

SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE
NUMBER 21-03298-06, VHS Children's Hospital of Michigan, Inc.

DATE: February 3, 2020

DOCKET NO.: 030-38328

LICENSE NO.: 21-03298-06

LICENSEE: VHS Children's Hospital of Michigan, Inc.
3901 Beaubien Blvd, Detroit, Michigan 48201

TECHNICAL REVIEWER: Magdalena R. Gryglak, Materials Licensing Branch, Division of
Nuclear Materials Safety

SUMMARY AND CONCLUSIONS

VHS Children's Hospital of Michigan, Inc. ("the transferor") is authorized by U.S. Nuclear Regulatory Commission (NRC) License No. 21-03298-06 for the production and use of Positron Emission Tomography (PET) material. The NRC staff reviewed a request for consent to a direct license transfer submitted by the licensee and Karmanos Cancer Center ("transferee"). Based on the information provided, Karmanos Cancer Center will purchase all assets of the PET Cyclotron Center from VHS Children's Hospital of Michigan, Inc. and will continue to conduct licensed activities under NRC License No. 21-03298-06. The direct transfer of control is described in letters dated October 28, 2019, and October 29, 2019 (Agency Documents Access and Management System (ADAMS) Accession Nos. ML19323C779 and ML19329C273).

The request for consent was reviewed by NRC staff for a change in control of a Title 10 *Code of Federal Regulations* (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 June 2016. The NRC staff finds that the information submitted by the licensee sufficiently describes and documents the transaction and commitments made by the transferor and the transferee.

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 licensee 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 to promote the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing System, VHS Children's Hospital of Michigan, Inc. has been an NRC licensee since June 29, 2012. No violations of NRC requirements were identified during the last two inspections in February 2019 (ML19071A032) and March 2017 (ML17068A428).

The commitments made by the transferee and the transferor state that the licensee:

- 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; and
- E. will keep regulatory required surveillance records and decommissioning records.

In addition, for security purposes, Karmanos Cancer Center 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," January 29, 2019 revision (basis-for-confidence checklist). The purpose of the basis-for-confidence 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. Karmanos Cancer Center holds an NRC License No. 21-04127-06 and has been inspected by the NRC in the past.

The licensee is required to provide decommissioning financial assurance based on the types and amount of material authorized by License No. 21-03298-06. Karmanos Cancer Center submitted decommissioning financial assurance in letter dated October 28, 2019 (ML19322D063).

REGULATORY FRAMEWORK

VHS Children's Hospital of Michigan, Inc., License No. 21-03298-06, 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." The review was completed in accordance with NUREG 1556, Volume 15, and informed by 63 *Federal Register* 66721, "10 CFR Parts 2 and 51, RIN 3150-AG09, Streamlined Hearing Process for NRC Approval of License Transfers, Nuclear Regulatory Commission, Final Rule," dated December 3, 1998.

DESCRIPTION OF TRANSACTION

By letter dated October 28, 2019, and October 29, 2019, VHS Children's Hospital of Michigan, Inc. ("the transferor") notified the NRC that Karmanos Cancer Center ("the transferee") will purchase all assets of the PET Cyclotron Center from VHS Children's Hospital of Michigan, Inc. The transfer of control is described in letters dated October 28, 2019, and October 29, 2019 available in ADAMS Accession Nos. ML19323C779 and ML19329C273. After the transaction, the transferee will remain in control of licensed activities under License No. 21-03298-06 with no changes in personnel, licensed facilities, or equipment. 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 NUREG-1556, Volume 15, Revision 1.

TRANSFEE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the commitments and information submitted by VHS Children's Hospital of Michigan, Inc. and Karmanos Cancer Center in letters dated October 28, 2019 and October 29, 2019 are consistent with the guidance outlined in NUREG-1556, Volume 15, Revision 1.

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 VHS Children's Hospital of Michigan, Inc. ("the transferor") and Karmanos Cancer Center ("the transferee"), with regard to a direct transfer of control of byproduct materials License No. 21-03298-06. The staff has found that the transfer of control has no significant impact on public health and safety. Accordingly, the staff provides the NRC consent to a transfer of control pursuant to 10 CFR 30.34(b).

Submitted information sufficiently describes the transaction, and documents both the transferor and the transferee understanding of the license and commitments. Since the change in control does not affect licensed facilities or personnel directly involved in licensed activities, staff finds that the request demonstrates that the licensee personnel have experience and training sufficient to properly implement and maintain the license. The staff further finds that the transferor and the transferee have committed to maintain existing records, and abide by all existing commitments to the license, consistent with the guidance in NUREG-1556, Volume 15, Revision 1.

In accordance with the above analysis, the staff concludes that the change in control would not alter previous findings, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.