UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
475 ALLENDALE ROAD
KING OF PRUSSIA, PENNSYLVANIA 19406-1415

January 12, 2009

Docket No. 03037882 License No. 52-31352-01
Control No. 143067

Frank Kolodziej Castro
President
International Cyclotrons, Inc.
P.O. Box 364443
San Juan, PR 00936-4443

SUBJECT: INTERNATIONAL CYCLOTRONS, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR NEW LICENSE, CONTROL NO. 143067

Dear Dr. Kolodziej Castro:

This is in reference to your application dated November 25, 2008 applying for a Nuclear Regulatory Commission license. In order to continue our review, we need the following additional information:

1. It appears that you may wish to utilize an accelerator to produce radioactive drugs. In addition to applying for a license as a commercial radiopharmacy, you must also submit a separate license application for the use of an accelerator. If approved, you will be issued two licenses. You should use NUREG 1556, Volume 21, “Program-Specific Guidance About Possession Licenses for Production of Radioactive Material Using an Accelerator” to aid in completing your application.

2. In Item 4 of your application, you indicated that Dr. Frank Kolodziej Castro was the name of the licensing entity, however, in attachment # 7.1 where you identify the management structure, the heading reads ”International Cyclotrons, Inc.” Also, the pharmacy license issued by the State Department appears to be issued to “International Cyclotrons”. Please verify the name of the entity to which the license should be granted.

3. You have requested that David S. Rhoe be named Radiation Safety Officer (RSO) on your license. It appears that this individual may be an outside consultant\contractor. If this is so, in support of this request, please address the following:

   a. Describe the control over the radiation safety program that will be delegated so that the consultant-RSO will be able to exercise authority over authorized users when confronted with radiation safety problems that require implementation of corrective actions.

   b. Describe the relationship that will exist between the consultant-RSO and your institutional management regarding expenditure of funds to facilitate the objectives of your radiation safety program and related regulatory requirements.

c. Identify other commitments of the consultant-RSO for other NRC or Agreement State licensed facilities, along with a description of how the consultant-RSO will allocate time to permit the performance of the duties of the RSO as described in the regulations. State the consultant-RSO's minimum amount of on-site time (hours per week).

d. Appoint an in-house representative who will serve as the point of contact during the RSO's absence. This person may be allowed to assist the consultant RSO with limited authority.

e. Describe the overall availability of the consultant-RSO to respond to questions or operational issues that arise during the conduct of your radiation safety program and related regulatory requirements. Specify the maximum amount of time it will take the RSO to arrive at the facility in the event of an emergency that requires his presence.

4. Although Mr. Rhoe is named on other licenses, these activities include calibration of instruments and medical use of radionuclides. Please provide evidence of training and experience with the types and quantities of materials being requested. Also, please provide dates and locations of training and/or experience.

5. Regulations set forth in 10 CFR 32.72(b) (2) require that each commercial nuclear pharmacy must have an Authorized Nuclear Pharmacist (ANP) to prepare or supervise the preparation of radioactive drugs for medical use. Please identify your proposed ANP and evidence of their training and experience, providing the information requested in Section 8.7.2 of NUREG 1556 Volume 13, “Program-Specific Guidance About Commercial Radiopharmacy Licenses”.

6. In your application, you identify several individuals as your proposed authorized users. Please describe these individuals’ formal training in the following areas:

a. principles and practices of radiation protection;

b. radioactivity measurements standardization and monitoring techniques and instruments;

c. unit of radiation dose and quantities;

d. NRC regulatory requirements and standards;

e. mathematics and calculations basic to the use and measurement of radioactivity; and

f. biological effects of radiation;

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 may wish to refer to NUREG 1556 Volume 13 section 8.7.3, “Program-Specific Guidance About Commercial Radiopharmacy Licenses” to help you with the formulation of your answer.

