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
Matt Trusner	03/03/2015	☐ E-MAIL ☐ INCOMING ☑ TELEPHONE ☐ OUTGOING
E-MAIL ADDRESS: mtrusner@zevacor.com	TELEPHONE NUMBER: (866) 364-4478	
ORGANIZATION: Zevacor Molecular	DOCKET NUMBER(S): 030-38230	
LICENSE NUMBER(S): 13-35179-01MD	CONTROL NUMBER(S): 584769	

SUBJECT

Application for new Manufacturing and Distribution license and NRC site visit conducted on February 25, 2015, in Noblesville, Indiana

SUMMARY AND ACTION REQUIRED (IF ANY)

I contacted Zevacor and spoke with Mr. Trusner about NRC's proposed licensing approach in follow-up to my February 25, 2015, site visit. Discussions were held between John Zehner, Todd Hockemeyer, and Matt Trusner of Zevacor and me on February 25 about Zevacor's September 2, 2014, application for a new manufacturing & distribution (M&D) license, and the current status of Zevacor's facilities and equipment that will be necessary to effectively and safely operate under the NRC license that they have requested.

After consideration of Zevacor's September 2 application for a new M&D license, and as a result of the February 25 site visit, the NRC concluded that the licensing of Zevacor's activities should be approached in phases.

Zevacor needs an initial NRC license that will authorize them to possess and use radioactive material so that they can validate certain equipment as required by the FDA. In order to achieve FDA validation, Zevacor needs to be licensed by the NRC for specific radionuclides and quantities that will be similar to the levels that they will ultimately be handling in their production processes.

Since Zevacor does not yet have the facilities and equipment in place to justify issuance of an M&D license, and because their initial activities will be limited to pre-production testing of equipment to meet FDA requirements, Zevacor will need to withdraw its September 2 application for an M&D license and resubmit a revised application for a limited scope, research and development (R&D) license following the guidance in NUREG-1556, volume 7. At the time of the site visit, the facilities that would be utilized for the pre-production testing also had not been completed, and safety-related equipment had not been installed. The revised application for R&D should not be submitted until the facilities and equipment for pre-production testing are completed and operational.

Only after the pre-production testing and FDA validation, and following completion of facilities and installation of equipment that will be utilized for M&D of molybdenum and rubidium generators, should Zevacor submit a request for an amendment to the R&D license requesting authorization for M&D.

Zevacor is also in the process of constructing an area within the Noblesville facility to house and operate 18 MeV and 70 MeV cyclotrons, and will need to submit a separate application for a cyclotron-production license in accordance with current NRC policy. Addition of this site as a location of use via amendment to an existing cyclotron-production license that Zevacor holds, or acquires, is a possible option in lieu of applying for a new cyclotron-production license.

Zevacor would also like to add nuclear pharmacy operations at the Noblesville, Indiana site some time after the M&D activities are licensed by the NRC. A nuclear pharmacy license is a stand alone license, separate from the M&D license. However, Zevacor could consider adding the Noblesville site as a location of use to their existing nuclear pharmacy license number 24-32827-01MD.

The NRC noted that several pages in Zevacor's September 2, 2014, application were marked as confidential. I informed Zevacor representatives during the site visit that they would be required to address and meet the criteria described in 10 CFR 2.390 in order for the NRC to withhold any of Zevacor's documents from public view, and they would need to address the criteria with any future submittals if

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CONVERSATION RECORD (continued)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

they choose to mark any documents as confidential.

NAME OF PERSON DOCUMENTING CONVERSATION

Kevin Null

SIGNATURE	DATE OF SIGNATURE
K. A. Null	3/4/15