

**SAFETY EVALUATION REPORT**  
**PROPOSED CHANGE OF CONTROL FOR BYPRODUCT MATERIALS LICENSE**  
**NUMBERS 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD,**  
**JUBILANT DRAXLMAGE RADIOPHARMACIES, INC.**

**DATE:** March 16, 2021

**DOCKET NOS.:** 030-38276, 030-38278, 030-38279, and 030-38280

**LICENSE NOS.:** 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD

**LICENSEE:** Jubilant DraxImage Radiopharmacies, Inc.  
d/b/a Jubilant Radiopharma  
790 Township Line Rd.  
Suite 175  
Yardley, PA 19067

**TECHNICAL REVIEWER:** Frank Tran

**SUMMARY AND CONCLUSIONS**

Jubilant DraxImage Radiopharmacies, Inc. is authorized by NRC Licenses 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD for the possession and use of byproduct material for purposes of preparation and distribution of radioactive drugs for medical uses. The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by Jubilant DraxImage Radiopharmacies, Inc. that will result from a sale between Jubilant DraxImage Inc. d/b/a Jubilant Radiopharma and Jubilant DraxImage Radiopharmacies Inc. d/b/a Jubilant Radiopharma. Jubilant DraxImage Inc. will acquire substantially all of Jubilant DraxImage Radiopharmacies, Inc.'s assets. After the transaction, Jubilant DraxImage Radiopharmacies, Inc. will be owned by Jubilant DraxImage, Inc. Jubilant DraxImage, Inc. will continue operating the licensed facilities and activities the same as their current operated under Jubilant DraxImage Radiopharmacies, Inc. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) accession number ML20338A439.

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, Revision 1, "Consolidated Guidance About Materials Licenses - Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses." The NRC staff finds that the information submitted by Jubilant DraxImage Radiopharmacies, Inc. sufficiently describes and documents the transaction and commitments made by Jubilant DraxImage Inc. and Jubilant DraxImage Radiopharmacies, Inc.

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, Jubilant DraxImage Radiopharmacies, Inc. 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 promotes the security of licensed material.

## **SAFETY AND SECURITY REVIEW**

According to data obtained from the NRC's Web Based Licensing System (WBL), Jubilant DraxImage Radiopharmacies, Inc. has been an NRC licensee since May 28, 2010. The NRC conducted main office inspections of Jubilant DraxImage Radiopharmacies, Inc. on February 8, 2019, July 31, 2019, February 12, 2019, and July 10, 2019 for NRC License Nos. 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD, respectively, and no violations were identified during those inspections. The commitments made by Jubilant DraxImage Inc. and Jubilant DraxImage Radiopharmacies, Inc. state that Jubilant DraxImage Radiopharmacies, Inc. (License Nos. 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD):

- A. will not change the radiation safety officer listed in 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 licenses;
- D. will not change the radiation safety program authorized in the NRC licenses; and
- E. will keep regulatory required surveillance records and decommissioning records.

Jubilant Life Sciences Ltd owns 100% of Jubilant Pharma Ltd who owns 100% of Jubilant DraxImage Inc. (the transferee) and 100% of Jubilant Pharma Holdings Inc. (with 15.52% via Jubilant Generics Ltd). Jubilant Pharma Holdings Inc. owns 100% of Jubilant DraxImage Radiopharmacies Inc. (the licensee). In addition, Jubilant DraxImage Inc. holds an active radiopharmacy license issued by an NRC Agreement State, North Carolina, License No. 092-1512-01 dated January 28, 2021. Therefore, for security purposes, Jubilant DraxImage Inc. 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 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.

Jubilant DraxImage Radiopharmacies, Inc. is required to have decommissioning financial assurance based on the types and amount of material authorized in License No. 09-32781-02MD. As a part of the transfer of control agreements between Jubilant DraxImage Radiopharmacies Inc. and Jubilant DraxImage Inc., Jubilant DraxImage Inc. will submit a revised financial assurance instrument to the NRC reflecting the change in ownership within 30 days of the completion of the sale.

## **REGULATORY FRAMEWORK**

Jubilant DraxImage Radiopharmacies, Inc.'s License Nos. 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD, were issued under 10 CFR Part 30, Rules of General Applicability to Domestic Licensing of Byproduct Material. The Commission is required by 10 CFR 30.34 to determine if the change of control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: “No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 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, Revision 1. As discussed in NUREG-1556, Volume 15, Revision 1, NRC is generally using the term “change of control” rather than the statutory term “transfer” to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. Jubilant DraxImage Radiopharmacies, Inc.’s request for consent describes a direct change of control resulting from a planned sale between Jubilant DraxImage Radiopharmacies, Inc. and Jubilant DraxImage Inc. Following the completion of the sale, Jubilant DraxImage Radiopharmacies, Inc. will be owned by Jubilant DraxImage Inc. and, as such, the transfer requires NRC consent.

## **DESCRIPTION OF TRANSACTION**

The transaction is described in ADAMS accession number ML20338A439. After completion of the sale, Jubilant DraxImage Radiopharmacies, Inc. will continue as the licensee and remain in control of all licensed activities under Materials License Nos. 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD. 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 Appendix F of NUREG-1556, Volume 15, Revision 1.

## **TRANSFeree’S COMMITMENT TO ABIDE BY THE TRANSFEROR’S COMMITMENTS**

The NRC staff finds that the information submitted by Jubilant DraxImage Radiopharmacies, Inc. sufficiently describes and documents the commitments made by Jubilant DraxImage Inc. and Jubilant DraxImage Radiopharmacies, Inc., and is consistent with the guidance 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)(14)(xi).

## **CONCLUSION**

The staff has reviewed the request for consent submitted by both parties with regard to a direct change of control of byproduct materials license Nos. 09-32781-01MD, 09-32781-02MD, 09-32781-03MD and 09-32781-04MD and approves the application pursuant to 10 CFR 30.34(b).

The 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.

Therefore, 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.