

SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 06-30793-01 CARDIOLOGY ASSOCIATES OF NORWICH, LLC

DATE: November 20, 2014

DOCKET NO.: 030-36181

LICENSE NO.: 06-30793-01

LICENSEE: Cardiology Associates of Norwich, LLC
79 Wawecus Street
Norwich, Connecticut 06360

TECHNICAL REVIEWER: Janice Nguyen

SUMMARY AND CONCLUSIONS

Cardiology Associates of Norwich, LLC (CAN) is authorized by NRC License 06-30793-01 for the possession and use of byproduct material for purposes of uptake, dilution and excretion studies permitted by 10 CFR 35.100 and for purposes of imaging and localization studies permitted by 10 CFR 35.200 at 79 Wawecus Street, Norwich, Connecticut. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by Cardiology Associates of Norwich, LLC that will result from a sale between Cardiology Associates of Norwich, LLC and Yale-New Haven Hospital (YNHH). The assets of Cardiology Associates of Norwich, LLC were purchased by Yale-New Haven Hospital on August 31, 2014, and became effective September 2, 2014. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML14260A421. The ADAMS package consists of the following agency documents: letter dated August 29, 2014 (ML14260A453) and email dated November 19, 2014.

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 Cardiology Associates of Norwich, LLC and Yale-New Haven Hospital sufficiently describes and documents the transaction and commitments made by both parties.

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 in control is in accordance with the Act. The staff finds that, after the change of control, the facilities at 79 Wawecus Street, Norwich, Connecticut, now operated by Yale-New Haven 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 promote the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Licensing Tracking System (LTS), Yale-New Haven Hospital has been an NRC licensee since August 13, 1985. The NRC conducted a main office inspection of Yale-New Haven Hospital on June 23-27, 2014, with an exit meeting on July 22, 2014, and three Severity Level IV violations were identified. The three violations involved the following: as of June 23, 2014, Yale-New Haven Hospital did not periodically (at least annually) review the radiation protection content and implementation as required by 10 CFR 20.1101(c), include a representative from the nursing service on the Radiation Safety Committee as required by 10 CFR 35.24(f), and include the determination of the length of the source transfer tubes and the lengths of the applicators in the full calibration measurements on the remote afterloader unit at St. Raphael's Campus as required by 10 CFR 35.633(b). The commitments made by Yale-New Haven Hospital (License No. 06-00819-03) and Cardiology Associates of Norwich, LLC state the following:

- A. The Yale-New Haven Hospital Radiation Safety Officer (RSO) will oversee the location at 79 Wawecus Street, Norwich, Connecticut; Cardiology Associates of Norwich, LLC's current RSO will remain as an authorized user (AU);
- B. YNHH will not change the personnel involved in licensed activities;
- C. YNHH will not change the locations, facilities, and equipment authorized in the NRC license;
- D. YNHH will not change the radiation safety program authorized in the NRC license;
- E. The location at 79 Wawecus Street, Norwich, Connecticut will be known as Yale-New Haven Hospital; and
- F. YNHH will keep regulatory required surveillance records and decommissioning records.

Yale-New Haven Hospital has an active NRC license. License No. 06-00819-03 is a medical broad scope license, authoring multiple modalities of medical use of diagnostic studies and therapy procedures. Therefore, for security purposes, Yale-New Haven 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.

Cardiology Associates of Norwich, LLC is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 06-30793-01.

REGULATORY FRAMEWORK

Cardiology Associates of Norwich, LLC's License No. 06-30793-01, 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 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. Cardiology Associates of Norwich, LLC's request for consent describes a direct change of control resulting from a planned sale between Yale-New Haven Hospital and Cardiology Associates of Norwich, LLC. Following the completion of the sale, the location at 79 Wawecus Street, Norwich, Connecticut will become a location of use for Yale-New Haven Hospital, and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS package accession number ML14260A421. The ADAMS package consists of the following agency documents: letter dated August 29, 2014 (ML14260A453) and email dated November 19, 2014. After completion of the sale, the location at 79 Wawecus Street, Norwich, Connecticut, will become a location of use for Yale-New Haven Hospital under Materials License No. 06-00819-03 and the Cardiology Associates of Norwich, LLC Materials License No. 06-30793-01 will be terminated. 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 Cardiology Associates of Norwich, LLC sufficiently describes and documents the commitments made by Yale-New Haven Hospital and Cardiology Associates of Norwich, 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 an direct change of control of byproduct materials license No. 06-30793-01 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.