



CONVERSATION RECORD

NAME OF PERSON(S) CONTACTED OR IN CONTACT WITH YOU John Zehner	DATE OF CONTACT 03/21/2016	TYPE OF CONVERSATION	
E-MAIL ADDRESS jzehner@zevacor.com mtrusner@zevacor.com	TELEPHONE NUMBER (317) 578-1251	<input type="checkbox"/> E-MAIL	<input type="checkbox"/> INCOMING
		<input checked="" type="checkbox"/> TELEPHONE	<input type="checkbox"/> OUTGOING
ORGANIZATION Zevacor Molecular	DOCKET NUMBER(S) 030-38903		
LICENSE NUMBER(S) 13-35179-03	CONTROL NUMBER(S) 590094		

SUBJECT

Application for a cyclotron production license

SUMMARY AND ACTION REQUIRED (IF ANY)

1. Radioactive Material

Sealed sources will be specifically listed 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 as described in Section 35.65" be will not be listed on your license in this manner. Please provide the make, model numbers, and activity for each sealed source.

2. Decommissioning Financial Assurance (DFA)

We received Zevacor's DFA cost estimate in the form of a Decommissioning Funding Plan (DFP) for an amount over 5 million dollars. However, in order for us to continue to process your request for the new license you will need to submit a financial instrument for the amount of the cost estimate that is described in your DFP. Please reference 10 CFR Part 30, Section 30.35 for acceptable financial assurance instruments.

3. Purpose for Which Licensed Material Will be Used

Please describe in more detail the purpose for which licensed material will be used. For example, in your application you stated that material in items A. through X. will be for preparation and distribution of radiochemicals in accordance with 10 CFR 31.72 (Note: your reference to Section 31.72 may be a typo - 10 CFR Part 31 does not include a Section 31.72). Please review Appendix D of NUREG-1556, Volume 21, and model your purpose for use of material after item 9 A. through F. of the sample, which includes production, possession, handling, packaging, and distribution.

4. Radiation Safety Officer (RSO)

Submit a delegation of authority for the RSO. The delegation of authority must be signed by a representative of upper management and the RSO. Attached is a form that you can use.

In your application you stated that the RSO will spend "sufficient" time at the facility to fulfill the duties of the RSO. Please define "sufficient." For example, we would like to see a commitment to a number of days per week that the RSO will be present at the facility fulfilling the RSO duties. This is especially important to us given the multiple duties that the RSO already has under other NRC and Illinois licenses.

5. Authorized User

The Virginia license that you provided which names Maxim Kiselev as an authorized user is not a cyclotron license, therefore, this cannot be used as evidence of qualifications for him to be named on your cyclotron license. Please submit evidence of Maxim's qualifications to be named as an authorized user on your cyclotron license by addressing the criteria described on pages 8-16 and 8-17, of NUREG-1556, Volume 21.

CONVERSATION RECORD (continued)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

6. Training Program

Submit a detailed description of your training program that includes topics covered and estimated time spent on each topic, and 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.

7. Facilities and Equipment

Submit a radiation profile of the cyclotron.

Submit a diagram of the hot cells and the delivery lines from the cyclotron to each hot cell.

Submit a diagram of the air effluent ventilation/exhaust system for the cyclotron and hot cells. Include air exhaust and intake locations, and the location of exhaust filtration.

Describe the location of the air effluent monitoring system(s). Confirm that you will implement the manufacturer's calibration procedure. Identify the radionuclide that will be used to calibrate the monitor, and describe how you will determine the activity of the nuclide that is used (it appears that the manufacturer recommends the use of a carbon-11 source of known activity). Also, please describe the frequency of the calibration.

Describe the type of air filtration that will be used and how you will determine when air effluent filters need to be changed out.

Describe where spent targets will be stored and secured from unauthorized access, and how the room/area where they will be stored will be shielded. Submit an evaluation of the shielding of the room/area that demonstrates the expected radiation levels on the outside of the storage rooms.

Submit an evaluation of the shielding effectiveness of the hot cells.

8. Radiation Monitoring Instruments

Describe the instruments, e.g., dose calibrators, that will be used to quantitatively measure the radioactivity of product that will be distributed before it is shipped. Include procedures that will be implemented to ensure accuracy of those measurements.

