Wilson, Scott

From:

Wilson, Scott

Sent:

Monday, December 12, 2016 6:38 AM

To:

'K. Paul Steinmeyer'

Cc:

Miller, John

Subject:

Request for Additional Information; NRC License; Vascumab, LLC; License No.

06-35389-01; Docket No. 03039010: Mail Control No. 592335

Importance:

High

K. Paul Steinmeyer, RRPT Radiation Safety Associates, Inc. 19 Pendleton Drive P.O. Box 107 Hebron, CT 06248

On behalf of: Vascumab, LLC 23 Business Park Drive Branford, CT 06405

License No.: 06-35389-01 Docket No: 03039010 Control No: 592335

Mr. Steinmeyer:

Please respond with an e-mail acknowledging your receipt of this message.

This refers to Vascumab, LLC's request for a new license dated November 18, 2016. In order to continue our review of your request, the following additional information is needed:

- 1. NRC's "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Academic, Research and Development, and Other Licenses of Limited Scope Including Gas Chromatographs and X-Ray Fluorescence Analyzers" (NUREG-1556, Volume 7) provides guidance for completing an application for license. Item 9 of NUREG-1556, Volume 7, requires, in part, that the applicant submit a diagram showing the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. Item 9 also states that for facilities where it is anticipated that more than one laboratory or room may be used, a generic laboratory or room diagram may be submitted. Vascumab, LLC's license application dated November 18, 2016 (Application), did not include a diagram of the facility or its laboratories. Please submit a diagram of the facility and laboratories as described above.
- 2. Item 8.7.2 of NUREG-1556, Volume 7, requires that the applicant name of each proposed authorized user (AU) with the types and quantities of licensed material to be used. The application listed two authorized users and the radiation safety officer without specifying any type and quantity limitations. Please respond with the types and quantities of licensed material the radiation safety officer and all authorized users are to be authorized for on the license.
- 3. NRC licensing guidance requires the license reviewer to determine if the applicant currently or previously was authorized on a radioactive materials license issued by the NRC or an Agreement State. Please respond with information regarding the applicant's involvement with licensed activities.
- 4. It is important that our office receive current information regarding the applicant. The Application did not include contact information for the owner, Paul DaSilva Jardine, or the Radiation Safety Officer, Dr. James Landro. Please provide contact information including mailing address, telephone number, fax number, and email address for these individuals as contact persons for the license.



5. 10 CFR 20.2001 describes the general requirements for disposal of licensed material. Section 11.3, Item (d) of the application states in part that contaminated samples of quantities less that concentrations listed in 10 CFR 30 Schedules A and B will be disposed of individually in normal trash. This appears to be in conflict with the requirements in 10 CFR 20.2001 and cannot be authorized. Please respond with additional information or rescind this portion of the application.

Please respond with a signed and dated letter. The letter may be scanned and submitted as a pdf document attached to an email; or it may be transmitted by facsimile to (610) 337-5269; or it may be sent by regular mail. If we do not receive a reply from you within 30 calendar days from the date of this e-mail, we will assume that you do not wish to pursue your Application.

Thank you for your assistance.

Sincerely, Scott Wilson Health Physicist NRC Region I 2100 Renaissance Blvd, Ste 100 King of Prussia, PA 19406 Phone: 610-337-5136 Fax: 610-337-5269