SAFETY EVALUATION REPORT PROPOSED TRANSFER OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER 06-00679-01, SAINT MARY'S HOSPITAL, INC.

- **DATE:** April 17, 2017
- **DOCKET NO.:** 030-01243
- LICENSE NO.: 06-00679-01
- LICENSEE: Saint Mary's Hospital, Inc. 56 Franklin Street Waterbury, Connecticut 06706

TECHNICAL REVIEWER: Shawn Seeley

SUMMARY AND CONCLUSIONS

Saint Mary's Hospital, Inc. (SMH) is authorized by U.S. Nuclear Regulatory Commission (NRC) License 06-00679-01 for the possession and use of byproduct material for purposes of medical diagnoses and therapy. The NRC staff reviewed a notification dated November 14, 2016, of the acquisition of SMH by Trinity Health – New England, Inc. f/k/a Saint Francis Care, Inc. (TH-NE) on August 1, 2016. Thus, SMH and TH-NE effectively requested post-hoc approval to transfer control of the license. SMH and TH-NE did not comply with NRC regulations as they did not receive the NRC's prior written approval for this transfer of control as required by 10 CFR 30.34(b) and Section 184 of the Atomic Energy Act of 1954, as amended.

Following the acquisition by the TH-NE on August 1, 2016, all SMH ownership units were transferred to TH-NE and TH-NE became the sole corporate member of the licensee. The transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML16348A036 [letters dated November 14, 2016 (ML16348A037) and March 6, 2017 (ML17076A272)].

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, Rev. 1, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated March 2016. The NRC staff finds that the information submitted by SMH sufficiently describes and documents the transaction and commitments made by TH-NE and SMH.

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, since the acquisition, SMH remained qualified to use byproduct material for the purpose requested, and will continue to have the equipment, facilities, and procedures needed to protect public health and safety, and promote the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web-Based Licensing System (WBL), SMH has been an NRC licensee authorized to use byproduct material for medical purposes since January 27, 1987.

The NRC conducted a main office inspection of SMH on December 16, 2014, and no violations were identified during this inspection. The commitments made by SMH and TH-NE state that, absent NRC approval, TH-NE (License No. 06-00679-01):

- A. will not change the radiation safety officer listed in the NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized in the NRC license;
- D. will not change the radiation safety program authorized in the NRC license;
- E. will not change the organization's name listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

For security purposes, TH-NE is considered a known entity following the guidance provided by the NRC's Office of Nuclear Materials 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.

TH-NE is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 06-00679-01. Under the acquisition, the transferee, TH-NE, has reserved to itself certain powers over the Licensee, including the power to:

- (a) Approve the amendment or restatement of the Certificate of Incorporation and Bylaws of the Licensee, in whole or in part, and recommend the same to Trinity Health for adoption;
- (b) Appoint and remove members of the Licensee's Board of Directors;
- (c) Appoint and remove the President of the Licensee;
- (d) Approve the strategic plan of the Licensee;
- (e) Approve Significant Finance Matters;
- (f) Approve the annual operating and capital budgets of the Licensee;
- (g) Approve any merger, consolidation, transfer or relinquishment of membership rights, or the sale of all or substantially all of the operating assets of the Licensee; and

- (h) Approve any dissolution, winding up or abandonment of operations, liquidation, filing of action in bankruptcy, receivership or similar action affecting the Licensee; and
- Approve all other matters and take all other actions reserved to members of nonprofit corporations by the laws of the state of Connecticut.

REGULATORY FRAMEWORK

SMH License No. 06-00679-01 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The NRC is required by 10 CFR 30.34(b) to determine if the transfer of control is in accordance with the provisions of the Act and give its consent to the transaction in writing.

10 CFR 30.34(b)(1) 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, Rev. 1. The central issue is whether the authority over the license has changed. SMH's request for consent describes an indirect transfer of control resulting from a acquisition by TH-NE. Following the completion of the acquisition, SMH continued operating as it did before the acquisition.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS package accession number ML16348A036 [letters dated November 14, 2016 (ML16348A037) and March 6, 2017 (ML17076A272)]. After completion of the acquisition, SMH retained licensed activities under NRC Materials License No. 06-00679-01. 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, Rev. 1.

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

The NRC staff finds that the information submitted by SMH sufficiently describes and documents the commitments made by both parties, and is consistent with the guidance in NUREG-1556, Volume 15, Rev. 1.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this consent to the described transfer of control is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by both parties with regard to an indirect transfer of control of byproduct materials License No. 06-00679-01 and consents to the transaction pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction, documents the licensee's commitments, and demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records. The submitted information also demonstrates that the licensee will abide by all existing commitments in the license, consistent with the guidance in NUREG-1556, Volume 15, Rev 1.

Therefore, the NRC staff concludes that the transfer of control does 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.