



UNITED STATES  
NUCLEAR REGULATORY COMMISSION

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

MAY 01 2017

Michael Roberts, PharmD  
Site Radiation Safety Officer  
Global Isotopes, LLC  
d/b/a Zevacor Molecular  
1968 Innerbelt Business Center Drive  
Overland, MO 63114

Enclosed is Amendment No. 11 to your NRC Material License No. 24-32827-01MD in accordance with your request.

A copy of this letter and the enclosed license amendment are also being provided to John Zehner, Site RSO for your Indiana facility via "cc."

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.

The request to add Matthew Mahlandt, Pharm.D. as an ANP was not approved at this time.

This request was made in the letters dated September 26, 2016, and January 31, 2017. In the preceptor forms supporting Dr. Mahlandt's request with the January 31, 2017, letter, his preceptor, Ms. Elledge, cites two different Kansas license numbers that he obtained his training and experience under.

A copy of a State of Kansas – issued license was attached to the January 31, 2017, letter but this license number did not match either of the license numbers provided in the preceptor forms prepared and signed by Ms. Elledge. Therefore we were unable to complete our review.

In addition, we received a letter dated March 23, 2017, signed by Todd Hockemeyer, VP – Quality/Regulatory Affairs, that Zevacor has discontinued its operations as a nuclear pharmacy effective January 27, 2017.

However, Mr. Hockemeyer did not withdraw this amendment request. So we approved the request changing the RSO for the Missouri sites only.

If you wish to pursue the request to name Dr. Mahlandt as an ANP, please call me first to discuss the practicality and logistics of doing so, when your nuclear pharmacy operations have already ceased.

If you have any questions concerning this amendment please contact me at either (630) 829-9841. My fax number is (630) 515-1078 and my email address is colleen.casey@nrc.gov.

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

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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.

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).

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.

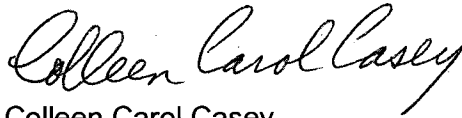
You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

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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. 11

Cc w/enclosures:

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