

SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL FOR BYPRODUCT MATERIALS
LICENSE NUMBER 08-07398-03, Sibley Memorial Hospital

DATE: August 31, 2017

DOCKET NO.: 030-14754

LICENSE NO.: 08-07398-03

LICENSEE: Sibley Memorial Hospital
5255 Loughboro Road, N.W.
Washington, DC 20016-2695

TECHNICAL REVIEWER: Janice Nguyen, Senior Health Physicist

SUMMARY AND CONCLUSIONS

Sibley Memorial Hospital is authorized by NRC License 08-07398-03 for the possession and use of byproduct material for the purpose of diagnostic imaging studies and therapeutic procedures permitted by 10 CFR 35.100, 35.200, 35.300, and 35.600. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by Sibley Memorial Hospital (SMH). The indirect transfer resulted from a transaction between SMH and Johns Hopkins Health System Corporation (JHHSC), which occurred on November 1, 2010. Under the terms of the transaction, which did not involve any financial exchange, Sibley became a wholly owned subsidiary corporation of JHHSC and a member of Johns Hopkins Medicine (JHM). The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML17173A423. The ADAMS package consists of the following agency documents: letter dated June 16, 2017, with attachments, letter dated April 14, 2017 (redacted version) (ML17173A425), letter dated June 16, 2017, with attachments, and letter dated April 14, 2017 (non-redacted version) (ML17173A424).

This was a request for post-hoc approval of an indirect license transfer that occurred on November 1, 2010, without receiving written consent from the Commission. The NRC conducted an inspection at the Washington, DC location on September 26-27, 2016, with telephonic exit on June 1, 2017, and issued a Severity Level IV violation for failure to receive written consent for the indirect license transfer in accordance with 10 CFR 30.34(b)(1). SMH submitted a letter dated June 16, 2017, requesting consent to the indirect license transfer as corrective actions for the violation.

The licensee's request for consent to an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2 and following the guidance provided in the NRC's Regulatory Issue Summary 2014-08. No comments were received from members of the public.

The request for consent was reviewed by NRC staff for an indirect transfer of control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000. The NRC staff finds that the information submitted by Sibley Memorial Hospital and Johns Hopkins Health System Corporation sufficiently describes and documents the transaction and commitments made by the both parties.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the application and finds that the proposed transfer of control is in accordance with the Act. The staff finds that, after the transfer of control, Sibley Memorial Hospital remains qualified to use byproduct material for the purpose requested, and continues to have the equipment, facilities, and procedures needed to protect public health and safety, and promote the common defense and security.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, Sibley Memorial Hospital has been an NRC licensee since January 4, 1985. The NRC conducted an inspection at the Washington, DC location on September 26-27, 2016, with telephonic exit on June 1, 2017, and identified three Severity Level IV violations. The first violation was issued because 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 1-131 in quantities less than or equal to 33 millicuries) before the administration of 1-131 sodium iodide greater than 1.11 megabecquerels (MBq) (30 microcuries (uCi)), contrary to 10 CFR 35.40(a). The second violation was issued because Sibley Memorial Hospital's Radiation Safety Committee did not include an authorized user of each type of use permitted by the license, contrary to 10 CFR 35.24(f). The third violation was issued because 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 on November 1, 2010, without notification and prior to receiving written consent from the Commission. The commitments made by Sibley Memorial Hospital and Johns Hopkins Health System Corporation state that there will be:

- A. no change to the radiation safety officer listed on the NRC license;
- B. no change in personnel involved in licensed activities;
- C. no change in the locations, facilities, and equipment authorized in the NRC license;
- D. no change in the radiation safety program authorized in the NRC license; and
- E. no change in the organization's name listed in the NRC license.

Further, the licensee will maintain required surveillance records and decommissioning records as required by NRC regulations.

Johns Hopkins Health System Corporation wholly-owns the following subsidiaries that hold radioactive materials licenses with the State of Maryland: The Johns Hopkins Hospital (license numbers 07-005-01, 03, 05, 06, 08), Johns Hopkins Bayview Medical Center, Inc. (license number 07-008-07), Howard County General Hospital, Inc. (27-016-01), Suburban Hospital, Inc. (license number 31-314-01), and Johns Hopkins Community Physicians, Inc. (31-110-01). The Johns Hopkins Health System Corporation along with The Johns Hopkins University make up Johns Hopkins Medicine. For security purposes, Sibley Memorial Hospital and Johns Hopkins Health System Corporation, the ultimate parent post-closing, are considered to be known entities following the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license," September 3, 2008 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use.

Sibley Memorial Hospital is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 08-07398-03.

REGULATORY FRAMEWORK

Sibley Memorial Hospital's License No. 08-07398-03 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the transfer of control is in accordance with the provisions of the Act and give its consent in writing. 10 CFR 30.34(b) states: "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."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15. Sibley Memorial Hospital's request for consent describes an indirect transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML17173A423. The ADAMS package consists of the following agency documents: letter dated June 16, 2017, with attachments, letter dated April 14, 2017 (redacted version) (ML17173A425), letter dated June 16, 2017, with attachments, and letter dated April 14, 2017 (non-redacted version) (ML17173A424). After completion of the sale, Sibley Memorial Hospital continued as the licensee and remained in control of all licensed activities under Materials License No. 08-07398-03. The NRC staff finds that the request for consent adequately provides a complete and clear description of the transaction and is consistent with the guidance provided in Appendix F of NUREG-1556, Volume 15.

TRANSFeree'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by Sibley Memorial Hospital and Johns Hopkins Health System Corporation sufficiently describes and documents the commitments made by both parties and is consistent with the guidance in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by the licensee with regard to an indirect transfer of control of byproduct materials license No. 08-07398-03 and consents to the transaction pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, the submitted information sufficiently describes the transaction; documents the understanding of the license and commitments of the transferee; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; and provides that, in the future, the transferee will abide by all existing commitments on the license.

Therefore, the staff concludes that the proposed transfer of control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.