SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE

Date: 15-May-2019
Docket No.: 030-35228
License No.: 13-32212-01
Licensee: Endocyte, Inc.
Address: 3000 Kent Ave., West Lafayette, IN 47906
Technical Reviewer: Sara A. Forster, M.S., Materials Licensing Branch, Division of Nuclear Materials Safety

SUMMARY AND CONCLUSIONS:

Endocyte, Inc. ("the licensee") is authorized by NRC License 13-32212-01 for the research and development 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 would result from Edinburgh Merger Corporation ("the transferee") being absorbed into the licensee via the oversight of the licensee's and transferee's parent corporation, Novartis AG ("the transferor"). As a result of the acquisition, the transferee would be merged with and into the licensee. The indirect transfer of control is described in the November 28, 2018 request letter (Agency Documents Access and Management System (ADAMS) accession number ML18333A248).

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," 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 licensee, the transferor, and the transferee.

As required by Title 10 of the Code of Federal Regulations ("CFR") Section 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 since December 9, 1999. The NRC most recently conducted inspections of the licensee on October 31, 2000, April 17, 2006, June 13, 2011, and June 17, 2016. No violations were identified during those inspections.

In the licensee's request for NRC consent to the indirect transfer of control, commitments made by the transferee and the transferor state that the licensee:

A. will not change the personnel authorized in the NRC license;

B. will not change the organization, locations, facilities, equipment, or procedures 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 and decommissioning records.

Novartis AG, the transferee, has at least one subsidiary – Novartis Pharmaceuticals Corp. – that previously held several NRC radioactive materials licenses, including NRC License No. 29-08978-02, that includes the scope of proposed licensed activities. That license was originally issued February 9, 1991. It was last inspected by the NRC on June 9-10, 2009 – prior to oversight of the licensee being assumed by the New Jersey Department of Environmental Protection ("NJDEP"), with no violations. In addition, the licensee provided documentation that the referenced licensee currently is assigned NJDEP License No. 507408 – RAD 180001 and was last inspected on June 7, 2018. Further, the current Amendment Nos. 25 to Massachusetts Department of Public Health Radiation Control Program License No. 55-0440, 57 to California Department of Public Health ("CDPH") Lic. 3940-01, and 31 to CDPH License No. 6655-37 for other Novartis AG subsidiaries Novartis Institutes for Biomedical Research, Inc. and Novartis Institute for Functional Genomics were verified via the WBL system.

Based on this information, 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," January 29, 2019 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 by License No. 13-32212-01.

REGULATORY FRAMEWORK

License No. 13-32212-01, 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, revision 1, 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 November 28, 2018, Endocyte, Inc. ("the licensee") notified the U.S. Nuclear Regulatory Commission that Spectrum Health System ("the transferee"), via an indirect transfer, planned to have another subsidiary – Edinburgh Merger Corporation – of the parent company to the licensee, Novartis AG ("the transferor"), be merged into its company and become part of the licensee's assets. The transaction is described in ADAMS accession number ML18333A248. After completion of the merger, the licensee would continue as the owner of all licensed activities authorized under NRC Materials License No. 13-32212-01, 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, revision 1, Appendix E, "Information Needed for Transfer of Control."

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

The NRC staff finds that the commitments and information submitted by Lakeland Regional Health System; Endocyte, Inc.; and Novartis AG, via letter dated November 28, 2018 (ML18333A248), 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 this action is categorically excluded under 10 CFR 51.22(c)(21).

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. 13-32212-01 and approves the application pursuant to 10 CFR 30.34(b).

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, 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.