SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE NUMBER 44-30124-01MD, PharmaLogic Ltd.

DATE: March 30, 2015

DOCKET NO.: 030-33449

LICENSE NO.: 44-30124-01MD

LICENSEE: PharmaLogic Ltd.

TECHNICAL REVIEWER: Janice Nguyen

SUMMARY AND CONCLUSIONS

PharmaLogic Ltd. (nuclear pharmacy) is authorized by NRC License 44-30124-01MD for the possession and preparation of byproduct material for distribution to individuals authorized to receive, possess and administer to humans licensed material in accordance with a medical specific license issued by the NRC or Agreement State. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect transfer of ownership in letter dated January 20, 2015 that will result from the merger of PL Holding Merger Sub, Inc. into PharmaLogic Holdings Corp. PharmaLogic Holdings Corp. will be the surviving company and will continue to operate its business and own its subsidiaries, including PharmaLogic Ltd. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession number ML15030A176, which includes: letter dated January 20, 2015 (ML15048A172), telephone log dated March 20, 2015, and letter with attachments received March 20, 2015.

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

The request for consent was reviewed by NRC staff for 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 PharmaLogic Ltd. sufficiently describes and documents the transaction and commitments made by the licensee.

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, PharmaLogic Ltd. 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, PharmaLogic Ltd. has been an NRC licensee since May 12, 1994. The NRC conducted a main office inspection of PharmaLogic Ltd. on July 29, 2014, and no violations were identified during the inspection. The commitments made by PharmaLogic Ltd. state that, absent NRC approval:

A. There will be no change in personnel or duties that relate to the licensed program, and no change in the Radiation Safety Officer listed on the license.

B. There will be no changes in the organization, location, facilities, equipment, or procedures that relate to the licensed program.

C. PharmaLogic Ltd., will continue to maintain compliance as it relates to area surveys, wipe tests, training, quality control and related records presently and upon closing of the transaction.

D. PharmaLogic Ltd., confirms that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to NRC, as appropriate.

E. PharmaLogic Ltd., confirms that both the transferor and transferee agree to transferring control of the licensed material and activity, and the conditions of transfer, and the transferee has been made aware of any open inspection items and its responsibility for possible resulting enforcement actions, as applicable.

F. PharmaLogic Ltd., confirms that the transferee will abide by all constraints, conditions, requirements, and commitments of the transferor.

G. There will be no change in the licensee's operations at the pharmacy and no change in the direct owner and operator of the pharmacy as a result of the transaction.

For security purposes, the indirect transferee, as described in letter dated January 20, 2015, 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.

The licensee is not required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 44-30124-01MD.

REGULATORY FRAMEWORK

PharmaLogic Ltd., License No. 44-30124-01MD 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 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-I 556, 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. PharmaLogic Ltd.’s request for consent describes an indirect change of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The transaction is described in ADAMS package accession number ML15030A176, which includes: letter dated January 20, 2015 (ML15048A172), telephone log dated March 20, 2015, and letter with attachments received March 20, 2015. After completion of the merger, PharmaLogic Ltd., will continue as the licensee and remain in control of all licensed activities under Materials License No. 44-30124-01MD. 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 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 the licensee sufficiently describes and documents the commitments made 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)(iii).

CONCLUSION

The staff has reviewed the request for consent submitted by the licensee with regard to an indirect change of control of byproduct materials License No. 44-30124-01MD and consents to the transaction 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.