

December 19, 2011

EA-11-086

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

**SUBJECT: INTERNATIONAL CYCLOTRON, INC. NOTICE OF VIOLATION AND
PROPOSED IMPOSITION OF CIVIL PENALTIES - \$7,000 - AND
ORDER SUSPENDING LICENSED ACTIVITIES WITHIN 60 DAYS**

Dear Dr. Castro:

This letter summarizes the efforts made by the U.S. Nuclear Regulatory Commission (NRC), since December 2009, to obtain from International Cyclotron, Inc. (International Cyclotron), an adequate decommissioning funding plan (DFP) with a signed original financial assurance instrument, as required by Title 10 of the Code of Federal Regulations (10 CFR) Section 30.35. During this timeframe, the NRC communicated repeatedly through letters, electronic mail, and telephone calls the requirement that International Cyclotron submit this information. International Cyclotron; however, did not adequately respond to these requests and, to date, has not submitted a complete DFP that includes a signed original financial assurance instrument.

On August 20, 2009, the NRC issued International Cyclotron two NRC materials licenses: 1) License No. 52-31352-02, authorizing the use of an accelerator (i.e., the cyclotron) to produce pharmaceutical radionuclides; and, 2) License No. 52-31352-01MD, authorizing the preparation and distribution of radioactive drugs and radiochemicals for medical and non-medical use.

International Cyclotron was required to apply for these NRC licenses, pursuant to the Energy Policy Act of 2005 (EPA). The EPA transferred regulatory authority over naturally occurring and accelerator-produced radioactive materials (NARM) to the NRC; the authority of the Department of Health of Puerto Rico over the activities of International Cyclotron was terminated. The final NRC rule implementing the transfer of authority became effective in the Commonwealth of Puerto Rico on November 30, 2007; all NARM users were required to apply for an NRC license within 12 months (by November 30, 2008). As a NARM user, International Cyclotron applied for, and was granted, the referenced licenses.

NRC regulations, specified in 10 CFR 30.35, require that applicants, for authorization to possess and use byproduct radioactive material above specified amounts, must provide a

guarantee or other financial arrangement to ensure that funds for decommissioning will be available when needed (i.e., financial assurance must be provided). The regulations at 10 CFR 30.35(f) describe the approved mechanisms for financial assurance and require that a suitable mechanism for financing the decommissioning of licensed facilities be in place in the event that a licensee is unable or unwilling to complete decommissioning. The requirements to provide financial assurance are in addition to the licensee's regulatory obligation to decommission its facilities. Licensee compliance with the financial assurance and decommissioning regulations is required to provide for orderly and timely decommissioning to protect public health and the environment.

When International Cyclotron submitted its NRC license application related to the cyclotron, it requested authorization to possess and use radioactive material of half-life greater than 120 days and in quantities exceeding 10^5 times the applicable quantities set forth in appendix B to Part 30. NRC regulations at 10 CFR 30.35(a)(1) require International Cyclotron to submit a DFP which, as described in 10 CFR 30.35(e), must consist of: 1) a cost estimate for decommissioning, 2) a description of the method for assuring funds for decommissioning, 3) a description of the means for adjusting cost estimates and associated funding levels periodically over the life of the facility, 4) a certification that financial assurance for decommissioning has been provided in the amount of the cost estimate, and 5) a signed original of the financial assurance instrument, which meets the regulatory requirements of 10 CFR 30.35(f).

International Cyclotron failed to submit the required DFP with its application. The NRC addressed this deficiency after issuing International Cyclotron its NRC license; in a letter dated December 7, 2009 (ML093430005)¹. The NRC notified International Cyclotron of the requirement to provide financial assurance, advised International Cyclotron that it was in non-compliance with 10 CFR 30.35, and requested that International Cyclotron come into compliance with NRC regulations and submit supporting documentation.

Between December 7, 2009, and October 12, 2011, the NRC contacted International Cyclotron on multiple occasions through letters, telephone calls, and electronic mail advising you of the requirement to submit the financial assurance documents. Dr. Kolodziej Castro, as president and owner of the licensee, you have not provided NRC with information that demonstrates International Cyclotron has established financial assurance as required by NRC regulations.

By letter dated August 2, 2011 (ML112150124), the NRC requested that International Cyclotron participate in a pre-decisional enforcement conference (PEC) with the NRC to discuss International Cyclotron's failure to provide financial assurance as required by 10 CFR 30.35. International Cyclotron's Radiation Safety Officer (RSO) submitted drafts of the decommissioning cost estimate on August 5, and August 30, 2011, electronically. On August 30, 2011, you and the International Cyclotron RSO attended the PEC at NRC Region I offices in King of Prussia, Pennsylvania. At the PEC, you committed to provide the signed and complete original financial assurance documents to bring International Cyclotron into compliance with NRC regulations.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS at the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

By letter dated September 2, 2011 (ML112450249), the NRC issued a Request for Additional Information (RAI) to International Cyclotron which identified significant deficiencies in the draft decommissioning cost estimate submitted via electronic mail on August 30, 2011, by Mr. David Rhoe, the RSO. The RAI also stated, "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." Additionally, the RAI advised you:

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 Appendices 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 you are actually providing (at a minimum, the funding required will be the amount of the cost estimate as accepted by the NRC).

