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TERRANCE ALEXANDER, EXECUTIVE DIRECTOR

February 17, 2015

Mr. Kevin Null
Senior Health Physicist
Division of Nuclear Materials Safety
U.S. Nuclear Regulatory Commission
2443 Warrenville Road, Suite 210
Lisle, IL 60532-4352

SUBJECT: Amendment to Byproduct Material License No. 21-00215-07—Response To Questions of 2-10-2015

Dear Mr. Null:

Mark Driscoll, Director of OSEH-Radiation Safety Service and Radiation Safety Officer, forwarded your questions from your conversation record of 2-10-15 regarding the amendment application we submitted on behalf of the University back in December to amend License No. 21-00215-07. We submitted the amendment application to add a description of the Ionetix SC-12 miniature cyclotron. The University is planning to acquire this machine for the production of nitrogen-13 ammonia in aqueous solution to be used in medical diagnostic and research use as well as attendant research and development associated with the design and operation of the Ionetix SC-12.

As a brief introduction, the plan is to house the SC-12 inside the existing concrete vault that currently houses the General Electric PETtrace cyclotron (as described in the original license application of July 29, 2010). The vault provides ample shielding for both the GE unit and the proposed Ionetix SC-12 as well as restricted access to the machine. The facility and system protections in place for the operation of the GE PETtrace will be in place for the Ionetix SC-12 and offer similar protection to personnel, public and the environment.

Most of the questions you forwarded in the Conversation Record from today are described in the documentation included in the Application for Amendment dated 12-3-2014 ("Amendment Application"). I've included appropriate citations to that document when applicable. I've restated your questions below along with our reply to each.

Please feel free to call or write if you have questions regarding these responses or if you have other questions regarding the application for an amendment. Thank you very much for your attention to our request.

Dennis A. Palmieri,
Sr. Health Physicist
OSEH-Radiation Safety Service
University of Michigan
734-764-9182 (desk)

Response to Questions from Conversation Record of 2-10-15

Q1. Describe where incidentally activated radionculides will occur, i.e., will they be both inside and outside of the device. Also, identify expected radionuclides that will be incidentally produced, as well as quantities of each nuclide. Please submit any available documentation from the manufacturer to support the information that you provide.

A1. The device is a largely self-contained unit that houses the target, coils, magnets, and other attendant equipment. See Attachment 1 of the Amendment Application. Incidentally activated materials produced from the operation of the unit are expected to be within and integral to the device and its housing. The bulk of the induced activity resulting from operation will occur from irradiation of the metal target assembly and target foil window. Page 3 of the Amendment Application along with Attachments 2 and 4 describe the target assembly and summarizes the expected activation products expected by the manufacturer to be produced in the target and in other components of the Ionetix cyclotron. Existing limits in License No. 21-00125-07 for incidental activation products are expected to be sufficient to accommodate the Ionetix without amendment. As such, we are not requesting any modification of current license limits.

Q2. Describe the expected radiation level profile surrounding the device both when it is being operated and when it is shut down. Please submit any available documentation from the manufacturer to support the information that you provide.

A3. The Ionetix SC-12 is a newly designed machine and we do not have any existing actual measurements for an exposure rate profile. Mr. Mark Leuschner, Vice President of Operations at Ionetix advises that Ionetix is contracting with an independent health physics consultant to obtain radiation field measurements. We cannot state with certainty when the measurements will be completed as that is not a matter under our control. However, Ionetix indicates it is willing to provide that data after it obtains a final report from its contractor. It is important to note that, for the purposes of this license amendment, the Ionetix unit will not be used in an openly accessible area. It will be housed in the same concrete vault as where the existing cyclotron (General Electric PETtrace) is located. See Attachment 3 of the Application Amendment. The vault consists of walls, door and ceiling with over 5 feet thick of concrete and sits on grade. The Ionetix operates at lower energy and beam current than the GE PETtrace and the target assembly is contained within the housing. Accordingly, this shielding is expected to be fully sufficient to protect anyone outside the vault when the machine is in operation. Personnel will not be in the vault during operation. See Response to Question 3.

Q3. Describe the proximity of the device relative to staff members who will be working with or near the device. Describe any restrictions that will be placed on staff members working near the device when it will be in operation.

A3. The Ionetix cyclotron will be housed inside the concrete vault that also houses the GE PETtrace. See Attachment 3. Personnel will not be allowed in the vault during operation of the cyclotron. Unescorted access to the vault is controlled and restricted to trained personnel at all times. Survey instrumentation is available and is used when entering the vault to ensure radiation levels have decayed to sufficiently low levels before entry. Trained and approved personnel are issued radiation monitoring to be worn when entering restricted areas like the vault. The Radiation Safety Section of the State of Michigan Occupational Safety and Health Administration (MIOSHA) regulates the use and operation of particle accelerators and the production of prompt radiation from the operation of such machines. State regulations require the use of facility alarms and interlocks to prevent inadvertent entry and exposure during machine operation. This device will be registered with the State of Michigan and subject to its approvals and inspections. See page 1 of the Amendment Application.

Q4. Describe any radioactive air effluent that may be generated as a result of target activation. Describe where and how the effluent is released, and how you will evaluate the concentration in order to demonstrate that you do not exceed 10 CFR Part 20 constraint limits on air emissions.

A4. The Ionetix SC12 uses liquid water as target material. The target holds approximately 3.5 cc of water which is subjected to proton bombardment to produce N-13 from a (proton, alpha) reaction with the oxygen atoms (stable O-16) in the water. The liquid target is fully housed within the cyclotron housing. In the event of a leak or rupture of the target, the liquid will be retained in the cyclotron and allowed to decay (~9 minute half-life). See pages 2 and 4 of the Amendment Application. There are no other expected gaseous isotopic contaminants. In the event there is some volatization or aerosolization of the product, the effluent from the vault is monitored using a ROTEM MediSmarts effluent monitor system. One detector system can trip and shut down vault ventilation trapping all effluent inside the vault until all products decay. A second detector system monitors effluent concentration that may be released from the vault. This is the same system that controls emissions from operation of the GE PETtrace cyclotron which is routinely used to produce carbon-11 as carbon dioxide, fluorine-18 hydrogen fluoride in solution and nitrogen-13 as ammonia in solution.