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April 24, 2009

Docket No. 030-37957 License No. 52-31352-02
Control No. 143376

Frank Kolodziej Castro, M.D.
President
International Cyclotron
Calle Jose Marti #56
Floral Park
Hato Ray, PR 00918

SUBJECT: INTERNATIONAL CYCLOTRON, REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 143376

Dear Dr. Kolodziej Castro:

This is in reference to your letter dated January 28, 2009 applying for a Nuclear Regulatory Commission license for production of radioactive material using an accelerator. In order to continue our review, we need additional information. In your January 28 application, you used guidance from NUREG-1556, Volume 13, "Program-Specific Guidance about Commercial Radiopharmacy Licenses." However, this license application is for production of radioactive materials using a cyclotron, and you should use NUREG-1556, Volume 21, "Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator" (NUREG-1556, Vol. 21), as guidance when responding to these deficiencies. Also, we understand that the cyclotron has in the past been in operation prior to requiring an NRC license. The procedures used during that time may provide valid information and may be considered as part of this review. Please respond to the following:

1. In accordance with Section 8.5.1 "Unsealed and/or Sealed Byproduct Material" of NUREG-1556, Vol. 21, provide a list of all radionuclides (element name and mass number), chemical form, and maximum requested possession limits that you intend to produce including incidentally activated products. For incidentally activated radionuclides, you may request authorization to posses and use byproduct material with atomic numbers from 1 through 83 as discussed in that section; you should indicate the activity per radionuclide and the total cumulative quantity for all radionuclides to be possessed at any one time under the '1 through 83" authorization. If certain incidentally activated radionuclides will be produced in much larger quantities than described in the "1 through 83" authorization, those nuclides should be listed separately. For potentially volatile material, indicate if the material will be free or bound and provide the requested possession limit for each form. NUREG-1556, Vol. 21 contains a discussion regarding this requirement, as well as examples in Table 8.5.1 and on the sample license in Appendix D.

2. In Item 5 of your application, you requested ammonium 13. Confirm if you intended to request nitrogen-13 (N-13) or provide another correct element.

3. In accordance with Section 8.5.2 of NUREG-1556, Vol. 21, the possession limits that you may request for radionuclides with half-lives greater than 120 days (such as atomic numbers 1 through 83 and cyclotron activation products such as zinc-65 (Zn-65), manganses-54 (Mn-54), cobalt-60 (Co-60), and europium-152 (Eu-152)) may require you to implement the financial assurance requirements. Regulations set forth in 10 CFR 30.35 requires that licensees authorized to possess and use unsealed licensed material with a half-life greater than 120 days in quantities greater than those described in 10 CFR 30.35(d) must submit certification for financial assurance or a decommissioning funding plan (DFP) in any new application. This plan must include an actual estimate of the costs for decommissioning your facility and a mechanism to fund the Plan. The appropriate level of detail for the cost estimate is discussed in Appendix A.3 to Volume 3, "Financial Assurance, Recordkeeping, and Timeliness" of NUREG-1757, "Consolidated NMSS Decommissioning Guidance." (NUREG-1757, Vol. 3). If financial assurance is required, you must submit certification for financial assurance in the prescribed amount using one or more of the approved financial assurance mechanisms provided in Chapter 4 of NUREG-1757, Vol. 3. Alternatively, you may request to limit the possession of unsealed licensed material of half-life greater than 120 days and thereby reduce or eliminate the required financial assurance. You will need to evaluate the radionuclides you wish to possess and determine the need for financial assurance and the amount necessary to provide financial assurance for this license.

4. Please provide the manufacturer and model of the cyclotron that you intend to use and a brief description of its operating procedures that may affect the production of activated components and/or facilities, and the radiation levels in the facility.

