NRC FORM 699
(10-2014)

U.S. NUCLEAR REGULATORY COMMISSION

CONVERSATION RECORD

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU	DATE OF CONTACT	TYPE OF CONVERSATION
John Zehner and Matt Trusner	09/18/2015	☐ E-MAIL ☐ INCOMING
E-MAIL ADDRESS jzehner@zevacor.com mtrusner@zevacor.com	TELEPHONE NUMBER (317) 578-1251	☑ TELEPHONE ☐ OUTGOING
ORGANIZATION Zevacor Molecular	DOCKET NUMBER(S) 030-38841	
LICENSE NUMBER(S) 13-35179-02	CONTROL NUMBER(S) 586983	

SUBJECT

Application for a new R&D license.

SUMMARY AND ACTION REQUIRED (IF ANY)

1. Radioactive Material

Sealed sources will be specifically list on your license by make and model number. Sealed sources authorized in Section 35.65 of 10 CFR Part 35 apply only to Part 35 licensees, therefore sealed sources described in Section 35.65 be will not be listed on your license. Appendix A5.1 to your application identified the make, model numbers, and quantity for 2 of 3 sealed sources. Please provide the model number and quantity for the barium-133 source.

2. Decommissioning Financial Assurance

Decommissioning financial assurance (DFA) applies to isotopes with a half life greater than 120 days. Your request for authorization of material with atomic numbers 1 - 83, 100 millcuries per isotope, will likely require Zevacor to establish and submit DFA, unless you place limitations on the types of radionuclides (e.g., radionuclides with atomic numbers 1 - 83 with a half life of less than or equal to 120 days, limitations on the sum of the ratios, etc.). Please revise possession limits accordingly to levels below that which requires DFA, or submit financial assurance in accordance with 10 CFR Part 30, Section 30.35.

3. Purpose for Which Licensed Material Will be Used

Please describe in more detail the purpose for which licensed material will be used. Explain what "pre-production of radiopharmaceuticals used for testing, validation, and qualification" means. Describe how material will be used to accomplish this.

4. Radiation Safety Officer (RSO) and Authorized User (AU)

Both the proposed RSO and AU have responsibilities beyond those that they will have as an RSO and authorized user on the R&D license. For example, the proposed RSO is also the COO for Zevacor, is the RSO and an authorized nuclear pharmacist for NRC license number 24-32827-01MD, and is an authorized user on an Illinois radioactive materials license. Your proposed authorized user is also an authorized user on NRC license number 24-32827-01MD, and an authorized user on the Illinois license. Given their multiple duties and responsibilities, please described how both individuals will be able to fulfill the duties under Zevacor's new R&D license.

5. Training Program

Submit a description of how you will evaluate the effectiveness of your training program and each attendees' understanding of the content of the training that is provided.

6. Facilities and Equipment

Page 3 of attachment A9.1 is a diagram of the area where licensed material will be used. Please identify where "area 1" (after hours receiving area) is located.

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CONVERSATION RECORD (continued)

LICENSE NUMBER(S)	CONTROL NUMBER(S)
13-35179-02	586983

SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

Submit a diagram which illustrates the location of all fume hoods and glove boxes where licensed material will be used, and include a diagram of ventilation duct work and air filtration associated with the fume hoods and glove boxes.

Confirm that ventilation system(s) which are associated with the fume hoods and glove boxes are independent of other air supply and exhaust system(s) for the building.

Describe the air effluent monitoring system(s). Include their location, and make and model numbers. Submit procedures that will be followed to calibrate the equipment, and confirm that the equipment will be calibrated on annual basis. Describe how you will convert instrument readings to concentrations of effluent that is released.

Describe how you will determine when air effluent filters need to be changed out.

Describe in more detail the security system that will be in place to prevent unauthorized access to the restricted area.

7. Survey Program

Submit a description of your survey program. Reference Appendix Q to NUREG-1556.

8. Waste Management

Submit a more detailed description of your waste management program in accordance with NUREG-1556, volume 7. Reference appendix T to volume 7.

9. Confidential Information

We noted that several pages in Zevacor's May 27, 2015, application were marked as "Confidential." In oder to for the NRC to withhold any or part of your application from public disclosure, you will need to address and meet the criteria described in 10 CFR 2.390(b)(1)(ii).

10. RSO delegation of authority

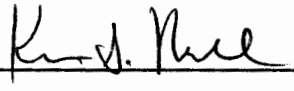
Please sign and submit the attached delegation of the authority for the RSO.

11. NRC license number 24-32827-01MD

On August 4, 2015, our office issued an amendment to license number 24-32827-01MD. The amendment approved a new location of use at 14395 Bergen Blvd., Noblesville, IN. This is the same address for the location of use in your application for the new R&D license. Please submit a facility diagram which illustrates the exact location where licensed activities authorized under both licenses at this address will be conducted. Describe how you will keep the activities under each license physically and administratively separate such that licensed material, documentation, paperwork and records of receipt, use, and storage of licensed material are not co-mingled.

NAME OF PERSON DOCUMENTING CONVERSATION

Kevin Null

SIGNATURE	DATE OF SIGNATURE
	09/18/2015