

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 13-15399-02, INDIANA UNIVERSITY HEALTH STARKE HOSPITAL**

DATE: 03/14/2016
DOCKET NO.: 030-35485
LICENSE NO.: 13-15399-02
LICENSEE: INDIANA UNIVERSITY HEALTH STARKE HOSPITAL

TECHNICAL REVIEWER: Cassandra F. Frazier

SUMMARY AND CONCLUSIONS

Indiana University Health Starke Hospital is authorized by NRC License 13-15399-02 to possess and use byproduct material for the purposes of human studies as permitted by 10 CFR 35.100 and 35.200. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct transfer of ownership and control submitted by Indiana University Health Starke Hospital that will result from a transfer of assets between Indiana University Health Starke Hospital, LLC d/b/a Indiana University Health Starke Hospital, an Indiana limited liability company and Knox Hospital Company, LLC, a Delaware limited liability company. This transfer of assets will result in a name change of the licensee from Indiana University Health Starke Hospital to Knox Hospital Company, LLC d/b/a Starke Hospital. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession numbers ML15356A465, ML16035A406, and ML16077A174.

The request for consent was reviewed by NRC staff for a direct change in control of a 10 CFR Part 30 license using the guidance in NUREG-1556, Volume 15, "Consolidated Guidance About Materials Licenses - 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 Indiana University Health Starke Hospital sufficiently describes and documents the transaction and commitments made by Indiana University Health Starke Hospital and Knox Hospital Company, LLC.

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 change of control is in accordance with the Act. The staff finds that, after the change of control, Indiana University Health Starke Hospital (the name will change to Knox Hospital Company, LLC d/b/a Starke Hospital) will remain 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 promotes the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing System (WBL), Indiana University Health Starke Hospital has been an NRC licensee since October 11, 2000. The name at that time of the initial license was Starke Memorial Hospital. The NRC conducted a main office inspection of Indiana University Health Starke Hospital on August 3, 2011, and one

violation was identified during this inspection. The violation is described in Adams accession number ML11319A100. The commitments made by Knox Hospital Company, LLC and Indiana University Health Starke Hospital (License No. 13-15399-02) state that it:

- 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 change the organization's name listed in the NRC license from Indiana University Health Starke Hospital to Knox Hospital Company, LLC d/b/a Starke Hospital;
- E. will not change the radiation safety program authorized in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

Based on the information in the preceding paragraphs and the guidance provided by the NRC's Office of Nuclear Materials Safety and Safeguards "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license", September 3, 2008 revision, for security purposes, Knox Hospital Company, LLC d/b/a Starke Hospital is a known entity. 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.

Indiana University Health Starke Hospital is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 13-15399-02.

REGULATORY FRAMEWORK

Indiana University Health Starke Hospital, License No. 13-15399-02, 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 change 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. As discussed in NUREG-1556, Volume 15, NRC is generally using the term "change of control" rather than the statutory term "transfer" to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. Indiana University Health Starke Hospital request for consent describes a direct change of control resulting from a planned transfer of assets between Indiana University Health Starke Hospital, LLC, an Indiana limited liability company

and Knox Hospital Company, LLC, a Delaware limited liability company and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession numbers ML15356A465, ML16035A406, and ML16077A174. After completion of the asset transfer, Knox Hospital Company, LLC d/b/a Starke Hospital will be the licensee and be in control of all licensed activities under Materials License No. 13-15399-02. 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 Indiana University Health Starke Hospital sufficiently describes and documents the commitments made by Knox Hospital Company, LLC 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)(14)(xi).

CONCLUSION

The staff has reviewed the request for consent submitted by both parties with regard to a direct change of control of byproduct materials license No. 13-15399-02 and approves the application pursuant to 10 CFR 30.34(b).

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

Therefore, the staff concludes that the proposed change in 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.