



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, ILLINOIS 60532-4352

September 15, 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 20 TO RADIOACTIVE MATERIALS LICENSE FOR JUBILANT DRAXIMAGE INC. D/B/A JUBILANT RADIOPHARMA, NRC LICENSE NOS. 09-32781-01MD AND 09-32781-03MD, OVERLAND, MO AND SAGINAW, MI LOCATIONS OF USE

Dear Mr. Kinne:

Enclosed are Amendment Nos. 21 and 20, respectively, to Jubilant DraxImage Inc. d/b/a Jubilant Radiopharma's (your) U.S. Nuclear Regulatory Commission (NRC) Materials License Nos. 09-32781-01MD and 09-32781-03MD, in accordance with your August 30, 2022 request to remove five authorized nuclear pharmacists from your NRC license, number ending in -01MD; and to add authorizations to receive and distribute RUBYFILL Strontium-82/Strontium-85/Rubidium-82 generators under both referenced licenses. Your letters are available electronically from the Agencywide Documents Access and Management System (ADAMS) at Accession Nos. ML22244A126, for the ANP removal letter; and ML22229A085 and ML22229A091, for the RUBYFILL amendment letters. The NRC's ADAMS is accessible from the NRC Web site at <https://www.nrc.gov/reading-rm/adams.html>.

Please review the enclosed documents 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.

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) 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 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.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice and Procedure," a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from the NRC's ADAMS.

Sincerely,

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

Docket Nos.: 030-38276 and 030-38279
License Nos.: 09-32781-01MD and
09-32781-03MD

Control Nos.: 632159 and 632160

Enclosures: 1. Amendment No. 21 to NRC
License No. 09-32781-01MD
2. Amendment No. 20 to NRC
License No. 09-32781-03MD