



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**

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

JUL 14 2015

John Zehner, R.Ph.
Executive Vice President, COO
Global Isotopes, LLC
d/b/a Zevacor Molecular
14395 Bergen Boulevard
Noblesville, IN 46060

Dear Mr. Zehner:

This refers to your letters to us dated May 1, 2015, and the application dated July 7, 2015, requesting another pharmacy address of use in Noblesville, Indiana.

We find that we will need additional information to complete our review.

Please respond to the items below within 15 calendar days from the date of this letter (July 29, 2015). If an alternative timeframe for response is needed, please contact me promptly to arrange that.

My direct telephone number is (630) 829-9841 and my fax number is (630) 515-1078. My email address is colleen.casey@nrc.gov.

Some general licensing correspondence guidance is also provided to enable us to better serve you.

1. We noted that your letter dated May 1, 2015, contained labelled dividers for its many attachments and was in a soft-bound cover.

Since 1999, we have used an electronic database called "ADAMS," that has some publicly available content (please see our website at <http://www.nrc.gov/reading-rm/adams.html>) and some non-publicly available content.

This database constitutes our only official agency record for all documents.

Therefore, we scan in all documents we receive from our applicants and licensees for permanent electronic storage. The best way for us to receive documents is in a legible, black ink on white hard copy paper that measures 8.5 by 11 inches.

Incorporating dividers and a softbound cover, or any kind of cover, into your documents is not useful and slows down our processing. We cannot scan these materials. Please refrain from using such materials in the future, which should also reduce your regulatory and financial burdens a bit also.

2. Please only send us one, complete, written, currently dated and signed (by an appropriate management official, which may be you) correspondence document. Please ensure that our questions/requests are answered completely and explicitly.

Please do not send multiple copies of licensing requests and responses. For example, please do not email a PDF document to us, and a faxed version, and/or a hard copy sent by mail. Only one copy transmitted in only one of these ways is appropriate to prevent administrative processing errors.

3. Given that you are adding a new pharmacy address of use, located in another state from the pharmacies currently listed on the license in Missouri, it appears that the structure of your license and the structure of your licensed radiation safety program are unclear.

For example, Rachel Ziegler, R. Ph. is the currently named Radiation Safety Officer (RSO) for this license. Yet, no mention of her has been made in your letter dated May 1, 2015, and application dated July 7, 2015.

On the letter dated May 1, 2015, you, John Zehner, stated your corporate identity in the signature block as "Corporate RSO," even though NRC has not named you as such on the license. NRC does not normally name a "Corporate RSO" for a licensee, absent compelling organizational and safety reasons.

The organization chart included as an attachment, Item 7, to the letter dated May 1, 2015, only shows Ken Smithmier, you and Scott Chance. RSO coverage for the original two Missouri sites on this license was not addressed.

Please describe how each site will have RSO coverage, who will be the "day to day RSO," with each site being located in a different city and the newest site to be located in a different state.

Please state how much time, at a minimum, each "day to day RSO" will be provided to accomplish the Radiation Safety Officer duties. A specific numeric range or a single minimum number of hours is being requested here for a specific frequency.

If RSO changes are proposed in your response, please have a senior manager complete a "Delegation of Authority" that clearly outlines the duties and responsibilities for each RSO and include each RSO's written consent to acknowledging these duties and responsibilities.

Please ensure that the boundaries and circumstances for each RSO are clearly stated.

Typical duties and responsibilities for commercial radiopharmacy RSO's are provided in Appendix H to NUREG 1556, Vol 13, Rev. 1, at:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v13/r1/>

Please note that the letter signed by Matthew Trusner dated July 7, 2015, an attachment to your application dated July 7, 2015, did not constitute a "Delegation of Authority."

For a sample "Delegation of Authority," please use the Model given in Appendix I, NUREG 1556, Vol. 9, Rev. 2, at <http://www.nrc.gov/reading-rm/docollections/nuregs/staff/sr1556/v9/r2/>

If you wish to discuss this matter with me, please contact me as shown below.

4. There are several issues with the newly proposed facility in Noblesville, Indiana. You submitted copies of blueprint diagrams, which typically show very little of what we need but a lot of what we do not need. Preparing simple, hand-drawn diagrams is best. Please see Section 8.9 Item 9 in the afore-mentioned NUREG 1556, Vol. 13, Rev. 1 and please utilize all of the information it contains as it relates to the newly proposed facility.

- a. In Item 9 of the attachments to your letter dated May 1, 2015, you provided two copies of "page 1 of 2" and no copy of "page 2 of 2." Please provide this information, in addition to the information below.
- b. Please show the dimensions for all rooms to be covered by the license amendment in the commercial nuclear pharmacy, both restricted and unrestricted..
- c. Does Zevacor intend to be the sole occupant of this building or will there be other tenants? Please explain.
- d. The location of the afterhours radioactive package drop-off area was not shown on your diagrams. It was listed but the area itself was not shown.

Please be advised that the descriptive information provided for Area 1 at the bottom of "page 1 of 2" did not yield much useful information. Please describe in simpler terms what is meant by "appropriately shielded radiation dense material."

- e. Beginning with the afterhours radioactive package drop-off area and proceeding through the rest of your normal pharmacy operations, please describe clearly and concisely what operations will be conducted and where.

Please include the logical operational flow, such as incoming radioactive package surveys and check-in; generator placement and radioisotope storage; storage for volatile and/or potentially airborne radionuclides; generator elution areas; kit preparation and dose preparation areas; QC areas; dose labelling and packaging areas; dose preparation for shipment and survey areas; the path and means for packaged doses to be taken to delivery vehicles; where delivery vehicles will be loaded and unloaded; where radioactive wastes and returned items, spent doses and spent generators, etc. will be stored for decay; etc.

Please include details about shielding materials and describe your ventilation program, equipment, procedures, etc. for airborne materials and volatile materials (xenon-133, iodine-131, etc.)

If sealed sources are to be provided to your customers through this pharmacy, please describe your inventory and control procedures for them, as well as your shielding and shipping procedures.

Please identify all areas on your diagrams by their functional identity and whether each is a restricted area or unrestricted area.

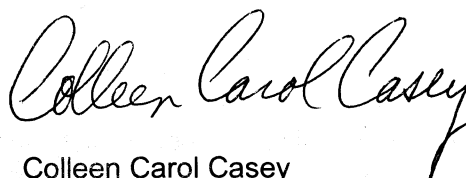
J. Zehner

- 4 -

5. Please confirm that all other radiation safety program elements currently in place for the two locations in Missouri will be extended to include the new program at the Noblesville, Indiana facility.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



Colleen Carol Casey
Materials Licensing Branch

License No. 24-32827-01MD
Docket No. 030-38460/030-37831
Control No. 586735