

SAFETY EVALUATION REPORT
CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
21-01549-02, "MIDMICHIGAN MEDICAL CENTER," NOW "MIDMICHIGAN HEALTH"

DATE: January 22, 2016

DOCKET NO.: 030-02013

LICENSE NO.: 21-01549-02

LICENSEE: MidMichigan Medical Center,
Now, "MidMichigan Health"
4000 Wellness Drive
Midland, MI 48670

TECHNICAL REVIEWER: Colleen Carol Casey

SUMMARY AND CONCLUSIONS

MidMichigan Medical Center is authorized by NRC License 21-01549-02 for the possession and use of byproduct material for purposes of diagnostic and therapeutic uses in humans in sealed and unsealed forms. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a partial direct license transfer of control submitted by MidMichigan Medical Center that resulted from the execution of an affiliation agreement between MidMichigan Medical Center and Michigan Health Corporation (MHC), a subsidiary of the University of Michigan Health System, on June 21, 2013. The licensee's request dated October 30, 2015, did not explicitly identify its letter as a request for "a partial direct transfer of control" but NRC staff considered that the request implicitly constituted as much.

The partial direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession ML15306A563.

The licensees' letter dated October 30, 2015, signed by appropriate management representatives for both parties, requested NRC's consent to the partial direct change in control.

The letter dated October 30, 2015, 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 MidMichigan Medical Center sufficiently describes and documents the affiliation agreement and commitments made by MidMichigan Medical Center and MHC.

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 October 30, 2015, and finds that the partial change in control was in accordance with the Act. The staff finds that MidMichigan Medical Center 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), MidMichigan Medical Center has been an NRC licensee since February 16, 1959. The NRC conducted an inspection of MidMichigan Medical Center on August 7, 2014, and one violation was identified during this inspection. The commitments made by MidMichigan Medical Center and MHC state that MidMichigan Medical Center License No. 21-01549-02:

- 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, MidMichigan Medical Center still owns and operates this facility. However, MHC now holds a 0.1% membership interest in MidMichigan Medical Center, resulting from this partial transfer of control and the "sharing" of control, as described in the October 30, 2015, letter and as follows. MidMichigan Medical Center is governed by a Board of Directors consisting of not less than 11 and not more than 18 persons. Its Board of Directors must now include at least two directors nominated by MHC (or 12% representation if the number of directors increases above 18%.) At least one MHC director must serve on the Executive Committee for MidMichigan Medical Center at all times. MHC also holds its own NRC license for the use of byproduct material. Therefore, for security purposes, MHC 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.

MidMichigan Medical Center is not required to have decommissioning financial assurance, based on the types and amount of material authorized in License No. 21-01549-02.

REGULATORY FRAMEWORK

MidMichigan Medical Center's License No. 21-01549-02 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.

The MidMichigan Medical Center’s request for consent describes a partial and minor direct change of control resulting from the execution of an affiliation agreement between MidMichigan Medical Center and MHC. As the completion of the transaction took place on June 21, 2013, MidMichigan Medical Center directly became affiliated with MHC and MidMichigan Medical Center’s control changed. As such, the transfer required NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession number ML15176A339. Since the transaction date of June 21, 2013, “MidMichigan Health,” as it is now known, has continued as the licensee and remains in control of all licensed activities under Materials License No. 21-01549-02, and in affiliation with MHC, as described above. 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 MidMichigan Medical Center sufficiently describes and documents the commitments made by MidMichigan Medical Center and MHC 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 partial direct change of control of byproduct materials license No. 21-01549-02 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.