SAFETY EVALUATION REPORT PROPOSED TRANSFER OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER 06-09522-01. GREENWICH HOSPITAL ASSOCIATION

DATE:

August 28, 2019

DOCKET NO.:

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LICENSE NO.:

06-09522-01

LICENSEE:

Greenwich Hospital Association

5 Perryridge Road

Greenwich, Connecticut 06830

TECHNICAL REVIEWER:

Penny Lanzisera

SUMMARY AND CONCLUSIONS

Greenwich Hospital Association (GHA) is authorized by U.S. Nuclear Regulatory Commission (NRC) License Number 06-09522-01 for the possession and use of byproduct material for the purpose of medical diagnosis and therapy. The NRC staff reviewed a post hoc request for consent to a previously completed indirect transfer submitted by GHA in letter dated May 28, 2019 [Agencywide Documents Access and Management System (ADAMS) Accession Number ML19162A296], as supplemented by letter dated June 14, 2019 (ADAMS Accession Number ML19169A302). The indirect transfer was completed in 1998 when Yale New Haven Health Services Corporation (YNHHS) became the sole corporate member of Greenwich Health Care Services, Inc. (GHCSI), and at that time GHCSI was the sole corporate member of GHA. That same year (i.e., 1998), GHA amended its Certificate of Incorporation to re-name the corporate entity Greenwich Hospital. In addition, in 2016, GHSCI merged with and into Greenwich Hospital (formerly GHA), with Greenwich Hospital (GH) as the surviving corporation and YNHHS as the sole corporate member. These transactions were completed without first requesting and obtaining the NRC's prior written approval as required by Section 30.34(b) of Title 10 of the Code of Federal Regulations (10 CFR) and section 184 of the Atomic Energy Act of 1954, as amended (the Act).

YNHHS is a Connecticut non-stock corporation. GHA (now known as GH after the name change in 1998) is also a Connecticut nonstock corporation and holds the NRC license noted above. As a result of the 1998 member substitution transaction, the Chief Executive Officer of YNHHS (or designee) serves on the Board of Trustees of GH. Even after the transactions noted herein, the assets of GH have remained with and under the control of GH, and GH has maintained a local fiduciary board, its own NRC license, medical staff, management, facility, operational staff, and tax identification number. GH has also maintained the same physical address, policies and procedures, national provider identifier, and control of clinical programs. The request for consent to the indirect transfer of control, requests for additional information and responses are available at ADAMS package accession number ML19162A295.

The licensee's request for consent to an indirect transfer of control 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 as 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," published June 2016 (ADAMS Accession No. ML16181A003). The NRC staff finds that the information submitted by GHA in the letter received May 28, 2019, and additional information submitted June 14, 2019, sufficiently describes and documents the transaction and commitments made by GHA and YNHHS.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954 (the Act), as amended, the NRC staff has reviewed the application and finds that, other than a failure to obtain the NRC's prior written approval of the indirect transfer of control, the proposed transfer of control, and requested name change to GH, is in accordance with the Act. The NRC staff finds that following the transaction, GH remains qualified to use byproduct material for the purpose requested and will have the equipment, facilities, and procedures needed to protect public health and safety and promote the common defense and security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing System (WBL), GHA has been authorized to use byproduct material for medical purposes since April 5, 1991. The NRC conducted a main office inspection of GHA on May 15, 2017, and no violations were noted. The commitments made by GHA and YNHHS state that, absent NRC approval, GHA and now GH:

- A. will not change the radiation safety officer listed in the NRC license issued to GHA (License No. 06-09522-01);
- 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; and
- E. will keep required surveillance records and decommissioning records.

Further, the licensee is requesting a name change to Greenwich Hospital and will maintain required surveillance records and decommissioning records as required by NRC regulations.

YNHHS is a Connecticut non-stock corporation that owns and operates a large teaching medical center, Yale-New Haven Hospital (YNHH), in New Haven, Connecticut, under License Number 06-00819-03. According to NRC's WBL, YNHH has been an NRC licensee since August 13, 1985. Therefore, YNHH is considered a known entity following the guidance provided by the NRC's Nuclear Material Safety and Safeguards "Checklist To Provide a Basis for Confidence that Radioactive Materials Will Be Used as Specified on the License," January 29, 2019 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.

GHA is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 06-09522-01.

REGULATORY FRAMEWORK

Section 184 of the Atomic Energy Act of 1954, as amended, prohibits the transfer of control of any license unless the Commission finds that the transfer is in accordance with the Act and consents to the transfer in writing.

License No. 06-09522-01 was issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material.

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. GHA's request for consent describes an indirect transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS package accession number ML19162A295, which includes a description of the 1998 member substitution transaction provided in the letter dated May 28, 2019 (ADAMS Accession Number ML19162A296), as supplemented by letter dated June 14, 2019 (ADAMS Accession Number ML19169A302). With the exception of licensee's failure to request and obtain the NRC's prior written approval of the license transfer, 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 E 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 GHA (now renamed GH) and YNHHS sufficiently describes and documents the commitments made by the transferee and is consistent with the guidance in NUREG-1556, Volume 15, Rev. 1.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required because this approval of the described transfer of control and the associated administrative license amendment are categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The NRC staff has reviewed the request for transfer of control and name change of byproduct materials License No. 06-09522-01 and, pursuant to 10 CFR 30.34(b), consents to the indirect transfer of control and name change.

Consistent with the guidance in NUREG-1556, Volume 15, Revision 1, the submitted information sufficiently describes the transaction, documents the transferee's understanding of the license and commitments, demonstrates that personnel have the experience and training to properly implement and maintain the license, and confirms that personnel will maintain the existing records. The submitted information also demonstrates that the transferee will abide by all existing commitments to the license, consistent with NRC regulations and the guidance in NUREG 1556, Volume 15.

Therefore, the NRC 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.