meeting was held on November 17, 2022, with you to discuss the apparent violation involving the failure to include all required information on the written directive for therapy administrations. Inspection Report No. 03017414/2022001(DRSS) was issued on December 12, 2022, and can be found in the NRC's Agencywide Documents Access and Management System (ADAMS) at accession number ML22342A025. ADAMS is accessible from the NRC web site at <http://www.nrc.gov/reading-rm/adams.html>.

In the letter transmitting the inspection report, we provided you with the opportunity to address the apparent violation identified in the report by either attending a predecisional enforcement conference or by providing a written response before we made our final enforcement decision. In a letter dated January 9, 2023 (ML23013A011), you provided a written response to the apparent violation.

Based on the information developed during the inspection and the information provided in your response, the NRC has determined that a violation of NRC requirements occurred. The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation involved the failure to document the route of administration on written directives for approximately 14 administrations of radium-223 dichloride.

The failure to develop a written directive appropriate for the circumstances is a significant safety concern in that the failure to develop appropriate written directives could result in a medical event. Therefore, this violation has been categorized in accordance with the NRC Enforcement Policy at Severity Level III. In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$8750 is considered for a Severity Level III violation.

Because your facility has not been the subject of escalated enforcement actions within the last two 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 Enforcement

Policy. Corrective actions included: (1) updated all written directive forms with required information on one sheet, including the route of administration; (2) Trained staff on the new written directive forms; (3) developed a new audit form that included the route of administration and changed how the audit will be reported to the Radiation Safety Committee; and (4) committed to using the new form for the first quarter audit of 2023 and report to the RSO and Radiation Safety Committee. Based on the above, credit for *Corrective Action* is warranted.

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 violation constitutes escalated enforcement action that may subject you to increased inspection effort. The NRC also includes significant enforcement actions on its web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

The NRC has concluded that information regarding: (1) the reason for the violation; (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 Inspection Report No. 03017414/2022001(DRSS) and your letter dated January 9, 2023. 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," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room and in the NRC's ADAMS, accessible from the NRC web site 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 personal privacy or proprietary information is necessary to provide an acceptable response, 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 withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (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).

Sincerely,



Signed by Giessner, Jack  
on 02/22/23

John B. Giessner  
Regional Administrator

Docket No. 030-17414  
License No. 24-18968-01

Enclosure: Notice of Violation

cc w/encl: Dr. Constance Courtois, RSO  
State of Missouri

Letter to D. LaBeau II from J. Giessner dated February 22, 2023.

SUBJECT: NOTICE OF VIOLATION; NRC ROUTINE INSPECTION REPORT NO.  
03017414/2022001(DRSS) - BARNES-JEWISH ST. PETERS HOSPITAL

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**OFFICIAL RECORD COPY**

## NOTICE OF VIOLATION

Barnes-Jewish St. Peters Hospital  
St. Peters, Missouri

Docket No. 030-17414  
License No. 24-18968-01  
EA-22-111

During a US Nuclear Regulatory Commission (NRC) inspection conducted on August 3, 2022, with continued in-office review through November 17, 2022, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 of the *Code of Federal Regulations* (10 CFR) 35.40(b)(2) requires, in part, that the written directive for an administration of a therapeutic dosage of unsealed byproduct material other than sodium iodide I-131 must contain the patient or human research subject's name, the radioactive drug, dosage, and route of administration.

Contrary to the above, between approximately 2019 and August 3, 2022, the licensee failed to include all required information on written directives for the administration of therapeutic dosages of radium-223 dichloride. Specifically, the written directives for approximately 14 administrations of radium-223 dichloride did not include the route of administration.

This is a Severity Level III violation (Enforcement Policy Section 6.3.c.2).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved, is already adequately addressed on the docket in Inspection Report No. 03017414/2022001(DRSS) and the licensee's letter dated January 9, 2023. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation, EA-22-111," and send it to the US Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, Region III, 2443 Warrenville Road, Suite 210, Lisle, IL 60532-4352 within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

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 ADAMS, accessible from the NRC web site 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.]

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 22 day of February 2023.