7. Describe the facilities and equipment (e.g., remote handling equipment, storage containers, shielding, fume hoods) to be made available at each location where licensed material will be used. Include methods used to physically transfer licensed material to the different processes (e.g. chemical synthesis, dispensing). Submit a description of the areas assigned for the receipt, storage, preparation, and measurement of licensed materials. Submit a diagram showing the locations of shielding and/or shielding equipment, the proximity of radiation sources to unrestricted areas, and other items related to radiation safety. For facilities where licensed materials may become airborne, include schematic descriptions of the ventilation system, with pertinent airflow rates, pressures, filtration equipment, and monitoring instruments. Finally, verify that ventilation systems are in place to ensure that effluents are ALARA and within the limits of 10 CFR 20.1301 and are within the constraints for air emissions established under 10 CFR 20.1101(d). Diagrams should be drawn to a specified scale, or dimensions should be indicated. Please refer to NUREG 1556 Volume 13, Sections 8.9.1 and 8.9.2, "Program-Specific Guidance About Commercial Radiopharmacy Licenses" to formulate your answer.

8. On a detailed version of your facility diagram, please indicate the position of each of the areas described below (a-d) and describe the type, dimensions, and thickness of shielding that you will use.

   a. Use and storage of Tc-99m generators.

   b. Storage of radiopharmaceuticals (refrigerated and non-refrigerated).

   c. Storage of radioactive waste, including decay-in-storage prior to disposal as nonradioactive waste. This area should be large enough to handle an accumulation of Tc-99m generators as well as other solid waste. If this area is not located within your main department, describe how you will secure the material.

   d. Preparation and dispensing of radiopharmaceuticals (e.g., lead glass L-block, etc.).

   In addition, identify adjacent areas across the walls from use and storage locations and 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 (enclosed).

9. Your application included procedures for safe use and handling of radioactive material. These procedures appear to be excerpts from your radiation safety manual. Please note that if you provide these procedures as part of your application package, you will have to submit an amendment in order to make any changes to it. Otherwise, you may state that procedures are in place and it will become an item of inspection. Please verify if you would like to include the procedures in the appendices as part of your application.

10. Please describe the types of systems (measurements or combinations of measurements and calculations) that you intend to use for the measurement of alpha-, beta-, gamma-, and photon-emitting radioactive drugs. In addition please confirm that you have

developed, and will implement and maintain a written procedure for the performance of dose measurement system checks and tests that meets the requirements in 10 CFR 32.72 (c). You may wish to refer to NUREG 1556 Volume 13, Section 8.10.9, "Program-Specific Guidance About Commercial Radiopharmacy Licenses"

11. Please confirm that the transportation of licensed materials will be in accordance with 10 CFR Part 71 (enclosed) and Department of Transportation regulations.

12. In section 10.14 of your application, you provided a statement that you have developed procedures for leak tests. If you wish to possess radioactive materials in the form of a sealed source, you must provide the following information; radionuclide, manufacturer, model number, and quantity. If you do not wish to use sealed sources, please confirm that you will not need a leak test procedure.

13. In your application, you submitted an example of the labeling you will use for radioactive drug distribution, however, please:

    a. Indicate the colors to be used for the labels and describe where each label would be placed.

    b. Please agree to affix the required labels to all "transport radiation shields" and to each container used to hold the radioactive drugs.

14. You have identified in your application that you will be using Pinestar Technology for radioactive drug shielding for distribution, however, for each radioactive drug to be distributed:

    a. Indicate the radionuclide and the maximum activity for each type of container (E.g. vial, syringe)

    b. Describe the type and thickness of the "transport radiation shield" provided for each type of container.

    c. Indicate the maximum radiation level to be expected at the surface of each "transport radiation shield" when the radioactive drug container is filled with the maximum activity.

15. Dr. Frank Kolodziej Castro is listed on your application as the president. We have also noted that Dr. Kolodziej Castro is the licensee representative of Somascan, Inc. Please describe the relationship or connection you may have to Somascan, Inc..

16. In your license application, you submitted a list of individuals which make up your organization. Please describe the flow of the organization, for example, to which individual would the radiation safety officer report to.

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 Farrah Gaskins at the Region I Office and refer to Mail Control No. 143067. If you have any technical questions regarding this deficiency letter, please call me 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 S. Rhoe, Radiation Safety Officer

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SUNSI Review Complete: FGaskins
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