



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

APR 20 2016

Scott C. Brower, R.Ph.
Radiation Safety Officer
Mid-America Isotopes, Inc.
706 E. Liberty Lane
Ashland, MO 65010

SUBJECT: REQUEST FOR CONSENT TO AN INDIRECT LICENSE TRANSFER

Dear Mr. Brower:

Enclosed is Amendment No. 15 to your NRC Material License No. 24-26241-01MD in accordance with your request.

Please review the enclosed document carefully and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

If you have any questions or comments concerning this amendment please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

By letters dated January 29, 2016, February 10, 2016, April 6, 2016, and April 7, 2016, Mid-America Isotopes, Inc. submitted to the U.S. Nuclear Regulatory Commission (NRC) a Request for Consent to Indirect License Transfer of NRC Materials License No. 24-26241-01MD. Based on the information you provided, we understand that as a result of the purchase of 100% of the stock of Mid-America Isotopes, Inc., by Pharmalogic Holdings Corp., control of Mid-America Isotopes, Inc., will be indirectly transferred. We further understand that this transfer will not result in any change to the licensed materials, persons using the licensed material, location of use of licensed material, or persons responsible for the licensee's radiation safety program.

Based on the above understandings and as more fully detailed in the enclosed NRC staff's Safety Evaluation Report, which documents the NRC staff's review of the request, we have no objection to the transfer.

You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you.

This could include issuance of a notice of violation, or imposition of a civil penalty, or an order suspending, modifying or revoking your license as specified in the General Statement of Policy and Procedure for NRC Enforcement Actions.

Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with

licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance which NRC expects of its licensees.

In accordance with 10 Code of Federal Regulations 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's *expectations* for individuals and organizations to establish and maintain a positive safety culture.

You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 24-26241-01MD
Docket No. 030-31896

Enclosures:

1. Amendment No. 15
2. SER dated April 19, 2016

**SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER
24-26241-01MD, MID-AMERICA ISOTOPES, INC.**

DATE: April 18, 2016

DOCKET NO.: 030-31896

LICENSE NO.: 24-26241-01MD

LICENSEE: Mid-America Isotopes, Inc.
706 E. Liberty Lane
Ashland, Missouri

TECHNICAL REVIEWER: Colleen Carol Casey

SUMMARY AND CONCLUSIONS

Mid-America Isotopes, Inc. (MAI) is authorized by NRC License No. 24-26241-01MD for the possession and use of byproduct material, mostly in unsealed forms, for purposes involving the preparation and distribution of radioactive drugs to authorized recipients, in accordance with 10 CFR 32.72. Redistribution activities involving molybdenum-99/technetium-99m generators, "in vitro" kits licensed under 10 CFR 31.11, and sealed sources under 10 CFR 35.400 and 35.500 are also permitted by this license. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer of control submitted by Mid-America Isotopes, Inc. that will result from the acquisition of 100% of the stock of the current individual indirect owners of MAI by Pharmalogic Holdings Corp (PHC). The transaction is expected to close on or about May 1, 2016.

The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession numbers ML16034A535, ML16042A253, ML16098A179, and ML16099A077.

The licensee's letters dated January 29, 2016, February 10, 2016, April 6, 2016, and April 7, 2016, signed by appropriate management representatives for both parties, requested NRC's consent to the indirect change in control.

The letters dated January 29, 2016, February 10, 2016, April 6, 2016, and April 7, 2016, were reviewed by NRC staff and considered to constitute a request for consent to 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 Mid-America Isotopes, Inc. sufficiently describes and documents the stock purchase and commitments made by Mid-America Isotopes, Inc. and Pharmalogic Holdings Corp.

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 letters dated January 29, 2016, and February 10, 2016, April 6, 2016, and April 7, 2016, and finds that the indirect transfer of control was in accordance with the Act. The staff finds that Mid-America Isotopes, Inc. 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), Mid-America Isotopes, Inc. has been an NRC licensee since January 24, 1991. The NRC conducted an inspection of Mid-America Isotopes, Inc. on July 25, 2014, and no violations were identified during this inspection. The commitments made by Mid-America Isotopes, Inc. and PHC state that Mid-America Isotopes, Inc. License No. 24-26241-01MD:

- 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. 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 transaction, PHC, as the Parent Company, will own and operate this facility. PHC also currently owns 13 similar licenses for the use of byproduct material. Five NRC licenses for the use of byproduct material, administered by different regional offices, are owned by PHC but are held in other names related to the "Pharmalogic" brand. In addition, eight licenses for the use of byproduct material are held by various Agreement States. These licenses have various names, some with and some without the "Pharmalogic" brand appearing in the name. All of the NRC and Agreement State license numbers were provided by PHC, as well as a complete, current copy of one NRC and one Agreement State license. Therefore, for security purposes, PHC 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.

Mid-America Isotopes, Inc. is not required to have decommissioning financial assurance, based on the types and amounts of material authorized in License No. 24-26241-01MD.

REGULATORY FRAMEWORK

Mid-America Isotopes, Inc.'s License No. 24-26241-01MD 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 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.

Mid-America Isotopes, Inc.'s request for consent describes an indirect change of control resulting from the acquisition of 100% of the stock of the current individual indirect owners of MAI by PHC. As the completion of the transaction will take place on or about May 1, 2016, MAI will indirectly become affiliated with PHC and MAI's control will change. As such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS accession numbers ML16034A535, ML16042A253, ML16098A179 and ML16099A077. As of the transaction date, on or about May 1, 2016, MAI will continue as the licensee but PHC will assume control of all licensed activities under Materials License No. 24-26241-01MD, 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 Mid-America Isotopes, Inc. sufficiently describes and documents the commitments made by Mid-America Isotopes, Inc. and PHC 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. 24-26241-01MD 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.