

**SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL OF BYPRODUCT MATERIALS LICENSE
NUMBER 24-32762-01MD, ESSENTIAL ISOTOPES**

DATE: January 24, 2020

DOCKET NO.: 030-38129

LICENSE NO.: 24-32762-01MD

LICENSEE: Essential Isotopes
1513 Research Park Drive
Columbia, Missouri 65211

TECHNICAL REVIEWER: Bryan A. Parker, Senior Health Physicist, Region III

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SUMMARY AND CONCLUSIONS

Essential Isotopes, LLC is authorized by NRC License 24-32762-01MD for the possession and use of byproduct material for the purposes of preparation and distribution of radioactive drugs and radiochemicals (radiopharmacy). The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request dated November 27, 2019, for consent to an indirect license transfer submitted by Essential Isotopes, a majority-owned subsidiary (55%) of Mid-America Cyclotron, Inc. The indirect transfer was scheduled to occur on or before February 27, 2020, or at such earlier time as the NRC provided consent. The transfer would result in a 100% acquisition of Mid-America Cyclotron by PharmaLogic Holdings Corp. As a result, Essential Isotopes will become an indirect majority-owned subsidiary of PharmaLogic Holdings Corp. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML19336D076.

The licensee's request for consent to an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2 and following the guidance provided in the NRC's Regulatory Issue Summary 2014-08. No comments were received from members of the public and was removed from posting on January 17, 2020.

The request for consent was reviewed by NRC staff for an indirect transfer of control of a 10 CFR Part 30 license using the guidance in NUREG 1556, Volume 15, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific 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 Essential Isotopes describes and documents the transaction and commitments made by the 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 transfer of control is in accordance with the Act. The staff finds that, after the transfer of control, Essential Isotopes 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 common defense and security.

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15, Rev. 1. Essential Isotopes' request for consent describes an indirect transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML19336D076. After completion of the transfer, Essential Isotopes will continue as the licensee and remains in control of all licensed activities under Materials License No. 24-32762-01MD. 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 E of NUREG-1556, Volume 15, Rev. 1.

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

The NRC staff finds that the information submitted by Essential Isotopes sufficiently describes and documents the commitments made by both parties and is consistent with the guidance in NUREG-1556, Volume 15, Rev. 1.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by the licensee with regard to an indirect transfer of control of byproduct materials License No. 24-32762-01MD and consents to the transfer pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, Rev. 1, the submitted information sufficiently describes the transaction; documents the understanding of the license and commitments of the transferee; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; and provides that, in the future, the transferee will abide by all existing commitments on the license.

Therefore, the staff concludes that the proposed transfer of 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.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, Essential Isotopes has been an NRC licensee since August 10, 2011. The NRC conducted an inspection at the licensee's location on October 23, 2019, and no violations were identified. The commitments made by Essential Isotopes state that there will be:

- A. no change to the radiation safety officer listed on the NRC licenses;
- B. no change in personnel involved in licensed activities;
- C. no change in the locations, facilities, and equipment authorized in the NRC license;
- D. no change in the radiation safety program authorized in the NRC license; and
- E. no change in the organization's name listed in the NRC license.

Further, the licensee will maintain required surveillance records and decommissioning records as required by NRC regulations.

PharmaLogic Holdings Corp. currently holds several similar licenses in NRC jurisdiction and several Agreement States, including NRC License Nos. 47-25375-01MD, 21-32190-01MD, and 13-26246-01MD, among others. A full list of these licenses was provided in the aforementioned letter dated November 27, 2019 (ML19336D076). Therefore, for security purposes, PharmaLogic Holdings Corp., the ultimate majority parent post-closing, is considered to be a known entity following the guidance provided by the NRC's Office of Nuclear Material Safety and Safeguards (NMSS) "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the application," January 29, 2019 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.

Essential Isotopes is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 24-32762-01MD.

REGULATORY FRAMEWORK

Essential Isotopes' License No. 24-32762-01MD 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 transfer 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."