

**SAFETY EVALUATION REPORT  
CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER  
21-03298-06, VHS CHILDREN'S HOSPITAL OF MICHIGAN, INC.**

**DATE:** April 14, 2015

**DOCKET NO.:** 030-38328

**LICENSE NO.:** 21-03298-06

**LICENSEE:** VHS Children's Hospital of Michigan, Inc.  
3901 Beaubien Boulevard  
Detroit, Michigan

**TECHNICAL REVIEWER:** Kevin Null

**SUMMARY AND CONCLUSIONS**

VHS Children's Hospital of Michigan, Inc. is authorized by NRC license number 21-03298-06 for production, possession, transfer and research and development of PET radionuclides. A similar NRC review and safety evaluation report was issued on March 25, 2014, for NRC license number 21-03298-05 for VHS Children's Hospital of Michigan, Inc. In the licensee's letter to the NRC dated February 16, 2015, they stated that the October 1, 2013, documentation that was submitted for the change in ownership for license number 21-03298-05 also applies directly to license number 21-03298-06. In its October 1 letter, due to an oversight on their part, the licensee neglected to include license number 21-032298-06 as being involved in the merger.

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the request for consent to an indirect license transfer submitted by VHS Children's Hospital of Michigan, Inc., that will result from the acquisition of its ultimate parent entity, Vanguard Health Systems, Inc. (Vanguard) by Tenet Healthcare Corporation (Tenet). The licensee's request dated October 1, 2013, was not identified explicitly "as a request for an indirect transfer of control," but NRC staff considered that it implicitly constituted as much. Vanguard sold 100% of its stock, by way of a planned merger, to Tenet. Upon closing, Vanguard became a wholly-owned subsidiary of Tenet, with Tenet as the new ultimate parent of Vanguard and its subsidiaries. Vanguard continues to exist and its downstream subsidiary, VHS of Michigan, Inc., continues to be the owner of VHS Children's Hospital of Michigan, Inc. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML13277A708.

The request for consent dated October 1, 2013, was characterized by the licensee as *not* being a change of ownership or control. However, the request was reviewed by NRC staff and was considered to constitute an indirect 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 VHS Children's Hospital of Michigan, Inc. sufficiently described and documented the transaction and commitments made by Vanguard/Tenet and VHS Children's Hospital of Michigan, 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 application and finds that the proposed change in control is in accordance with the Act. The staff finds that, after the change of control, VHS Children's Hospital of Michigan, Inc., will remain qualified to use byproduct material for the purposes requested, and will continue to have the equipment, facilities, and procedures needed to protect the public health and safety, and promoted the security of licensed material.

## **SAFETY AND SECURITY REVIEW**

NRC license number 21-03298-06 was initially issued on June 29, 2012. The NRC conducted inspections on October 19, 2012, and December 19, 2014, and no violations were identified during either inspection. The commitments made by Tenet and Vanguard state that, as a result of the change in ownership, VHS Children's Hospital of Michigan, Inc.:

- 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 not change 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 merger, Tenet, the new ultimate parent entity of Vanguard, has multiple subsidiaries, including three subsidiaries that possess active NRC licenses, each of which is affected in a similar fashion as VHS Children's Hospital of Michigan. Each of these subsidiaries/licensees authorize human use of byproduct materials for diagnostic and therapeutic purposes and they are: VHS Harper – Hutzell Hospital, Inc., license number 21-04127-02; VHS Huron Valley – Sinai Hospital, Inc., license number 21-24652-01; and VHS Sinai – Grace Hospital, Inc., license number 21-00299-04. Therefore, for security purposes, Tenet 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.

License number 21-03298-06 is required to have decommissioning financial assurance (DFA). DFA had initially been received by the NRC in the form of a payment surety bond for 782,000 dollars and is currently under NRC review. However, as a result of the change in name of the licensee, the DFA will need to be amended to reflect the new name of the licensee and submitted to the NRC.

## **REGULATORY FRAMEWORK**

VHS Children's Hospital of Michigan, Inc.'s, license number 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."

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. VHS Children's Hospital of Michigan, Inc.'s request for consent describes an indirect change of control resulting from a planned merger between Vanguard and Tenet, with Tenet as the new ultimate parent entity for Vanguard and its subsidiaries. As of the completion of the merger, which took place on October 1, 2013, VHS Children's Hospital of Michigan, Inc. will, indirectly through Vanguard, become a wholly-owned subsidiary of Tenet and, as such, the transfer requires NRC consent.

## **DESCRIPTION OF TRANSACTION**

The transaction is described in ADAMS accession number ML13277A708. After completion of the merger, VHS Children's Hospital of Michigan, Inc. has continued as the licensee and remains in control of all licensed activities under license number 21-03298-06. 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 VHS Children's Hospital of Michigan, Inc. sufficiently described and documented the commitments made by Tenet and VHS Children's Hospital of Michigan, 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 an indirect change of control of byproduct materials license No. 21-03298-06 and approves the application pursuant to 10 CFR 30.34(b).

The submitted information sufficiently described the transaction; documented the understanding of the license and commitments; demonstrated 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.