



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

Sharon Updike  
Radiation Safety Officer  
Methodist Physician Group/Methodist Hospital  
200 E. 86<sup>th</sup> Place  
Merrillville, IN 46410

JUL 20 2016

Dear Ms. Updike:

This refers to the letter dated April 11, 2016, signed by Harish Shah, M.D., as Administrative Officer for Cardiovascular Clinics, P.C. and by W. Wright Alcorn, Vice President of Operations for The Methodist Hospitals, Inc. This letter described a change of ownership and control transaction that occurred on May 1, 2016.

This letter describes the transaction as an asset purchase agreement for The Cardiovascular Clinics, P.C. with The Methodist Hospitals, Inc.

Our review has concluded that this transaction resulted in a change of ownership and control for Cardiovascular Clinics, P.C. and that the transaction has resulted in the change of the name of the licensee only to the new name of "Methodist Physician Group/Methodist Hospital."

Your letter has been reviewed by our staff. We have concluded that Cardiovascular Clinics, P.C. has experienced a change of ownership and control involving NRC-regulated materials under your License No. 13-32122-01.

NRC hereby consents to the change of ownership transaction as described in your letter dated April 11, 2016, signed by Harish Shah, M.D., as Administrative Officer for Cardiovascular Clinics, P.C. and by W. Wright Alcorn, Vice President of Operations for The Methodist Hospitals, Inc.

Only the name of the licensee in Subitem No. 1 and the last condition of your license have changed in relation to your licensed program so Amendment No. 9 is enclosed. At this time we also deleted Condition No.13, as it appeared on Amendment No. 09, because we have added 10 CFR Part 71 to the Preamble at the top of the first page of your license instead.

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).

Please note that, in your next amendment request, we would find it helpful to have the fax number and email address for your Radiation Safety Officer, in order to complete our records.

If you have any questions concerning these matters 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.

S. Updike

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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. 13-32122-01  
Docket No. 030-34833

Enclosures:

1. Amendment No. 10
2. SER dated July 20, 2016

**SAFETY EVALUATION REPORT  
CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER  
13-32122-01, CARDIOVASCULAR CLINICS, P.C.**

**DATE:** July 20, 2016

**DOCKET NO.:** 030-34833

**LICENSE NO.:** 13-32122-01

**LICENSEE:** Cardiovascular Clinics, P.C.  
200 E. 86<sup>th</sup> Place  
Merrillville, IN 46410

**TECHNICAL REVIEWER:** Colleen Carol Casey

**SUMMARY AND CONCLUSIONS**

Cardiovascular Clinics, P.C. is authorized by NRC License 13-32122-01 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 a request for consent to a direct license transfer submitted by Cardiovascular Clinics, P.C. that resulted from an asset purchase agreement with The Methodist Hospital, Inc. on May 1, 2016. The licensee's request dated April 11, 2016, did not explicitly identify its letter as a request for "a direct transfer of control" but NRC staff considered that the request implicitly constituted as much.

The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession ML16112A261.

The licensees' letter dated April 11, 2016, signed by appropriate management representatives for both parties, requested NRC's consent to the change in control. This letter also contained information pertaining to a change to the affected license.

The letter dated April 11, 2016, was reviewed by NRC staff and considered to constitute a request for consent to direct changes 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 Cardiovascular Clinics, P.C. sufficiently describes and documents the transaction and commitments made by Cardiovascular Clinics, P.C. and The Methodist Hospitals, Inc.

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 letter dated April 11, 2016, and finds that the change in control was in accordance with the Act. The staff finds that Cardiovascular Clinics, P.C. remains qualified to use byproduct material for the purposes requested, and continues 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), Cardiovascular Clinics, P.C. has been an NRC licensee since September 16, 1998. The NRC conducted an inspection of Cardiovascular Clinics, P.C. on January 25, 2014, and no violations were identified during this inspection. The commitments made by Cardiovascular Clinics, P.C. and The Methodist Hospitals, Inc. state that Cardiovascular Clinics, P.C. License No. 13-32122-01:

- A. has not changed 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. has changed the organization's name listed in the NRC license; and
- F. will keep regulatory required surveillance records and decommissioning records.

As a result of this transaction, The Methodist Hospitals, Inc. owns and operates this facility. The Methodist Hospitals, Inc. also has at least one other NRC-licensed facility in Indiana, according to data obtained from the NRC's WBL. Therefore, for security purposes, The Methodist Hospitals, Inc. is considered a known entity, 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.

Cardiovascular Clinics, P.C. is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 13-32122-01.

## **REGULATORY FRAMEWORK**

Cardiovascular Clinics, P.C.'s License No. 13-32122-01 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 change in 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-I 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 Cardiovascular Clinics, P.C. request for consent describes a direct change of control resulting from the asset purchase agreement with The Methodist Hospitals Inc., as the new owner for Cardiovascular Clinics, P.C. As the completion of the transaction took place on May 1, 2016, Cardiovascular Clinics, P.C. directly became owned by The Methodist Hospitals, Inc. and, as such, the transfer required NRC consent.

### **DESCRIPTION OF TRANSACTION**

The transaction is described in ADAMS accession number ML16112A261. Since the transaction date of May 1, 2016, The Methodist Hospitals, Inc. has continued as the licensee and remains in control of all licensed activities under Materials License No. 13-32122-01. The NRC staff finds that the request for consent adequately provides complete and clear descriptions 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 Cardiovascular Clinics, P.C. sufficiently describes and documents the commitments made by Cardiovascular Clinics, P.C. and The Methodist Hospitals, Inc. 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. 13-32122-01 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently describes the transaction; documents the understanding of the licensee and commitments; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they have and 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.