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

September 2, 2011

Docket No. 030-37957 License No. 52-31352-02
Control No. 144277
EA-11-086

Frank S. Kolodziej Castro, M.D.
President and Owner
International Cyclotron, Inc.
Calle Jose Marti #56
Floral Park
Hato Rey, PR 00918

SUBJECT: INTERNATIONAL CYCLOTRON, INC., REQUEST FOR ADDITIONAL INFORMATION CONCERNING APPLICATION FOR AMENDMENT TO LICENSE, CONTROL NO. 144277 AND THE PREDECISIONAL ENFORCEMENT CONFERENCE HELD ON AUGUST 30, 2011

Dear Dr. Kolodziej:

On August 2, 2011, the NRC sent you a letter requesting your attendance at a predecisional enforcement conference to discuss your apparent failure to provide adequate financial assurance in accordance with 10 CFR 30.35. You had failed to respond to multiple prior requests for such information. On August 30, 2011, you and David Rhoe, the Radiation Safety Officer for your license, attended the conference in King of Prussia, Pennsylvania where this issue was discussed.

Following the letter requesting the conference, you submitted a Decommissioning Funding Plan (DFP) by electronic mail from Mr. Rhoe on August 5, 2011. A revision of this DFP was submitted by electronic mail from Mr. Rhoe on August 30. The NRC staff reviewed the DFP and revision, which are not accepted at this time because revisions and additional information are required. The NRC staff also reviewed the Certification of Financial Assurance, submitted with the DFP on August 5, and it is not accepted.

At this time, you remain in noncompliance with NRC regulations in 10 CFR 30.35 that require you to provide a DFP with cost estimate, and to provide financial assurance in the amount of the cost estimate using an approved method. In order to facilitate compliance with NRC requirements, you must provide additional information within 30 days for our review. The information needed is listed below. Failure to adequately respond to the request for additional information within 30 days will result in the NRC consideration of appropriate enforcement actions, as described during the conference and later in this letter.

1. The following items refer to the decommissioning funding plan (DFP) and a certification of financial assurance (CFA) for Nuclear Regulatory Commission License No. 52-31352-02, submitted on August 5, 2011, and the revised total decommissioning cost estimate submitted August 30. The cost estimate of $139,918 in the August 5 DFP is significantly different than the cost estimate of $375,962 stated in a January 13 draft DFP. The cost estimates for most similar cyclotrons licensed by the NRC are in the range of $350,000 to $570,000. Your August 5 cost estimate of $139,918 does not appear to provide adequate funding of your expected decommissioning activities. The August 30 revised total decommissioning cost estimate of $440,024 is within the range stated above, but you did not provide any basis in the revised DFP submitted to justify the cost estimates.

   You must re-submit your DFP and cost estimate in full, with all tables and any additional pages to provide sufficient description of the bases for your work and cost estimates In accordance with NUREG 1757 "Consolidated NMSS Decommissioning Guidance", Volume 3, "Financial Assurance, Recordkeeping, and Timeliness" (NUREG-1757, Vol. 3). In particular, address the following items:

   a. In accordance with NUREG 1757, Vol. 3, Appendix A.3.1.1 and A.3.4, your facility description should include the number and dimensions of facilities and components that may require decontamination. In Section A.3.4 of your DFP, you stated that only the cyclotron and its components will be addressed. Tables A.3.5 and A.3.7 lists only the cyclotron under facility components that may require decommissioning. However, it is our understanding that facilities outside the cyclotron will require assessment of contamination and possible decontamination or waste disposal, such as target work areas, hot cells, radioactive waste storage areas, ductwork and filtration systems, concrete flooring under the cyclotron, and other similar areas where long-lived contamination may be present. Revise the DFP to include such areas in Tables A.3.5 and A.3.7 and adjust the cost estimate.

   b. Table A.3.6, "Planning and Preparation (Work Days) of the August 5 DFP lists significantly fewer days of work in all categories, compared to the Table A.3.6. submitted with the January 13, 2011 draft DFP. The estimated work days in the August 5 submission seem inadequate for decommissioning of your facility. Please note that, in accordance with the guidance in NUREG-1757, Vol. 3, Appendix A.3.1, you should assume that a) inventories of materials and wastes are consistent with routine activities; b) decommissioning occurs immediately when operations cease, without multiple years for decay of radioactive materials; and c) all work will be performed by a third party. Revise your estimates, and explain the bases for these work day estimates.