5. In your application, you identify David Rhoe as your Radiation Safety Officer. Please note that the two license numbers referenced as evidence of qualifications do not support the qualifications needed for the type of license you are requesting. In accordance with Section 8.7.1 of NUREG-1556, Vol. 21, provide details of the pertinent training and experience Mr. Rhoe has received with respect to the types of activities for which you are requesting to be licensed. Specifically, provide dates for training, the training provider, the list of topics covered, and any certificates or grades that you ay have received. For related experience, specifically describe the activities and the dates you obtained the specific experience. In addition, describe the specific isotopes the individual has handled, the maximum quantities of materials handled, where the experience was gained, the duration of the experience and the type of use. You should consider also the training that was gained in operating the cyclotron and related activities at your facility prior to requiring an NRC license.

6. You have identified several individuals as proposed authorized users. In accordance with Section 8.7.2 of NUREG-1556, Vol. 21, provide details of the pertinent training and experience each individual has received with respect to the types of activities you for which are requesting to be licensed. Specifically, provide dates for training, the training provider, the list of topics covered, and any certificates or grades that you ay have received. For related experience, specifically describe the activities and the dates you obtained the specific experience. The description of the use of licensed materials should include the specific isotopes handled, the maximum quantities of materials handled, where the experience was gained, the duration of experience, and the type of use.

7. You have identified an Authorized Nuclear Pharmacy (ANP) for this license. Please note

that you are applying for this license in order to produce radioactive materials using an accelerator. This license does not require an ANP; therefore, no response to this item is required.

8. Individuals, whose assigned duties involve exposure to radiation and/or radioactive materials, must receive instruction commensurate with potential radiological health protection present in the workplace, as required buy 10 CFR 19.12. Specifically, those individuals who would likely receive an occupational dose within a year greater than 100 millirem must receive such training. In accordance with Section 8.8 of NUREG-1556, Vol. 21, submit a description of the radiation safety training program, including the topics covered, groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training. Ensure that the description addresses training for operators, hot cell staff, maintenance, ancillary personnel, and any other groups of workers that in the restricted areas. In addition, confirm that your training program includes a discussion on hazardous materials package preparation and transport if you will be shipping radioactive material. Appendix F of NUREG-1556, Vol. 21, may be used to develop a training program.

9. In accordance with Section 8.9 of NUREG-1556, Vol. 21, describe the facilities and equipment to be made available at each location where radioactive material will be produced, possessed, and/or used. In your letter dated January 28, 2009, you referenced Docket No. 030-37882 and Control No. 143067 to support your responses. Please note that your previous responses did not afford sufficient information and descriptions to meet these requirements. Diagrams should be drawn to a specified scale, or dimensions should be indicated. You may use NUREG-1556, Volume 21, Appendix G as a guide for the facilities and equipment to be addressed. Include the following areas and provide the requested information:

    a. Areas for use and storage of licensed material within the cyclotron vaults. If you have an interlock system, include a description of the interlock operation of the cyclotron and a description of the required surveys prior to entering the cyclotron vault after operation. In addition, confirm whether storage areas are used for activated components. If so, describe the shielding of the areas used to store neutron activated components and provide the typical dose rates measured near activated components and the storage facility for them.

    b. Target and product transfer areas. On your facility diagrams, identify the areas of the facility used for transfer of F-18 and N-13 from the cyclotron to the hot cells and out of the hot cells, showing the location of any transfer lines, and describe the shielding of these lines. Although you provided a short description in your application, it is unclear how many delivery lines exist, where they are located, or how they are shielded.

    c. Areas assigned for the receipt, storage, preparation, and measurement of licensed materials. Identify the locations of these areas on your diagrams, and submit a description of these areas. The diagram should show the locations of shielding, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety such as shielding of areas used for storage of prepared product prior to transfer.

d. Other specialized facilities. Please show the locations of such facilities on the diagram, and provide detailed description of all specialized facilities such as hot cells/mini-cells, automated equipment used for handling targets/product, liquid waste holding tanks, solid waste storage facilities, effluent hold-up bags, etc. Provide typical dose rates measured near each of these areas and describe any shielding used in these areas.

e. Unrestricted areas. On your diagram, identify any unrestricted areas within your facility as well as unrestricted adjacent areas that may belong to other facilities or are public areas. Be sure to address areas above and below your facility, if applicable. Provide enough information to show that adequate steps have been taken to assure that radiation levels in unrestricted areas will not result in doses to individual members of the public in excess of those specified in 10 CFR 20.1301.

f. Ventilation and effluent monitoring systems. Your diagram should include the locations of your ventilation systems and effluent monitoring systems. Provide schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments.

