

**SAFETY EVALUATION REPORT
CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
21-26330-01, DOWNRIVER CARDIOLOGY CONSULTANTS, P.C.**

DATE: May 19, 2015

DOCKET NO.: 030-32396

LICENSE NO.: 21-26330-01

LICENSEE: Downriver Cardiology Consultants, P.C.
23050 West Road
Suite 120
Brownstown, MI

TECHNICAL REVIEWER: Colleen Carol Casey

SUMMARY AND CONCLUSIONS

Downriver Cardiology Consultants, P.C. is authorized by NRC License 21-26330-01 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 Downriver Cardiology Consultants, P.C. that resulted from the acquisition of the hard assets and employed physicians of Downriver Cardiology Consultants, P.C. by Henry Ford Wyandotte Hospital on June 1, 2012. The licensee's requests dated March 23, 2015, and March 27, 2015, were not identified explicitly as requests for "direct transfers of control" but NRC staff considered that the requests implicitly constituted as much.

The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession numbers ML15086A252 and ML15089A165.

The original correspondence from Downriver Cardiology Consultants, P.C. dated February 27, 2015, contained errors in signatories, assumptions, conclusions and misunderstandings made by the licensee directing NRC's actions regarding the change in control which rendered it unsuitable for use as a request for consent to the change in control. This letter was disregarded in NRC's review of the request for consent to the change in control.

Two subsequent letters, dated March 23, 2015, and March 27, 2015, signed by appropriate management representatives, requested NRC's consent to the change in control. These letters also contained information pertaining to changes to another NRC license, Wyandotte Hospital's license no. 21-12930-01, and references to changes to another facility, Henry Ford Health Center – Brownstown, which was excluded from the review. The exclusions are noted in Condition No. 14.B. The licensee was advised to submit these changes under separate cover as amendment requests to the other affected license(s), apart from this review.

The letters dated March 23, 2015, and March 27, 2015, were reviewed by NRC staff and were considered to constitute requests for consent to 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 Downriver Cardiology Consultants, P.C. sufficiently describes and documents the transaction and commitments made by Downriver Cardiology Consultants, P.C. and Henry Ford Wyandotte Hospital.

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 dated March 23, 2015, and March 27, 2015, and finds that the change in control was in accordance with the Act. The staff finds that Downriver Cardiology Consultants, P.C., now known by the new name of "Henry Ford Wyandotte Hospital," 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 Licensing Tracking System (LTS), Downriver Cardiology Consultants, P.C. has been an NRC licensee since August 8, 1991. The NRC conducted an inspection of Downriver Cardiology Consultants, P.C. on August 21, 2012, and no violations were identified during this inspection. The commitments made by Downriver Cardiology Consultants, P.C. and Henry Ford Wyandotte Hospital state that Downriver Cardiology Consultants, P.C.'s License No. 21-26330-01:

- A. has 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, Henry Ford Wyandotte Hospital owns and operates this facility. Therefore, for security purposes, Henry Ford Wyandotte Hospital 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.

Downriver Cardiology Consultants, P.C. is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 21-26330-01.

REGULATORY FRAMEWORK

Downriver Cardiology Consultants, P.C.'s License No. 21-26330-01, 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-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.

Downriver Cardiology Consultants, P.C.'s request for consent describes a direct change of control resulting from the hard asset and employed physicians acquisition of Downriver Cardiology Consultants, P.C., by Henry Ford Wyandotte Hospital, as the new owner for Downriver Cardiology Consultants, P.C. As the completion of the transaction took place on June 1, 2012, Downriver Cardiology Consultants, P.C. directly became owned by Henry Ford Wyandotte Hospital and, as such, the transfer required and requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession numbers ML15089A165 and ML15086A252. Since the transaction date of June 1, 2012, Henry Ford Wyandotte Hospital has continued as the licensee and remains in control of all licensed activities under Materials License No. 21-26330-01. 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 Downriver Cardiology Consultants, P.C. sufficiently describes and documents the commitments made by Downriver Cardiology Consultants, P.C. and Henry Ford Wyandotte 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 request for consent submitted by both parties with regard to a direct change of control of byproduct materials license No. 21-26330-01 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.