   c. Table A.3.14 lists only costs for packing materials and shipping costs. It does not include any cost for waste disposal. Please note that, in accordance with the guidance in NUREG-1757, Vol. 3, Appendix A.3.1, you should assume that inventories of materials and wastes are consistent with routine activities, without any delay of multiple years for decay of radioactive materials. These wastes, such as targets and activated components, as well as other wastes from

decommissioning, must be included in your waste disposal costs. Although the August 30 total cost now includes a waste disposal estimate, no basis for this estimate was provided (Table A.3.14 was not submitted). Explain the bases of the cost estimate. If necessary, revise the DFP to include waste disposal cost, and revise the total cost estimate.

d. Table A.3.16 does not list any costs for analyses of samples by a laboratory. Such samples may include removable contamination samples (wipes) as well as concrete samples or other media. Please note that, in accordance with the guidance in NUREG-1757, Vol. 3, Appendix A.3.1, you should assume that all work will be performed by a third party, and you cannot reduce your decommissioning costs by assuming you will perform your own analyses at no cost. Although the August 30 total cost now includes a laboratory cost estimate of $10,000, no basis for this estimate was provided (Table A.3.16 was not submitted). Explain the bases of your cost estimate. If necessary, revise the DFP to include laboratory costs, and revise the total cost estimate.

e. Table A.3.17, “Miscellaneous Costs” of the August 5 DFP estimates a total of $3050, compared to the Table A.3.17 estimate of $40,000 submitted with the January 13, 2011 draft DFP. Although the August 30 total cost showed an increase in miscellaneous costs to $30,000, no basis for this estimate was provided (Table A.3.17 was not submitted). Explain the bases for your Table A.3.17 cost estimates. If necessary, revise your Table A.3.17 estimates and the total cost estimate for the DFP.

2. The certification of financial assurance (CFA) is not accepted because a) it is not an original, signed document by a management representative; and b) the CFA states that financial assurance in the amount of $1,125,000 has been obtained. Confirm that you will submit a revised CFA, and that it will be an original document with a signature from a management representative, in accordance with Appendix A.2.2, A.2.3, A.2.4 and A.2.5 of NUREG-1757, Vol.3; and that it will reflect the amount of decommissioning funding your are actually providing (at a minimum, the funding required will be the amount of the cost estimate as accepted by the NRC).

3. Confirm that when our review of your revised DFP and cost estimate is completed, and you receive a letter from us stating that the DFP and cost estimate is accepted, you will immediately begin the activities needed to obtain an acceptable financial assurance instrument in the amount of the accepted cost estimate.

4. Confirm that, if you cannot respond to this letter within 30 days, you will submit a letter or email that describes the actions you have taken, and the actions you need to take, in order to complete your response.

5. Confirm that, during the period that you are obtaining your financial assurance instrument, with all required associated documents, you will provide an update by electronic mail or telephone or letter, at least every 30 days, describing the actions you have taken and any actions that you are awaiting.

Note regarding "all required documents": All financial assurance instruments require submission of a Certificate of Financial Assurance. The various financial assurance instruments have additional documentation requirements. For example, you indicated in an earlier letter that you were considering the use of Surety Bonds as a financial assurance instrument. Guidance for Surety Bonds can be found in Appendix A.9 of NUREG-1757, Vol. 3. Surety Bonds require that you provide a Standby Trust Agreement along with the Schedules A, B, and C; the Specimen Certificate of Event, the Specimen Certificate of Resolution, and the Letter of Acknowledgement; a copy of the broker/agent power of attorney to issue the bonds; and Checklist 9-B if the model wording is not used.

6. A copy of this letter will be mailed directly to your home address as you requested during the August 30 meeting. If you wish to permanently change the mailing address of the license, you must request in writing that the license be amended to the new mailing address. If the mailing address for the RSO will be different than the mailing address of the license, you should provide that information.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses;** then **Licensee Toolkits, see our toolkit index page.** 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. 144277. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5040.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice for Domestic Licensing proceedings and Issuance of Orders," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of the NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html

If we do not receive a reply from you within 30 calendar days from the date of this letter, we will consider appropriate enforcement actions, including civil penalties or Orders than can modify, suspend, or revoke your license.

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
Frank S. Kolodziej Castro, M.D., President and Owner

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