

SAFETY EVALUATION REPORT
PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE

Date: 27-February-2020
Docket Nos.: 030-38841; 030-38903
License Nos.: 13-35179-02; 13-35179-03
Licensee: Zevacor Molecular
Addresses: 14395 Bergen Blvd., Noblesville, IN 46060
Technical Reviewer: Sara A. Forster, M.S., Materials Licensing Branch, Division of Nuclear Materials Safety

SUMMARY AND CONCLUSIONS:

Zevacor Molecular ("the transferor") is authorized by NRC License Nos. 13-35179-02 and 13-35179-03 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's parent company – Illinois Health and Science (IHS) – that will result from an acquisition of 100% of the ownership interest in Zevacor Molecular by Curium US PET LLC (Curium US PET), which is a future subsidiary of Curium US Holdings LLC. The indirect transfer of control is described in Zevacor's December 20, 2019 letter. The letter may be found at the NRC's Agency Documents Access and Management System (ADAMS), accession number ML19357A266.

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 Zevacor Molecular ("the transferor"), to Curium US PET LLC (Curium US PET) ("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 December 29, 2015. The NRC identified no violations at the licensee's initial inspection, which was conducted on October 27, 2016. At that time, the licensee was still in pre-production and had produced two batches of strontium-82. As a result of the licensee's October 22, 2018 inspection, the NRC issued three Severity Level IV violations. Although those violations remain open until the next inspection, both transferor and transferee – via the initial December 20, 2019 letter and an additional information letter dated February 24, 2020 – have provided statements confirming that the licensee:

- A. will not change the Radiation Safety Officer (RSO) listed on the NRC license;
- B. will not change the personnel involved in licensed activities;
- C. will not change the locations, facilities, and equipment authorized on the NRC license;
- D. will not change the radiation safety program authorized in the NRC license;
- E. will keep regulatory required surveillance records and decommissioning records;
- F. will submit updated decommissioning financial assurance instruments, in accordance with 10 CFR 30.35(f), within 30 days of the transaction; and
- G. will abide by all existing constraints, conditions, requirements, representations, and commitments, including those identified in the December 20, 2019 letter.

The February 24, 2020 letter may be found in NRC's ADAMS at Accession No. 20056C981.

As the result of this transaction, Curium US PET will own and operate facilities at the listed location of use. Curium US LLC, a subsidiary of Curium US PET's parent company Curium, owns three NRC radioactive materials licenses – License Nos. 24-04206-01, 24-04206-02, and 24-04206-05MD - for the use of byproduct material. Therefore, for security purposes, Curium US PET 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 (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.

The licensee continues to be required to have decommissioning financial assurance based on the types and amount of material authorized by License Nos. 13-35179-02 and 13-35179-03.

REGULATORY FRAMEWORK

License Nos. 13-35179-02 and 13-35179-03 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 December 20, 2019, Zevacor Molecular (Zevacor) and Curium US PET LLC ("the transferor") notified the U.S. Nuclear Regulatory Commission that Curium US PET LLC (Curium US PET) ("the transferee"), intends to acquire all of the licensee's manufacturing & development and research & development assets. The transaction is described in ADAMS accession number ML19357A266. After the transferee purchases the transferor's assets, the licensee will remain in control of all licensed activities under License Nos. Nos. 13-35179-02 and 13-35179-03, 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 TRANSFEE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the commitments and information submitted by Zevacor Molecular and Curium US PET LLC (Curium US PET), under letters dated December 20, 2019 (ML19357A266) and February 24, 2020 (ML20056C981), 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 Zevacor Molecular ("the transferor") and Curium US PET LLC (Curium US PET) ("the transferee"), with regard to a transfer of control of byproduct materials license Nos. 13-35179-02 and 13-35179-03. 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.