

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

Date: October 18, 2018
Docket Nos.: 030-08546 and 030-38755
License Nos.: 21-11315-02 and 21-11315-04
Licensee: MPI Research, Inc.
Addresses: 54943 N Main St., Mattawan MI 49071
Technical Reviewer: Sara A. Forster, M.S., Health Physicist, Materials Licensing Branch,
Division of Nuclear Materials Safety, Region III Office

SUMMARY AND CONCLUSIONS:

MPI Research, Inc. ("the licensee") is authorized by NRC License Nos. 21-11315-02 and 21-11315-04 for the possession and use of byproduct material in broad scope research and development and limited scope research and development. Prior to April 3, 2018, the licensee was a wholly owned subsidiary of ACP Mountain Holdings, Inc. ("ACP") On March 12, 2018, the licensee notified the NRC of its plans for an indirect transfer of the licensee resulting from a merger between ACP and Charles River Laboratories International, Inc. ("CRLII"). That merger was completed on April 3, 2018. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to an indirect license transfer submitted by the licensee that would result from the merger of the ACP and CRLII. As a result of that merger, the licensee remained as its own legal entity, a wholly-owned subsidiary of the merged companies but with full control over the referenced licensed activities. The indirect transfer of control is described in Agency Documents Access and Management System (ADAMS) accession numbers ML18092B265, ML18094A812, and ML18096A822. The NRC staff issued its consent to the indirect Transfer of Control via letter dated June 4, 2018 (ML18157A052) and two Safety Evaluation Reports (SERs) dated May 25, 2018 (ML18157A054 and ML18157A120).

On July 24, 2018, the licensee notified the NRC of its plans for a direct transfer of the licensee via a merger between its parent – ACP – and another wholly-owned CRLII subsidiary – Charles River Laboratories, Inc. (CRLI). The U.S. NRC accordingly reviewed a request for consent to a direct license transfer submitted by the licensee that would result from the merger. The merger is anticipated to be effective no later than January 1, 2019. As a result of the merger, the licensee and its parent ACP would cease to exist as legal entities. CRLI is expected to assume control over the licensed program upon completion of the merger. The direct transfer of control is described in ADAMS accession numbers ML18206A648 and ML18206A652.

The licensee's initial request for an indirect transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with Title 10 of the *Code of Federal Regulations* (CFR) Part 2 and followed the guidance provided in the NRC Regulatory Issue Summary (RIS) 2014-08, Rev. 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses." No comments from members of the public were received regarding that request, which was removed from posting on April 23, 2018. The licensee's current request for a direct transfer of ownership also was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2, and also followed the guidance provided in RIS 2014-08, Rev. No comments were received for the current direct transfer of control consent request, which was removed from posting on September 20, 2018.

The request for consent was reviewed by NRC staff for a direct 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 June 2016. The NRC staff finds that the information submitted by the licensee sufficiently describes and documents the transaction and commitments made by the licensee 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

According to data obtained from the NRC's Web Based Licensing (WBL) System, the licensee has held an NRC license (NRC License No. 21-11315-02) since April 10, 1972. It has held a second NRC license (NRC License No. 21-11315-04) since September 19, 2014. The NRC most recently conducted inspections of the licensee under NRC License No. 21-11315-02 on August 24, 2005, July 12 & 25, 2011, September 25, 2015, and September 15, 2016, and identified no violations during those inspections. The NRC most recently conducted inspections of the licensee under NRC License No. 21-11315-04 on September 25, 2015, and July 24, 2017, and identified no violations during those inspections. In the licensee's request for NRC consent to the indirect transfer of control, statements made by the licensee confirm that the licensee:

- A. Will not change the Radiation Safety Officer (RSO) listed on the NRC licenses;
- 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 make substantive changes to the radiation safety program authorized in the NRC license;
- E. will update any existing financial assurance instruments and supporting documents will be updated to contain any name change in the licensee's name, and will be effective as of the date of the merger; and
- F. will keep regulatory required surveillance records and decommissioning records.

Until license termination due to transfer of licensing authority to Agreement State Pennsylvania Bureau of Radiation Protection License No. PA-1261, CRLI subsidiary Charles River Laboratories – Malvern held an NRC limited scope Research & Development Radioactive Materials License, NRC Lic. No. 37-28306-01. That license was originally issued on January 31, 1989, and was last renewed on March 18, 2005. The NRC most recently conducted an inspection of CRLM on September 13, 2006, and identified no violations during that inspection.

Although CRLM's Pennsylvania Bureau of Radiation Protection License No. PA-1261 was recently terminated, CRLI and its subsidiaries currently hold additional Agreement State Radioactive Materials Licenses: Nevada License No. 11-16-0368 and Ohio License No. 06320030003. Accordingly, the transferee is 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," August 9, 2018 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 required to hold decommissioning financial assurance based on the types and amounts of material authorized under NRC Lic. No. 21-11315-04. Because the licensee will no longer remain as an independent legal entity with a name change as a result of the merger, the financial assurance must be amended as a result of the transaction. As noted above, a commitment has been received from the licensee and from CRLI that the required amended financial assurance will be completed and submitted to the NRC, at the completion of the transaction.

REGULATORY FRAMEWORK

MPI Research, Inc.'s NRC License Nos. 21-11315-02 and 21-11315-04 were issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." For licenses "issued or granted pursuant to the regulations in [Parts 30] through 36," the Commission is required by 10 CFR 30.34(b) to determine if the change of control is in accordance with the provisions of the Act, and to 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."

As previously indicated, the staff evaluation is based on guidance in NUREG 1556, Volume 15, rev. 1. It is also 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. MPI Research, Inc.'s request for consent describes a direct transfer of control and – as such – the transfer requires the NRC consent.

DESCRIPTION OF TRANSACTION

A previous indirect transfer of control from MPI Research, Inc. ("the licensee") to Charles River Laboratories International, Inc. ("CRLI") was described in two letters dated April 3, 2018 (ADAMS Accession Nos. ML18092B265 and ML18094A812) and one letter dated April 4, 2018 (ML18096A822). After the completion of that merger, the licensee continued as the licensee and remained in control of all licensed activities under NRC Materials License Nos. 21-11315-02 and 21-11315-04.

The current direct transfer of control from MPI Research, Inc. ("the licensee"), now a subsidiary of CRLII, to its sister company, Charles River Laboratories, Inc. ("the transferee") is described in two letters dated July 24, 2018 (ADAMS Accession Nos. ML18203A648 and ML18206A652). After completion of the merger, the transferee would be the sole owner of all licensed activities authorized under NRC Materials License Nos. 21-11315-02 and 21-11315-04, with no significant changes to the RSO, other key responsible personnel, radiation protection programs, 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 applicable guidance provided in NUREG-1556, Volume 15, rev. 1, Appendix E, "Information Needed for Transfer of Control Application."

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

The NRC staff finds that the information submitted by MPI Research, Inc., and Charles Rivers Laboratories, Inc., under two letters dated July 24, 2018, sufficiently describes and documents the commitments made by both parties and is consistent with the guidance outlined 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 change of control of byproduct materials license Nos. 21-11315-02 and 21-11315-04 and consents to the transfer pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, rev. 1, 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, in the future, will abide by all existing commitments on the license.

Therefore, in accordance with the above analysis, 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.