The RAI letter required that International Cyclotron respond to the NRC within 30 days and stated that enforcement action would be initiated against International Cyclotron, if financial assurance requirements were not established.

International Cyclotron failed to respond within 30 days. On October 14, 2011, you submitted a late response containing a signed cost estimate for decommissioning, a description of the method for assuring funds for decommissioning, and a description of the means for adjusting cost estimates and associated funding levels periodically over the life of the facility (items 1, 2, and 3 as noted above). The NRC reviewed those documents and found them to be acceptable. On October 24, 2011, you submitted another response which contained a signed certification statement (item 4 as noted above). The October 24, 2011, response, however, was incomplete and International Cyclotron remained in non-compliance because a financial assurance instrument fulfilling the requirements of 10 CFR 30.35(f) was not provided. International Cyclotron has not submitted the financial assurance instrument (item 5 as noted above) as of the date of this letter.

The NRC staff conducted a review of all available information submitted by International Cyclotron and established International Cyclotron's failure to submit the required financial assurance instrument is a violation of 10 CFR 30.35. The Notice of Violation and a Proposed Imposition of Civil Penalty (Notice) detailing the NRC's actions are enclosed.

In assessing the significance of this violation, the NRC considered that International Cyclotron's failure to obtain and submit a financial assurance instrument for a period of 2 years has prevented the NRC from ensuring that funds will be available at the time of shutdown to provide for orderly and timely decommissioning to protect public health and the environment. This violation is Severity Level (SL) III, in accordance with the NRC Enforcement Policy.

The Enforcement Policy provides a base civil penalty in the amount of \$7,000 for an SL III violation. The NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section 2.3.4 of the Enforcement Policy because the violation is International Cyclotron's first SL III violation. The NRC

determined that credit for corrective action is not warranted because International Cyclotron failed to provide the required financial assurance instrument for a period of 2 years, and remains in violation of NRC requirements, notwithstanding your commitment to come into compliance made during the pre-enforcement conference on August 30, 2011. The NRC issues the enclosed Notice and Proposed Imposition of Civil Penalty in the amount of \$7,000, to emphasize the importance of prompt and comprehensive correction of violations that could adversely affect public health and safety, as well as, life and property.

International Cyclotron failed to respond fully and in a timely manner to numerous NRC requests for information, failed to provide the information requested in a formal RAI, and failed to comply with the commitments made by its president and owner at the August 30, 2011, PEC, and has failed to come into compliance with NRC regulations at 10 CFR 30.35. For these reasons, the NRC is issuing the enclosed Order Suspending Licensed Activities (Order).

The Order stipulates that International Cyclotron must submit to the NRC a financial assurance instrument that conforms to the requirements of 10 CFR 30.35(f) within 60 days of the date of the Order or International Cyclotron will suspend all activities authorized under License Nos. 52-31352-02 and 52-31352-01MD (excluding possession and storage). The Order remains in effect until International Cyclotron submits a financial assurance instrument acceptable to the NRC and the NRC formally notifies International Cyclotron that the instrument has been approved. Pursuant to Section 223 of the Atomic Energy Act of 1954, as amended, any person who willfully violates, attempts to violate, or conspires to violate any provision of this Order shall be subject to criminal prosecution as set forth in that section. Violation of this Order may also subject the person to an additional civil monetary penalty.

International Cyclotron is required to respond to this letter and should follow the instructions specified in the enclosed Notice and Order when preparing the response. If International Cyclotron has additional information that it believes the NRC should consider, you may provide it in the response. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room and from the NRC's Agency-wide Documents Access and Management System, accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. The NRC also includes significant enforcement actions on its Web site at (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Roy P. Zimmerman, Director
Office of Enforcement

Docket Nos. 03037882 & 03037957
License Nos. 52-31352-01MD & 52-31352-02

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalties
2. NUREG/BR-0254 Payment Methods
3. Order Suspending Licensed Activities

cc: Commonwealth of Puerto Rico

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/RA/

Roy P. Zimmerman, Director
Office of Enforcement

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License Nos. 52-31352-01MD & 52-31352-02

Enclosures: 1. Notice of Violation and Proposed Imposition of Civil Penalties
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cc: Commonwealth of Puerto Rico ML11347A244 (pkg)

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