Describe instrumentation that will be used for real time monitoring of neutron radiation outside the vault. Include the location of the monitor(s), action levels, and calibration procedures and frequency of calibration.

9. Occupational Dosimetry

Describe dosimetry that will be assigned to radiation workers. In particular, given the potential for radiation workers who handle PET radionuclides to receive significant extremity radiation exposure, please describe dosimetry that will be assigned to monitor extremity exposure. Also, please consider and provide a response to assigning extremity dosimetry to both hands for workers who handle targets and product.

Describe dosimetry that will be worn by workers to evaluate for exposure to neutron radiation.

10. Air Monitoring in the Workplace

Describe how you will monitor and measure for the presence radioactive air concentrations within the building where occupational workers may be present.

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

In the worker areas, the ambient exposure rate may mask the detectors response to air borne contamination. The area radiation monitor may not be able to detect the air concentration due to higher ambient background. Please describe how you will assure that airborne concentrations will be detected and measured.

11. Public Dose from Air Effluent

Describe methodology and/or equipment that will be used to minimize dose to members of the public from radioactive air effluent that is released to the environment.

Submit an estimate of what the expected concentrations of radioactive air effluent will be at the point of release through the exhaust stack on the roof. Describe roof access controls that will be in place to prevent non-occupational workers from being exposed to radioactive air effluent.

Describe the maximum activity per radionuclide of air effluent that you expect will be released from the roof stack on an annual basis, and an estimate of the concentration that will be present at the nearest building air intake.

12. Safe Handling of Radionuclides

Please include a statement that procedures will be revised if:

- the changes are reviewed and approved by the RSO;
- staff is trained in the revised procedures before they are implemented;
- the changes are in compliance with NRC regulations and the license; and
- the changes do not degrade the effectiveness of the program.

13. Survey Program

In your survey program you made a statement that you will perform contamination checks on all manufactured sealed sources prior to distribution. Manufacturing and distribution of sealed sources was not an activity that you requested to be authorized for, therefore, please delete this statement, or provide clarification.

14. Stack Monitoring Program

Calculate and submit the minimum detectable concentration for the detector based on the background counting rate and calibration factor.

Develop and submit a procedure for performing a daily functional check of the detector, including a commitment to recalibrate the detector if the detector ever fails the daily check.

15. Waste Management

Submit a more detailed description of your waste management program in accordance with NUREG-1556, Volume 21. Reference 8.11, Item 11, and Appendix P to Volume 21.

In particular, describe a specific program for off-site disposal of long lived waste (i.e., greater than 120 day half-life) on a regular, consistent frequency in lieu of storing for 5 years before disposal. Also, develop and submit a specific procedure for holding, surveying, and disposal of short-lived waste (i.e., less than or equal to 120 day half life). Describe the location and security for storing both short and long lived radioactive waste.

CONVERSATION RECORD (continued)

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SUMMARY AND ACTION REQUIRED (IF ANY) (Continued)

NAME OF PERSON DOCUMENTING CONVERSATION

Kevin Null

SIGNATURE

Kevin A. Null

DATE OF SIGNATURE

03/21/2016

Null, Kevin

From: Null, Kevin
Sent: Thursday, March 31, 2016 11:49 AM
To: 'mtrusner@zevacor.com'
Subject: new license application
Attachments: NRCform699ZEVACOR032016.pdf

Hi Matthew,

This is in follow-up to our discussion today about your application for a new cyclotron production license (C/N 590094).

Since you will not be able to complete and submit a timely response to my request for additional information as described in the conversation record dated 3/21/2016, we will void this action.

However, as we discussed you can resubmit the application with no additional fee after you complete your response to the questions from the conversation record.

Therefore, when you resubmit the application please submit an exact duplicate of the original application (dated 1/25/16), except with a new signature and a current date. As a separate attachment to the resubmitted application, submit your response to the questions from the 3/21 conversation record.

Once again, since you already paid the fee for the original application, no additional fee will be required for the resubmittal. Simply include a cover letter stating that you are resubmitting the application, and reference the old control number 590094, and indicate that a fee has already been paid.

Lastly, also as we discussed today I revised items 8 and 9 of the conversation record (attached) to address monitoring for neutron radiation in the vault area, and neutron dosimetry for radiation workers.

Please contact me if you have any questions.

Kevin Null
630-829-9854