



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

March 18, 2022

Craig S. Kinne, CHP, MHP
Corporate Radiation Safety Officer
Jubilant DraxImage Inc.
d/b/a Jubilant Radiopharma
790 Township Line Rd.
Ste. 325
Yardley, PA 19067

SUBJECT: AMENDMENT NOS. 21 AND 14 TO RADIOACTIVE MATERIALS LICENSES
FOR JUBILANT DRAXIMAGE INC. D/B/A JUBILANT RADIOPHARMA,
NRC LICENSE NOS. 09-32781-02MD AND 09-32781-04MD, 2795 UNIVERSAL
DR., SAGINAW, MI AND 3101 TERRENCE ST., KANSAS CITY, MO

Dear Mr. Kinne:

Enclosed are Amendment Nos. 21 and 14 to Jubilant DraxImage Inc. d/b/a Jubilant Radiopharma's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License No. 09-32781-02MD and 09-32781-04MD in accordance with your February 8, 2022, and March 1, 2022 requests to (1) add a second yttrium-90 radioactive materials use authorization, limited to SIR-Spheres, to each of your licenses; and to (2) change the Radiation Safety Officer (RSO), listed on your License No. 09-32781-02MD, from Kaylene Evans, Pharmacy Manager, to Bryan Brittain, Staff Pharmacist. Your letters are available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession Nos. ML22040A237, ML22040A276 and ML22062B326. The NRC's ADAMS is accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Please review the enclosed document carefully, and be sure that you understand all conditions. If there are any errors or questions, please notify the U.S. NRC Region III office at 630-829-9892 so that we may provide appropriate corrections and answers. Please note that additional information may be needed in support of your decommissioning financial assurance submission, which is being reviewed under a separate action. Our office will contact you when additional information is needed, in support of that review.

An environmental assessment for this action is not required because this action is categorically excluded under Title 10 of the *Code of Federal Regulations* (10 CFR) Section 51.22(c).

The enclosures to this letter contain sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

C. Kinne

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You will be periodically inspected by NRC. Failure to conduct your program in accordance with NRC regulations, license conditions, and representations made in your license application and supplemental correspondence with NRC will result in enforcement action against you. This could include issuance of a notice of violation; or imposition of a civil penalty; or an Order suspending, modifying, or revoking your license as specified in the NRC Enforcement Policy. Since serious consequences to employees and the public can result from failure to comply with NRC requirements, prompt and vigorous enforcement action will be taken when dealing with licensees who do not achieve the necessary meticulous attention to detail and the high standard of compliance that NRC expects of its licensees.

The NRC's Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency's expectations for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <https://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

NRC's Regulatory Issue Summary (RIS) RIS 2005-31 provides criteria to identify security-related sensitive information and guidance for handling and marking of such documents. This ensures that potentially sensitive information is not made publicly available through NRC's ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," the enclosed license document is exempt from public disclosure because its disclosure to unauthorized individuals could present a security vulnerability. The RIS may be located on the NRC's Generic Communications Web page under "Regulatory Issue Summaries" at <https://www.nrc.gov/reading-rm/doc-collections/gen-comm/>, and the link for frequently asked questions regarding protection of security-related sensitive information may be located at <https://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS.

Sincerely,

Sara A. Forster  Digitally signed by Sara A. Forster
Date: 2022.03.18 12:40:12 -05'00'

Sara A. Forster
Health Physicist
Materials Licensing Branch
Division of Nuclear Materials Safety

Docket Nos.: 030-38278 and 030-38280
License Nos.: 09-32781-02MD and
09-32781-04MD

Control Nos.: 630041 and 630043

Enclosures: 1. Amendment No. 21 to NRC License No. 09-32781-02MD
2. Amendment No. 14 to NRC License No. 09-32781-04MD