



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION III
2443 WARRENVILLE RD. SUITE 210
LISLE, IL 60532-4352

October 12, 2022

David Persinger, R.Ph.
Radiation Safety Officer
Jubilant Draximage Inc.
d/b/a Jubilant Radiopharma
790 Township Line Rd.
Suite 325
Yardley, PA 19067

Dear Mr. Persinger:

Enclosed is Amendment No. 16 to your NRC Material License No. 09-32781-04MD in accordance with your request.

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. Nuclear Regulatory Commission, Region III office at (630) 829-9887 so that we can provide appropriate corrections and answers.

This amendment approves the requests made in your letter dated August 11, 2022.

Please note that the requests made in your letter dated July 12, 2022, for the addition of Germanium-68 and Gallium-68 generators to your license are undergoing further review by our staff. We will update you about the progress of that review, especially if any additional information is needed, within 30 days of the date of this letter.

If you have any questions or comments concerning this amendment please contact me at either (800) 829-9500, ext. 9841 or (630) 829-9841. My fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov. Since I am teleworking about half of the time, it is easiest to reach me by email.

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 General Statement of Policy and Procedure for NRC Enforcement Actions.

The enclosed document contains sensitive security-related information.
When separated from this cover letter this letter and attached SER are
uncontrolled.

[REDACTED]

D. Persinger

- 2 -

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 which NRC expects of its licensees.

NRC's Regulatory Issue Summary (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 ADAMS, the NRC's electronic document system. Pursuant to NRC's RIS 2005-31 and in accordance with 10 CFR 2.390, 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 Web site at: <http://www.nrc.gov/reading-rm/doc-collections/gen-comm/reg-issues/2005/ri200531.pdf> and the link for frequently asked questions regarding protection of security related sensitive information may be located at: <http://www.nrc.gov/reading-rm/sensitive-info/faq.html>.

A copy of this letter and the attached SER will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records (PARS) component of NRC's document system (ADAMS). The NRC's document system is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html> (the Public Electronic Reading Room). 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 <http://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.

Sincerely,

Colleen C. Casey

Digitally signed by Colleen C.

Casey

Date: 2022.10.12 19:24:29 -05'00'

Colleen Carol Casey
Health Physicist
Materials Licensing Branch

License No. 09-32781-04MD
Docket No. 030-38280

Enclosure :

Amendment No. 16

[REDACTED]