



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

APR 27 2015

Robert A. Conner, M.D.
Radiation Safety Officer
Fort Wayne Indiana Ancillary
Services, LLC (on and after June 1, 2015)
The Imaging Center (until June 1, 2015)
7631 West Jefferson Blvd.
Fort Wayne, IN 46804

Dear Dr. Conner:

This refers to your letters dated January 26, 2015, signed by your outside counsel, Evelyn Hill; February 9, 2015 (with attachments); and April 23, 2015 (with attachments), describing a two - step change of control transaction that is expected to occur on or about June 1, 2015.

These letters describe the transaction as an Asset Purchase Agreement wherein Fort Wayne Indiana Ancillary Services, LLC, will temporarily acquire substantially all of the assets of The Imaging Center. After conformation of the assets, Fort Wayne Indiana Ancillary Services, LLC, will permanently transfer ownership to IOM Health System, L.P., d/b/a Lutheran Hospital of Indiana.

Our review has concluded that this transaction will result in changes of control for The Imaging Center and that the transaction's steps will not result in any changes that affect the license or licensed program aside from the name changes.

Your letters have been reviewed by our staff. We have concluded that The Imaging Center will experience two changes of ownership or control involving NRC-regulated materials under your License No. 13-26508-01.

NRC hereby consents to the change of ownership transactions as described in your letters dated January 26, 2015, signed by your outside counsel, Evelyn Hill; February 9, 2015 (with attachments); and April 23, 2015 (with attachments).

It is important to note that, upon the completion of the conformation of the assets under the temporary ownership of Fort Wayne Indiana Ancillary Services, LLC, the second step in the transaction process will take place and the name on your license will need to be changed again by us.

Please submit an amendment request making the name change amendment request by preparing a written business letter, addressed to my attention at the above address, as "additional information to control number 585825." You may model this letter as you have prepared the others submitted for the changes in control thus far.

It is especially important that this request be in writing, currently dated, and contain the authorized signatures of management representatives for both Fort Wayne Indiana

Ancillary Services, LLC, and IOM Health System, L.P., d/b/a Lutheran Hospital of Indiana.

Please refer to the Information Notice, IN 89-25, Rev. 1 and 10 CFR Part 30 for guidance concerning future changes of ownership and/or control of licensed activities. The IN can be found on our website at:

<http://www.nrc.gov/reading-rm/doc-collections/gen-comm/info-notices/1989/in89025r1.html>

and 10 CFR 30 can be found at:

<http://www.nrc.gov/reading-rm/doc-collections/cfr/part030/>

Only the name of your license has changed in relation to your licensed program so Amendment No. 05 is enclosed. We appreciate the opportunity to review the description of your change of control letters with respect to compliance with 10 CFR 30.35 (b)(4). If you have any questions concerning this matter please contact me at either (630) 829-9841 or (800) 522-3025, ext. 9841. My fax number is 630-515-1078. My email address is colleen.casey@nrc.gov.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of the enclosed license amendment, Safety Evaluation Report (SER) and this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

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/regulatory/enforcement/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.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 13-26508-01
Docket No. 030-33221

Enclosures:

1. Amendment No. 05
2. SER dated April 27, 2015

**SAFETY EVALUATION REPORT
CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
13-26508-01, THE IMAGING CENTER**

DATE: April 27, 2015

DOCKET NO.: 030-33221

LICENSE NO.: 13-26508-01

LICENSEE: The Imaging Center
7631 West Jefferson Boulevard
Fort Wayne, Indiana

TECHNICAL REVIEWER: Colleen Carol Casey

SUMMARY AND CONCLUSIONS

The Imaging Center is authorized by NRC License 13-26508-01 for the possession and use of byproduct material for purposes of diagnostic uses in humans in unsealed forms. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed requests for consent to a direct license transfer submitted by The Imaging Center that will result from the a two - step process involving execution of an Asset Purchase Agreement between Fort Wayne Indiana Ancillary Services, LLC ("the Affiliate"), an interim company affiliated with IOM Health System, L.P. d/b/a Lutheran Hospital of Indiana ("the Hospital") and The Imaging Center. The licensee's requests dated January 26, 2015, February 9, 2015, and April 23, 2015, were not identified explicitly as requests for "direct transfers of control" but NRC staff considered that the requests implicitly constituted as much. The Affiliate will purchase substantially all of the assets of the Imaging Center on or about June 1, 2015 as the first step in the change of control process.

