



UNITED STATES
NUCLEAR REGULATORY COMMISSION

REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

June 25, 2021

Kaylene Evans, R.Ph.
Radiation Safety Officer
Jubilant DraxImage Inc.
d/b/a Jubilant Radiopharma
790 Township Line Rd.
STE. 325
Yardley, PA 19067

SUBJECT: AMENDMENT NO. 18 TO RADIOACTIVE MATERIALS LICENSE FOR JUBILANT DRAXIMAGE INC. D/B/A JUBILANT RADIOPHARMA, NRC LICENSE NO. 09-32781-02MD

Dear Ms. Evans:

Enclosed is Amendment No. 18 to your U.S. Nuclear Regulatory Commission (NRC) Materials License No. 09-32781-02MD in accordance with your April 19, May 26 and June 3, 2021 requests. Please note that, based on your request for an authorization of Jubilant DraxImage Inc. Model RUBY-FILL Rubidium Rb 82 generators with a total of 1.5 curies, we added strontium-82, strontium-85 and rubidium-82 as Items 6.R., 6.S., and 6.T. to your license.

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) 829-9887 so that we may provide appropriate corrections and answers.

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

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

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter is uncontrolled.

K. Evans

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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, accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

Frank P. Tran

Digitally signed by Frank P. Tran
Date: 2021.06.25 17:58:53
-05'00'

Frank P. D. Tran
Health Physicist
Materials Licensing Branch

Docket No.: 030-38278
License No.: 09-32781-02MD
Control No.: 625473

Enclosure: Amendment No. 18 to NRC License No. 09-32781-02MD