

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

Date: 20-November-2017
Docket No.: 030-38464
License No.: 24-32829-01
Licensee: Confluence Discovery Technologies, Inc.
Address: 4320 Forest Park Ave., STE. 303, St. Louis, MO 63108
Technical Reviewer: Sara A. Forster, M.S., Materials Licensing Branch, Division of Nuclear Materials Safety

SUMMARY AND CONCLUSIONS:

Confluence Life Sciences, Inc. ("the transferor") is authorized by NRC License 24-32829-01 for the possession and use of byproduct material. Via letter and Safety Evaluation Report dated January 23, 2017, the staff consented to an indirect Transfer of Control of the transferor to its subsidiary Confluence Discovery Technologies, Inc. ("the licensee"). Via letter dated February 23, 2017 (ML17062A507), the licensee confirmed that the previous Transfer of Control had been completed. No name change was requested at that time. However, via letter dated October 12, 2017, (ML17285A547), the licensee notified the U.S. Nuclear Regulatory Commission (NRC) of a high-level Transfer of Control of the transferor to Aclaris Therapeutics, Inc. ("the transferee") The letter indicated that the Board of Directors had changed, as a result of the transfer. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed the request for consent to a direct license transfer submitted by the licensee that would result from the high-level transfer. As a result of the reassignment of oversight over the licensed operations, the transferee would be the owner of licensed operations, the licensee would have control over the licensed material. As noted above, the direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML17285A547.

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," rev.1, dated June 2016 The NRC staff finds that the information submitted by the licensee describes and documents the transaction and commitments made by the licensee and the transferee, as applicable, sufficient to provide consent to the Transfer of Control. Additional information may be needed from the transferor and transferee to complete a license amendment incorporating this consent.

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 since August 31, 2011. The NRC conducted inspections of the licensee on February 3, 2012 and January 11, 2017, and identified no violations during those inspections. In the licensee's request for NRC consent to the direct transfer of control, commitments made by the licensee on behalf of the transferee and the transferor state 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 in the NRC license;
- D. will not change the radiation safety program authorized in the NRC license; and
- E. will keep regulatory required surveillance records and decommissioning records.

The authority of Confluence Discovery Technologies, Inc., over licensed activities has changed only at a high level, as a result of the parent transferee company's acquisition by Aclaris Therapeutics, Inc. Accordingly, the licensee remains 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, as no other aspects of the company have changed. 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. 24-32829-01. Financial assurance requirements have not changed.

REGULATORY FRAMEWORK

License No. 24-32829-01, 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, 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 October 12, 2017, Confluence Discovery Technologies, Inc. notified the U.S. Nuclear Regulatory Commission that the transferee, via a direct transfer, planned to assume direct control over the licensee's parent – Confluence Life Sciences, Inc. The transaction is described in ADAMS accession number ML17285A547. After completion of the reassignment, the licensee would continue as the owner of the subsidiary, which is the new owner of the licensee, who has authority over all licensed activities authorized under NRC Materials License No. 24-32829-01, with no significant changes to the RSO, other 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.

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

The NRC staff finds that the commitments and information submitted by Confluence Discovery Technologies, Inc. under letter dated October 12, 2017, is sufficiently consistent with the guidance outlined in NUREG-1556, Volume, 15 to authorize the Transfer of Control.

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. 24-32829-01 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, rev. 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.