Upon closing, the Affiliate will hold the Assets of The Imaging Center temporarily while the Assets are being conformed to the Hospital's standards. Once the conformation is made, which is expected to take about 45 days, the Affiliate will transfer the Assets to the Hospital, under the new permanent name of IOM Health System, L.P. d/b/a Lutheran Hospital of Indiana ("the Hospital", as above). The Hospital will operate The Imaging Center as an outpatient department. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession numbers ML15027A548, ML15048A158 and ML15114A467.

The original correspondence dated January 26, 2015, was characterized by the licensee as a "notification of proposed transaction," and was signed only by an attorney serving as outside counsel, which was unacceptable and contrary to 10 CFR 35.12(a). Information addressing the transaction as a change of control was included in the initial correspondence. Two subsequent letters, signed by appropriate management representatives, requested NRC's consent to the planned changes in control. The correspondence was reviewed by NRC staff and was considered to constitute requests for direct changes in control of a 10CFR 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 The Imaging Center sufficiently describes and documents the transactions and commitments made by the Affiliate, the Hospital and The Imaging Center.

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 letters and finds that the proposed changes in control are in accordance with the Act. The staff finds that, after the changes of control, The Imaging Center will remain qualified to use byproduct material for the purposes 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 Licensing Tracking System (LTS), The Imaging Center has been an NRC licensee since November 10, 1993. The NRC conducted a main office inspection of The Imaging Center on October 29, 2013, and no violations were identified during this inspection. The commitments made by The Imaging Center, the Affiliate and the Hospital state that The Imaging Center's License No. : 13-26508-01:

- 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 change the organization's name (once temporarily and once permanently) listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

As a result of these transactions, the Affiliate will temporarily own and operate the Imaging Center as an outpatient facility. Subsequently the Hospital will own and operate The Imaging Center as an outpatient facility of the Hospital. Therefore, for security purposes, the Affiliate and the Hospital are considered known entities, following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "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.

The Imaging Center is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 13-26508-01.

REGULATORY FRAMEWORK

The Imaging Center's License No. 13-26508-01, 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 changes in control are 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-1 556, 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.

The Imaging Center's requests for consent describe a direct change of control resulting from the Asset Purchase Agreement with the Affiliate, and then with the Hospital, as the new owners for The Imaging Center. As of the completion of the first transaction, which is expected to take place on June 1, 2015, The Imaging Center will directly become owned by the Affiliate and, as such, the transfer requires NRC consent. After the Assets conformation has been concluded, approximately 45 days after the June 1, 2015, closing, the Affiliate will directly become owned by the Hospital and, as such, the transfer requires NRC consent.

The Affiliate will have to request an amendment from NRC after the Assets conformation has concluded, in order to change the name permanently to IOM Health System, L.P. d/b/a Lutheran Hospital of Indiana.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession numbers ML15027A548, ML15048A158 and ML15114A467. After completion of both steps in the transaction of the Asset Purchase Agreement, and conformation of Assets, IOM Health System, L.P. d/b/a Lutheran Hospital of Indiana will continue as the licensee and remain in control of all licensed activities under Materials License No. 13-26508-01. The NRC staff finds that the requests for consent adequately provide complete and clear descriptions of the transactions, and are 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 The Imaging Center sufficiently describes and documents the commitments made by The Imaging Center, the Affiliate and the Hospital 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 requests for consent submitted by both parties with regard to a direct change of control of byproduct materials license No. 13-26508-01 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the steps in 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 changes 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.