



**UNITED STATES  
NUCLEAR REGULATORY COMMISSION**  
REGION I  
2100 RENAISSANCE BOULEVARD, SUITE 100  
KING OF PRUSSIA, PA 19406-2713

June 5, 2017

Richard O. Davis, Ph.D.  
President and Chief Executive Officer  
Sibley Memorial Hospital  
5255 Loughboro Road, N.W.  
Washington, D.C. 20016-2695

**SUBJECT: NRC INSPECTION REPORT NO. 03014754/2016001, SIBLEY MEMORIAL HOSPITAL SITE, WASHINGTON, D.C. AND NOTICE OF VIOLATION**

Dear Dr. Davis:

On September 26 and 27, 2016, Janice Nguyen of this office conducted a safety inspection at the above address of activities authorized by the listed NRC license. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspector, interviews with personnel, and a selective examination of representative records. Additional information provided in your correspondence dated November 9, 2016, December 5 and 13, 2016, April 14, 2017, and the telephone conversation on May 15, 2017, between Dennis Reed and other members of your organization, Esther Houseman of the NRC Office of General Counsel, and this office, were also examined as part of the inspection. The findings of the inspection were discussed with Dennis Reed, Director of Imaging Services, and Jordie Keck, Radiation Safety Officer, of your organization at the conclusion of the inspection on June 1, 2017.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>). The violations involved: A) the failure to have a written directive dated and signed by an authorized user before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)) in accordance with 10 CFR 35.40(a); B) the failure to include an authorized user of each type of use permitted by the license on the Radiation Safety Committee (RSC) in accordance with 10 CFR 35.24(f); and, C) the failure to notify and receive consent in writing from the Commission, prior to an indirect transfer of control of the NRC radioactive materials license to another entity in accordance with 10 CFR 30.34(b)(1).

The violations are cited in the enclosed Notice of Violation (Notice), because the violations were identified by the NRC. The NRC expects licensees to conduct their programs with meticulous attention to detail and high standards of safety and compliance. Because of the potential for radiation exposure to employees and the public which could result from failure to comply with NRC requirements, you must conduct your program according to NRC regulations, the conditions of your NRC license, and the representations made in your application.

During our inspection exit meeting on June 1, 2017, you stated that you have taken corrective and preventative actions to address Violations A and B, that corrective and preventative actions for Violation C are almost complete, and that Sibley Memorial Hospital is committed to radiation safety and to compliance with NRC regulations and licensed conditions. Further, you stated verbally and you documented in your November 9, 2016, December 5 and 13, 2016, and April 14, 2017 correspondence, that you have taken the following corrective and preventative actions:

- A) had a current 35.300 authorized user review the three administrations to confirm that they were appropriate, retrained staff on the administration of I-131, revised the current I-131 policy to indicate that diagnostic I-131 whole body scans in excess of 30 uCi require a written directive, and revised the written directive form to include verbiage intended to draw attention to the fact that the signing authorized user must be listed on the NRC license;
- B) added a 35.300 authorized user to the RSC; and
- C) verbally committed to notify the NRC in writing of the indirect change of control of Sibley Memorial Hospital to The Johns Hopkins Health System Corporation.

Regarding Violation A and B, the NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violation and prevent recurrence is already adequately addressed in our records and in your correspondence dated November 9, 2016, December 5, 2016, and December 13, 2016. Therefore, you are not required to respond to this letter for Violations A and B unless the description of your corrective actions in this letter and your November 9, 2016, December 5, 2016, and December 13, 2016, correspondence 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.

Regarding Violation C, you are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC review of your response to the Notice will also determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (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, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations and guidance are included on the NRC's Web Site at [www.nrc.gov](http://www.nrc.gov); select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's Web Site at [www.nrc.gov](http://www.nrc.gov); select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web Site at: <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

If you have any questions regarding this matter, please contact Janice Nguyen of my staff at (610) 337-5006 or via electronic mail at [janice.nguyen@nrc.gov](mailto:janice.nguyen@nrc.gov).

Thank you for your cooperation.

Sincerely,



James P. Dwyer, Chief  
Medical Branch  
Division of Nuclear Materials Safety  
Region I

Docket No. 030-14754  
License No. 08-07398-03

Enclosure:  
Notice of Violation

cc w/Encl: Jordie Keck, Radiation  
Safety Officer  
District of Columbia

## NOTICE OF VIOLATION

Sibley Memorial Hospital  
Washington, D.C.

Docket No. 030-14754  
License No. 08-07398-03

During an NRC inspection conducted on September 26-27, 2016, three violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

- A. 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 I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)).

Contrary to the above, on July 30, 2014, September 8, 2014, and October 23, 2015, a written directive was dated and signed by a 10 CFR 35.100 and 35.200 authorized user, rather than a 10 CFR 35.392 authorized user (oral administration of sodium iodide I-131 in quantities less than or equal to 33 millicuries) before the administration of I-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)). Specifically, two 35.200 authorized users signed three written directives for the oral administration of 5.0 mCi of I-131 sodium iodide.

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.1.).

Corrective actions included having a current 35.300 authorized user review the three administrations to confirm that they were appropriate, retrain staff on the administration of I-131, revise the current I-131 policy to indicate that diagnostic I-131 whole body scans in excess of 30 uCi require a written directive, and revise the written directive form to include verbiage intended to draw attention to the fact that the signing authorized user must be listed on the NRC license.

- B. 10 CFR 35.24(f) requires, in part, that licensees that are authorized for two or more different types of uses of byproduct material under Subparts E, F, and H, of this part, shall establish a Radiation Safety Committee (RSC) to oversee all uses of byproduct material permitted by the license. The Committee must include an authorized user of each type of use permitted by the license, the Radiation Safety Officer, a representative of the nursing service, and a representative of management who is neither an authorized user nor a Radiation Safety Officer.

Contrary to the above, as of September 26, 2016, Sibley Memorial Hospital's Radiation Safety Committee did not include an authorized user of each type of use permitted by the license. Specifically, the RSC did not include a 10 CFR 35.300 authorized user.

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.3.).

Corrective actions included adding a 35.300 authorized user to the RSC.

- C. 10 CFR 30.34(b)(1) requires that no license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing.

Contrary to the above, during the last quarter of 2010, Sibley Memorial Hospital completed an indirect transfer of control of the NRC radioactive materials license to another entity before the Commission found that the transfer was in accordance with the provisions of the Act and gave its consent in writing. Specifically, The Johns Hopkins Health System Corporation became the sole corporate member of Sibley Memorial Hospital without notification and prior to receiving a consent in writing from the Commission.

This is a Severity Level IV violation (Enforcement Policy Example 6.3.d.7).

Corrective actions included a verbal commitment to notify the NRC in writing of the indirect change of control of Sibley Memorial Hospital to The Johns Hopkins Health System Corporation.

Regarding Violations A and B, 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. 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," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Regarding Violation C, pursuant to the provisions of 10 CFR 2.201, Sibley Memorial Hospital is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This 5<sup>th</sup> day of June 2017