

SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE

Date: 12-October-2016
Docket No.: 030-31910
License No.: 13-26246-01MD
Licensee: Radiopharmacy Incorporated
Address: 1409 East Virginia Street, Evansville, IN 47711
Technical Reviewer: Sara A. Forster, M.S., Materials Licensing Branch, Division of Nuclear Materials Safety

SUMMARY AND CONCLUSIONS:

Radiopharmacy Incorporated ("the transferor") is authorized by NRC License 13-26246-01MD for the possession and medical use of byproduct material. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by the licensee that will result from a stock transfer from the three current owners (Timothy M. Quinton Trust, Harold Quinton, Jr., and E. Dean Dome) to PharmaLogic Holdings Corp. As a result of the purchase, the licensee's name will not change. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML16200A238.

The request for consent was reviewed by NRC staff for a direct change in control of a Title 10 *Code of Federal Regulations* (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 the licensee sufficiently describes and documents the transaction and commitments made by the transferor and the transferee.

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, the licensee 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 to promote the security of licensed material.

SAFETY AND SECURITY REVIEW

The transfer of control of Radiopharmacy Incorporated ("the transferor"), to PharmaLogic Holdings Corp. ("the transferee"), together with any associated amendments, such as a name change, is essentially administrative in nature. Under 63 FR 66721, pp. 66727-28, such an administrative amendment, following the review and approval of the transfer itself, "presents no safety questions and clearly involves no significant hazards considerations." Further the Commission has noted that, "Safety Evaluation Reports (SERs) prepared in connection with previous license transfers confirm that such transfers do not, as a general matter, have significant impacts on the public health and safety." Accordingly, the transferee's acquisition of the licensee via transfer of assets by purchase presents no safety questions and involves no significant hazards evaluations.

According to data obtained from the NRC's Web Based Licensing System, the licensee has held an NRC license since January 8, 1991. The NRC most recently conducted main office inspections of the licensee on January 17, 2002, November 20, 2003, January 12, 2006, February 14, 2008, May 12, 2010, August 22, 2012, March 25 through April 1, 2014, and May 11, 2016, and identified no violations during those inspections.

The commitments made by the transferee and the transferor state that the licensee:

- 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 on the NRC license; and
- F. will keep regulatory required surveillance records.

In addition, for security purposes, because the transferee is Pharmalogic Holdings Corp., the transferee 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 (basis-for-confidence checklist). This is because the transferee is the parent company to several radioactive materials medical use licenses within NRC and Agreement State jurisdiction, throughout the country. Licenses held by subsidiaries to the transferee include NRC License No. 44-30124-01MD, which was last inspected on July 29, 2014, with no violations identified. The purpose of the basis-for-confidence 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. Observations made during inspections of other subsidiaries of the transferee are sufficient to provide reasonable assurance that the licensee, once under the control of the transferee, will use material as intended and not for malevolent purposes.

The licensee is not required to have decommissioning financial assurance based on the types and amount of material authorized by License No. 13-26246-01MD.

REGULATORY FRAMEWORK

License No. 13-26246-01MD was issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." Under 10 CFR 30.34(b), for licenses "issued or granted pursuant to the regulations in [Parts 30] through 36," the Commission is required to determine if the change of control is in accordance with the provisions of the Act, and give its consent in writing. Specifically, no 10 CFR Part 30 licenses, "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."

The review was completed in accordance with NUREG 1556, Volume 15, and informed by 63 *Federal Register* 66721, "10 CFR Parts 2 and 51, RIN 3150-AG09, Streamlined Hearing Process for NRC Approval of License Transfers, Nuclear Regulatory Commission, Final Rule," dated Dec. 3, 1998.

DESCRIPTION OF TRANSACTION

In letter dated July 15, 2016, Radiopharmacy Incorporated ("the transferor") notified the U.S. Nuclear Regulatory Commission that PharmaLogic Holdings Corp. ("the transferee"), intends to acquire all stock in the licensee. The transaction is described in ADAMS accession number ML16200A238. After the transferee purchases the transferor's assets, the licensee will remain in control of all licensed activities under License No. 13-26246-01MD, with no significant changes to key responsible personnel, licensed facilities, or equipment. 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 NUREG-1556, Volume 15, Appendix F. Further, the NRC staff finds that the Transaction, with respect to licensed operations, is limited to a transfer of control that is essentially administrative in nature.

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

The NRC staff finds that the commitments and information submitted by the Radiopharmacy Incorporated and PharmaLogic Holdings Corp., under letters dated July 15, 2016 (ML16200A238) and October 4, 2016 (ML16280A373), respectively, are consistent with the guidance outlined in NUREG-1556, Volume 15.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since approvals of direct and indirect transfers of control are categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by Radiopharmacy Incorporated ("the transferor") and PharmaLogic Holdings Corp. ("the transferee"), with regard to a transfer of control of byproduct materials license No. 13-26246-01MD. The staff has found that the transfer of control, including any associated amendments, is essentially administrative in nature, and has no significant impact on public health and safety. Accordingly, the staff approves the request for consent to a transfer of control pursuant to 10 CFR 30.34(b).

Submitted information sufficiently describes the transaction, and documents both the licensee and the transferee understanding of the license and commitments. Since the change does not affect licensed facilities or personnel directly involved in licensed activities, and is essentially administrative in nature, staff finds that the request demonstrates that the licensee personnel have experience and training sufficient to properly implement and maintain the license. The staff further finds that the licensee and the transferee have committed to maintain existing records, and abide by all existing commitments to the license, consistent with the guidance in NUREG-1556, Volume 15.

In accordance with the above analysis, the staff concludes that the proposed change in control would not alter previous findings, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.