

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
21-32378-01, GREAT LAKES HEART CENTER OF ALPENA**

DATE: 12/15/2015
DOCKET NO.: 030-35958
LICENSE NO.: 21-32378-01
LICENSEE: Great Lakes Heart Center of Alpena
TECHNICAL REVIEWER: Toye L. Simmons *Toye L. Simmons*

SUMMARY AND CONCLUSIONS

Great Lakes Heart Center of Alpena is authorized by NRC License No. 21-32378-01 to possess and use byproduct material for the purposes of human diagnostic studies as permitted by 10 CFR 35.200. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct transfer submitted by Great Lakes Heart Center of Alpena that will result from a sale of stocks to Alpena Regional Medical Center, NRC License No. 21-17754-01, who will obtain possession of all radioactive materials, sealed sources and radiation safety equipment. This sale will result in a name change of the licensee from Great Lakes Heart Center of Alpena to ARMC Medical Group Cardiology Associates. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML15268A427.

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 – Program-Specific 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 Great Lakes Heart Center of Alpena sufficiently describes and documents the transaction and commitments made by Alpena Regional Medical Center and Great Lakes Heart Center of Alpena.

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, ARMC Medical Group Cardiology Associates (formerly Great Lakes Heart Center of Alpena) 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 promotes the security of licensed material.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing System (WBL), Great Lakes Heart Center of Alpena has been an NRC licensee since April 2002. The NRC conducted a main office inspection of Great Lakes Heart Center of Alpena on June 29, 2012 and July 9, 2012, no violations were identified during this inspection.

The commitments made by Alpena Regional Medical Center and Great Lakes Heart Center of Alpena state that they:

- 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.

The transferee, Alpena Regional Medical Center has been an NRC licensee since April 12, 1978. NRC License No. 21-17754-01 was issued to Alpena General Hospital and the name was changed with Amendment 17 in September 2005. Therefore, for security purposes, Alpena Regional Medical Center is considered a known entity following the guidance provided by the NRC's Office of Nuclear Materials Safety and Safeguards '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.

Great Lakes Heart Center of Alpena is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 21-32378-01.

REGULATORY FRAMEWORK

Great Lakes Heart Center of Alpena's License No. 21-32378-01, 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. Great Lakes Heart Center of Alpena's request for consent describes a direct change of control resulting from a planned sale between Great Lakes Heart Center of Alpena and Alpena Regional Medical Center and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession numbers ML15268A427 and ML15294A398. After completion of the sale, Great Lakes Heart Center of Alpena with a new name of ARMC Medical Group Cardiology Associates will continue as the licensee and remain in control of all licensed activities under Materials License No. 21-32378-01. 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 Great Lakes Heart Center of Alpena sufficiently describes and documents the commitments made by Alpena Regional Medical Center and Great Lakes Heart Center of Alpena, 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. 21-32378-01 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.