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

NOV 0/6 2019

Craig S. Kinne, Pharm.D., CHP Corporate Radiation Safety Officer Jubilant DraxImage Radiopharmacies, Inc. d/b/a Jubilant Radiopharma 790 Township Line Rd. STE. 175 Yardley, PA 19067

Dear Mr. Kinne:

Enclosed are Amendment Nos. 16, 12, and 11, respectively to your NRC Material License Nos. 09-32781-02MD, 09-32781-03MD, and 09-32781-04MD in accordance with your four August 7, 2019 requests and your one September 30, 2019 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.

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. 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.

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 <u>http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html</u>. 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.

The enclosures to this letter contain sensitive securityrelated information. When separated from this cover letter this letter is uncontrolled. - 2 -

C. Kinne

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 Title 10 of the *Code of Federal Regulations* Section 2.390, the enclosures to this letter are exempt from public disclosure because their disclosure to unauthorized individuals could present security vulnerabilities. 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.

In accordance with 10 CFR 2.390, a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's ADAMS, which is accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

Aara a. Forster

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

License Nos. 09-32781-02MD 09-32781-03MD 09-32781-04MD

- Docket Nos. 030-38278 030-38279 030-38280
- Enclosures: 1. Amendment No. 16 to NRC Lic, No. 09-32781-02MD
 - 3. Amendment No. 12 to NRC Lic. No. 09-32781-03MD
 - 4. Amendment No. 11 to NRC Lic. No. 09-32781-04MD