

**SAFETY EVALUATION REPORT**  
**PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE**

**Date:** 16-January-2020  
**Docket Nos.:** 030-29642; 030-36453; and 030-34090  
**License Nos.:** 21-24828-01MD; 24-32462-01MD; and 21-26707-01MD  
**Licensee:** Medi-Physics, Inc. d/b/a GE Healthcare  
**Addresses:** 12300 Hubbard Rd., Livonia, MI 48150; 1623 Lotsie Blvd., Overland, MO 63132; 4380 Brockton SE, Ste. 3, Kentwood, MI 49512  
**Technical Reviewer:** Sara A. Forster, M.S., Materials Licensing Branch, Division of Nuclear Materials Safety

**SUMMARY AND CONCLUSIONS:**

Medi-Physics, Inc. d/b/a GE Healthcare ("the transferor") is authorized by NRC License Nos. 21-24828-01MD, 24-32462-01MD, and 21-26707-01MD for the possession and 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 an acquisition of 100% of the ownership interest in the Medi-Physics, Inc. d/b/a GE Healthcare radiopharmacies owned by GE Healthcare to Radioisotope Life Sciences (RLS (USA) Inc.). The indirect transfer of control is described in its July 15, 2019 letter. The letter may be found at the NRC's Agency Documents Access and Management System (ADAMS), accession number ML19204A292.

The request for consent for an indirect change in control of a Title 10 *Code of Federal Regulations* (CFR) Part 30 license was reviewed by NRC staff in accordance with 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," revision 1, dated June 2016. 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 Medi-Physics, Inc. d/b/a GE Healthcare ("the transferor"), to Radioisotope Live Sciences (RLS (USA) Inc.) (RLS) ("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 stock 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 9, 1987. Since April 27, 2006, the NRC has inspected each of the three locations at least seven times, identifying no violations. The NRC most recently conducted inspections of the licensee's three locations between April 13, 2018 and April 4, 2019. The commitments made by the transferee and the transferor include statements confirming that the licensee:

- A. will not change the personnel involved in licensed activities;
- B. will not change the locations, facilities, and equipment authorized in the NRC license;
- C. will not change the radiation safety program authorized in the NRC license; and
- D. will keep regulatory required surveillance records.

As the result of this transaction, RLS will own and operate facilities at the three locations of use. RLS does not own any other licenses – in the United States – for the use of byproduct material. Therefore, for security purposes, RLS is not considered 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 (basis-for-confidence checklist). 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.

In accordance with this checklist and guidance, a pre-licensing site visit was conducted on November 13, 2019, of License No. 21-24828-01MD at the Livonia, Michigan location. No adverse findings resulted from this visit and NRC concluded that RLS will use its licensed material in accordance with the conditions stated in Medi-Physics, Inc. d/b/a GE Healthcare's previous applications and supporting documents.

The licensee is not required to have decommissioning financial assurance based on the types and amount of material authorized by License No. 21-24828-01MD, 24-32462-01MD, and 21-26707-01MD.

## **REGULATORY FRAMEWORK**

License Nos. 21-24828-01MD, 24-32462-01MD, and 21-26707-01MD were 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, 2019, Medi-Physics, Inc. d/b/a GE Healthcare and Medi-Physics, Inc. ("the transferor") notified the U.S. Nuclear Regulatory Commission that Radioisotope Live Sciences (RLS (USA) Inc.) ("the transferee"), intends to acquire all of the licensee's radiopharmacy assets. The transaction is described in ADAMS accession number ML19204A292. After the transferee purchases the transferor's assets, the licensee will remain in control of all licensed activities under License Nos. 21-24828-01MD, 24-32462-01MD, and 21-26707-01MD, 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, rev. 1, Appendix E. 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 Medi-Physics, Inc. d/b/a GE Healthcare and Radioisotope Life Sciences (RLS (USA) Inc.), under letter dated July 15, 2019 (ML19204A292), are consistent with the guidance outlined in NUREG-1556, Volume 15, revision 1.

## **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 Medi-Physics, Inc. d/b/a GE Healthcare ("the transferor") and Radioisotope Life Sciences (RLS (USA) Inc.) ("the transferee"), with regard to a transfer of control of byproduct materials license Nos. 21-24828-01MD, 24-32462-01MD, and 21-26707-01MD. 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, revision 1.

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.