



UNITED STATES
NUCLEAR REGULATORY COMMISSION

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

NOV 29 2016

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

Enclosed is Amendment No. 10 to your NRC Material License No. 24-32827-01MD in accordance with requests signed by John A. Zehner, R.Ph., Site Radiation Safety Officer (RSO) for the Noblesville, Indiana facility and COO and by Todd Hockemeyer, V.P. – Quality/Regulatory Affairs.

The mailing address for this license is for the Overland, Missouri location as this license was originally administered for a Missouri location, i.e., the license number is based upon our state code for Missouri.

However, since John A. Zehner, R.Ph., is the Site RSO for the Noblesville, Indiana location and since he is also the COO for your company, it is our understanding that Mr. Zehner is the primary RSO for this license.

You, Dr. Ziegler, are still the Site RSO for the two Missouri locations.

A copy of this letter and the enclosed license amendment are also being provided to Mr. Zehner via "cc." If you have any questions about these matters, please contact me at (630) 829-9841.

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. 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.

This amendment included the review of five separate requests submitted by Messrs. Zehner and Hockemeyer.

However, only two of these requests were approved at this time. The requests adding James Presley, Pharm.D. and Micah Sukany, Pharm.D. as new authorized nuclear pharmacists (ANPs) were approved.

The requests to add Matthew Mahlandt, Pharm.D. as an ANP (failure to meet 10 CFR 35.55); change the site RSO for the two Missouri locations from you, Ms. Ziegler, to Michael Roberts, Pharm.D. (lack of Delegation of Authority signed by management and Dr. Roberts); and add Craig Ogden as an ANP (insufficient documentation for referenced license, no degree or registration included) were not approved.

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

R. Ziegler

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These requests were made in the letters dated September 20, 2016, September 26, 2016, and November 17, 2016.

Please note that I sent an email request to inform Messrs. Zehner and Hockemeyer of the status of the amendment requests on November 22, 2016, that was not responded to or acknowledged. I am concerned about whether it was received by them.

Please submit their email addresses to ensure that we have the most current and correct information for them.

If you wish to pursue the unapproved requests described above, please submit a complete, written, currently dated and physically, legibly signed response, addressed to my attention as "additional information to control number 591830" at the above address. We will then continue our review.

Please contact me, in conjunction with Messrs. Zehner and Hockemeyer, to schedule a telephone call and discuss the remaining deficient issues to ensure a more complete understanding of them, support a better written response and to prevent recurrence of similar deficient issues in the future.

The following regulations, guidance, etc. are strongly recommended to assist you in formulating appropriate responses and preparing better licensing correspondence going forward: 10 CFR 35.55; Appendix D to NUREG 1556, Vol. 9, Rev. 2; my letter to Mr. Zehner dated July 14, 2015, outlining deficiencies with requests made in your letter dated July 7, 2015, and your application dated July 7, 2015; a sample delegation of authority for RSOs from Appendix I to NUREG 1556, Vol. 9, Rev. 2; and NRC Information Notice 2007-38 "ENSURING COMPLETE AND ACCURATE INFORMATION IN THE DOCUMENTATION OF TRAINING AND EXPERIENCE FOR INDIVIDUALS SEEKING APPROVAL AS MEDICAL AUTHORIZED USERS," which contains best practices information for all types of authorized persons, including ANPs.

All of the above documents, with the exception of my letter to Mr. Zehner dated July 14, 2015, are available on our website at <http://www.nrc.gov>. The easiest way to find each is to simple search for it, i.e., "google it."

Please also be reminded of the provisions in 10 CFR 30.9(a) (copy attached), "Completeness and accuracy of information, which states, in part..."(a) Information provided to the Commission by an applicant for a license or by a licensee or information required by statute or by the Commission's regulations, orders, or license conditions to be maintained by the applicant or the licensee shall be complete and accurate in all material respects."

Further, we deleted Condition No. 19, as it appeared on Amendment No. 09, in favor of including reference to 10 CFR Part 71 in the Preamble at the top of page 1 of your license. We also added ADAMS accession numbers to the documents listed in the re-ordered, new Condition No. 19, your "tie-down" condition, and we re-formatted and deleted some extraneous language referring to attachments that previously appeared in this condition.

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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.

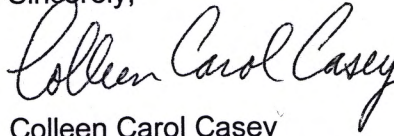
You can access the policy statement and supporting material that may benefit your organization on NRC's safety culture Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>.

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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. 10

Cc w/enclosures:

John A. Zehner, R.Ph., COO
Site Radiation Safety Officer
Zevacor Molecular – Noblesville
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Noblesville, IN 46060