(1) In your application, you stated that the restricted areas are under negative pressure with respect to the unrestricted areas, and provided the exhaust flow rate. However, it is not clear if only one exhaust stack exists and how the air from hot cells, cyclotron etc are linked to the exhaust system.

(2) For airborne effluents, please provide a detailed description of the design of your effluent monitoring systems. Although it was stated in the application that the ventilation system is monitored using the MediSMART Radiation System, more information about this system is required, such as the location and method of monitoring by this system. You may provide the manufacturer or supplier information about this system in addition to how the system is implemented at your facility.

(3) Describe any unmonitored effluent releases (doors, windows etc) and provide the basis upon which you have determined that unmonitored releases will not exceed 30% of the total estimated effluent releases or 10% of the permissible air effluent concentrations found in column 1 of Table 2 in 10 CFR Part 20, whichever is greater.

g. Contamination control equipment and procedures. Describe equipment and/or procedures for controlling hot particles from vault operations (e.g., Co-60). Such equipment may include step-off mats (sticky mats) and protective clothing used in areas where hot particles may be expected. Describe equipment and/or procedures for contamination control, such as hand and foot monitors at the exits from the restricted areas and required surveys by personnel prior to leaving potentially contaminated areas; and use of lab coats, disposable gloves, lead-impregnated gloves, shoe covers or other protective clothing. Such equipment was not listed in your January application.

h. Packaging and shipping facilities. Describe any facilities where materials

(product or wastes) would be packaged and stored prior to shipment from your cyclotron. Describe any special equipment in this area such as compactors, remote handling equipment, etc. This does not include radiopharmaceuticals prepared and distributed under the radiopharmacy license which is under separate review.

10. You application did not describe any equipment which may be required during routine maintenance activities of the cyclotron and hot cells. Describe your routine maintenance activities for such areas, and any safety precautions or procedures used to ensure that personnel exposures are ALARA. If respiratory protection is required for activities such as cleaning cyclotron internals or machining activated components, describe your respiratory protection program and the use of process or other engineering controls in place to limit the use of respirators to control exposures. In addition, describe your respiratory protection equipment, protective clothing, and any additional dosimetry that may be needed when doing this sort of activity.

11. In your application, you specified that you would perform a sealed source inventory; however you have not specified that you wish to possess any sealed sources. If you desire to possess sealed sources, you will need to specifically request them. When requesting sealed sources, please also provide the make, model number, and quantity desired.

12. In accordance with Section 8.10.5 of NUREG-1556, Vol. 21, it is the licensee's responsibility to ensure that licensed material will be used, transported, stored, and disposed of in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, not more than 0.1mSv (10 mrem) from air emissions in one year, and not more that .02 mSv (2mrem) in any one hour in any unrestricted area. Demonstrate that that effluents and radiation levels (including the outside wall, floors, and ceiling) will be maintained within public dose limits

13. You have stated that you will use decay-in-storage for short-lived waste. In accordance with Section 8.11 of NUREG-1556, Vol. 21, provide procedures for waste collection, storage, and disposal for long-lived radionuclides (such as incidentally activated materials). Also, address release of licensed materials in air and/or water, if applicable.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications.** You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 7:00 a.m. to 6:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 143376. If you have any technical questions regarding this deficiency letter, please call Farrah Gaskins at (610) 337-5143.

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will assume that you do not wish to pursue your application.

Sincerely,

Original signed by Elizabeth Ullrich

Betsy Ullrich
Senior Health Physicist
Commercial and R&D Branch
Division of Nuclear Materials Safety

cc:
David Rhoe, Radiation Safety Officer

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