



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

APR 01 2015

Rachel Ziegler, R.Ph.
Radiation Safety Officer
Global Isotopes, LLC
d/b/a Zevacor Molecular
1968 Innerbelt Business Center Drive
Overland, Missouri 63114

Dear Ms. Ziegler:

Enclosed is Amendment No. 08 to your NRC Material License No. 24-32827-01MD in accordance with your request. Note that the major changes made to your license are printed in **bold font**.

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.

Your letter dated March 13, 2015, made reference to "...a Radiation Safety Manual (RSM) describing the radiation safety program," ostensibly included with your original RAM license application.

This letter also mentions that "These procedures are periodically reviewed and updated as necessary to ensure the continued safe and effective operation of the radiopharmacy, including the irradiator."

An outline of procedures Zevacor undertakes when updating RSM procedures is included, which also makes mention that "...the changes do not compromise safety of irradiator operation...."

We noted that:

- *Your license and the documents that support it do not include an RSM. We checked back to the inception of this license under "Pioneer Pharmacy" and did not find an RSM. Therefore, there appears to be nothing for Zevacor to update in an RSM for this license because it does not have one. Please also note that NRC strongly discourages submittal of RSMs because they typically contain many prescriptive procedures and extraneous information that is not needed to generate or support the license. Please do not submit an RSM.*
- *Your license does not now, and has not in the past, authorized an irradiator. We do not know what is being referred to here.*

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

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- *Nothing appeared to be “requested” for NRC to change on this license at this time in the March 13, 2015, letter. Therefore, we concluded that its submission must have been in error. No action has been taken to change anything in your license as a result of this particular letter.*

Please always include the telephone number and fax number of at least one person who serves as a point of contact for all future licensing requests. It is also helpful to provide us with the email address of at least one contact person.

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 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). 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.

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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 Carol Casey
Materials Licensing Branch

License No. 24-32827-01MD
Docket No. 030-38460/030-37831

Enclosure:

Amendment No. 08