CONVERSATION RECORD (time) (date) | TIME | DATE 3/5/10

VISIT ○ CONFERENCE TELEPHONE X

○ INCOMING
X OUTGOING

NAME OF PERSON(S) CONTACTED OR IN CONTACT	ORGANIZATION (OFFICE, DEPT.ETC.)	TELEPHONE NO.
Marc Weichelt	Essential Isotopes	573-882-0245

SUBJECT

C/N's 318475 and 318478

SUMMARY

I contacted Marc and informed him that I completed the review of Essential Isotopes applications for two new licenses. Reference C/N's 318475 and 318475. We discussed the deficiencies identified below, which were e-mail to Marc on 3/5

Essential Isotopes - Cyclotron Deficiencies

1. **Since you will be conducting licensed activities on the campus of the University of Missouri which involves utilizing University equipment and staff, please submit a letter signed by representatives of the University and Essential Isotopes (EI) which describes the relationship between both parties with regard to licensed operations conducted by Essential Isotopes. Please also delineate between the safety responsibilities of both parties with regard to activities that will be conducted under Essential Isotopes' license on the University campus.**

2. **With regard to the proposed Radiation Safety Officer, Ronald Dobey, describe the duties that he currently holds with the University and demonstrate how these duties will not impact his ability to perform the duties as RSO for EI's license. Describe the minimum amount of time that Mr. Dobey will dedicate to fulfilling the duties as RSO for EI.**

3. **Please note that the NRC cannot issue your new licenses until it has received and approved EI's financial assurance. We are currently reviewing EI's decommissioning funding plan (DFP) and Cost Estimate (CE); however, we are waiting for EI's submittal of its financial assurance instrument (FAI). Please advise us as to the status of your FAI.**

4. **In your application you listed 4 Authorized Nuclear Pharmacists (ANP's) and 2 additional EI Staff members. Please identify which individuals you are requesting to be named as authorized users on the license. For each individual that you wish to be named on the license as an AU, please submit a description of their training and experience as requested in NUREG-1556, volume 21 pages 8-16 through 8-18. The resumes that you submitted in Item 7 of your application do not fully address the training and experience requirements of volume 21.**

5. **The training program describe in Item 8 of your application will need some clarification and revisions. For example, the program includes references to a Corporate RSO; Regional Health Physicists;**

Human Resources; Students/Temp workers; references to "PETNET SOP's, etc. Please describe the relationship of these references to EI. For example, your application did not identify a Corporate RSO. Reference is also made in Item 8 to an "Attachment 2" that contains training topics. However, the application that we received did not include Attachment 2. Please also explain the relevance of submitting the training booklet for the University Research Reactor. Although the University may require EI staff to be trained in accordance with this document due to the location of EI in the MURR facility, EI needs to develop a stand alone training program. Please clarify Item 8 and resubmit your Training Program in accordance with NUREG-1556, Volume 21, page 8-18.

6. Describe the use of alarming system that is employed in the cyclotron room that would be activated in the event of entry into the cyclotron room while the unit is in operation. Describe the interlock system and how with works.

7. Describe the use of personnel dosimetry of staff that will be responsible for maintenance of the cyclotron and handling and removal of targets from the cyclotron. The use of alarming ratemeters with established set points should be considered for use, or provide justification why they are not used.

8. Describe procedures that will be implemented to evaluate skin dose should an individual receive a skin dose due to exposure to any of the cyclotron products, e.g., F-18. Also, submit a bioassay program to evaluate staff for intake of cyclotron-produced material in the event of an airborne release in worker breathing zones.

9. Describe how you will detect an accidental airborne release resulting from, for example, a defective valve in the transfer tubing between the cyclotron and hot and mini cells, or a release due to manual intervention in a normally automated synthesis procedure.

10. Submit calibration procedures for your Medi-Smart cyclotron room area monitor and effluent monitoring systems. Verify that the monitors will be calibrated on an annual basis, and after repair.

11. Describe your procedure for calibrating alarming ratemeters worn by staff who conduct maintenance on the cyclotron.

12. Identify, by name, the cyclotron engineer(s) who will be responsible for target installation, target change-out, and performing maintenance on the cyclotron. Describe in detail the training and experience in performing these duties in accordance with NUREG-1556, Volume 21, pages 8-16 through 8-18.

<u>Essential Isotopes - Pharmacy Deficiencies</u>

1. Same as Item 2 for cyclotron above, i.e., RSO duties and time commitments with the University and EI.

2. In accordance with NUREG-1556, Volume 13, please identify authorized users of licensed material other than material that will be authorized for the purpose of preparation and distribution of radioactive drugs, e.g., material used for instrument calibration, etc. Include relevant training and experience.

3. Regarding Item 7 of your application, please describe the material that L. Saale and J. Hoyt will be authorized to handle on your

license. Include their relevant training and experience, or state that they will use the material under supervision of the ANP's.

4. Same as Item 8 for cyclotron above, with regard to skin dose and internal dose.

5. Same as Item 5 for cyclotron above, with regard to training program.

6. Submit calibration procedures for your Medi-Smart pharmacy room area monitor, and effluent monitoring systems for pharmacy operations. Verify that the monitors will be calibrated on an annual basis, and after repair.

7. Submit calibration procedures for your dose calibrators and the frequency for each procedure. Ref. NUREG-1556, volume 9, revision 2.

8. Describe your procedure for monitoring effluent filters for saturation, and exchanging the filters (for cyclotron too).

9. Describe procedures that will be implemented to safely conduct maintenance on the chemical synthesis units/mini cells, and to safely perform mini cell component replacement activities.

10. Describe procedures that will be implemented and equipment that will be used, e.g., remote handling tools, to safely handle unit doses that are removed from the hot cell and prepared for shipment.

ACTION REQUIRED

Respond to the above within 30 days.

NAME OF PERSON DOCUMENTING CONVERSATION	SIGNATURE	DATE
Kevin Null	Kevin A. Null	3/5/10

ACTION TAKEN

SIGNATURE TITLE DATE