



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

February 22, 2019

Mr. Brant Russell, Chief Operating Officer
Ascension St. John Hospital
22101 Moross Road
Detroit, MI 48236-2172

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002028/2018001(DNMS) AND
NOTICE OF VIOLATION – ASCENSION ST. JOHN HOSPITAL

Dear Mr. Russell:

On November 8-9, 2018, an inspector from the U.S. Nuclear Regulatory Commission (NRC) conducted a routine inspection at your Detroit and Rochester Hills, Michigan, hospitals with continued in-office review through January 25, 2019. 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. The in-office review included a review of package survey results and security-related records that were not available during the on-site inspection. Ms. Deborah Piskura of my staff conducted a final exit meeting by telephone with Ms. Laura T. Smith of your staff on January 25, 2019 to discuss the inspection findings. This letter presents the results of the inspection.

During this inspection, the NRC staff examined activities conducted under your license related to public health and safety. Additionally, the staff examined your compliance with the Commission's rules and regulations as well as the conditions of your license. Within these areas, the inspection consisted of selected examination of procedures and representative records, observations of activities, and interviews with personnel.

Based on the results of this inspection, the NRC has determined that Severity Level IV violations of NRC requirements occurred. The violations were evaluated in accordance with the NRC's 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>. One safety-related violation involving the licensee's failure to monitor the external surfaces of a package, received on November 2, 2018, for radiation levels, no later than three hours after the package was received as required by Title 10 of the *Code of Federal Regulations* (CFR) 20.1906(c) was identified by the inspector and is being cited in the enclosed Notice of Violation (Enclosure 1).

Enclosures 2 & 3 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 & 3, this transmittal letter and Enclosure 1 are decontrolled.

B. Russell

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On November 2, 2018, the radiation oncology department received a “Radioactive Yellow II” labeled package containing approximately 10 curies of iridium-192 as a special form source. After your staff became aware of the delivery, your staff secured the package within a locked cabinet inside your treatment room. For reasons that could not be determined, the staff apparently forgot about the receipt of this package and failed to perform the required surveys. The inspector noted there were no records of the surveys and prompted the staff to perform these package surveys. The device service representative surveyed this package on the afternoon of November 8, 2018, on your behalf. Your corrective actions included adding an entry to your MOSAIQ therapy tracking software to prompt the staff to survey incoming radioactive packages. Your radiation safety officer also committed to review these surveys during her periodic audits.

The other violation is of a security-related nature and is cited in the enclosed, non-public Notice of Violation (Enclosure 2). The violation is being cited because it was identified by the inspector. Details of the violation, as well as the corrective actions that have been taken to restore compliance, are discussed in the enclosed, non-public Security Addendum to the inspection report (Enclosure 3).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence, and the date when full compliance will be achieved is already adequately addressed on the docket in this letter and the security addendum. Therefore, you are not required to respond to this letter unless the description herein 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 Notices.

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’s Public Document Room or from the NRC’s Agencywide Documents Access and Management System (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, proprietary, or safeguards information so that it can be made publicly available without redaction.

B. Russell

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Please feel free to contact Ms. Piskura of my staff if you have any questions regarding this inspection. Ms. Piskura can be reached at 630-829-9867.

Sincerely,

/RA by Michael A. Kunowski Acting for/

Aaron T. McCraw, Chief
Materials Inspection Branch

Docket No. 030-02028
License No. 21-03210-01

Enclosures:

1. Notice of Violation (public)
2. Notice of Violation (non-public)
3. Security Addendum (non-public)

cc w/encls:

Laura T. Smith, M.S, Radiation Safety Officer
Robert Hoban, President

cc w/encl 1: State of Michigan

B. Russell

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Letter to Brant Russell from Aaron McCraw dated February 22, 2019.

SUBJECT: NRC ROUTINE INSPECTION REPORT NO. 03002028/2018001(DNMS) AND
NOTICE OF VIOLATION – ASCENSION ST. JOHN HOSPITAL

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| DATE | 2/20/2019 | | 2/22/2019 | | | | | |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

Ascension St. John Hospital
Detroit, MI

License No. 21-03210-01
Docket No. 030-02028

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted on November 8-9, 2018, with continued in-office review through January 25, 2019, one 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* (CFR) 20.1906(b) requires each licensee to monitor the external surfaces packages labeled with a Radioactive White 1, Yellow II, or Yellow III label for: (1) radioactive contamination, unless the package contains only radioactive material in the form of a gas or in special form as defined in 10 CFR 71.4; and (2) radiation levels, unless the package contains quantities of radioactive material that are less than or equal to the Type A quantity, as defined in 10 CFR 71.4 and Appendix A to Part 71.

Title 10 CFR 20.1907(c) requires licensees to perform the monitoring required by paragraph (b) above, as soon as practicable, but not later than 3 hours after receipt of the package if it is received during the licensee's normal working hours, or not later than 3 hours from the beginning of the next working day if it is received after working hours.

Contrary to the above, on November 2, 2018, the licensee received a package labeled with a Radioactive Yellow II label during working hours, the package was not exempt from the monitoring requirement for radiation levels, and the licensee did not perform the required monitoring within 3 hours after receipt. Specifically, the package received by the licensee contained approximately 10 curies of iridium-192 in special form, and the licensee did not monitor the package until November 8, 2018, a period in excess of 3 hours after receipt.

This is a Severity Level IV violation (Section 6.7).

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 this letter and the subject inspection report. 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, IR 03002028/2018001(DNMS) " 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, Region III, within 30 days of the date of the letter transmitting this Notice.

Enclosures 2 & 3 contain Sensitive Unclassified Non-Safeguards Information. When separated from Enclosures 2 & 3, this transmittal letter and Enclosure 1 are decontrolled.

Enclosure 1

Notice of Violation

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

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.

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

Dated this 22nd day of February, 2019.