



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 13, 2016

Docket Nos. 030-37882
030-37957
EA-16-055

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

Frank S. Kolodziej Castro, M.D.
President and Owner
International Cyclotron, Inc.
Ashford Avenue 888 PH
San Juan, PR 00907

SUBJECT: NRC INSPECTIONS REPORT NO. 03037882/2016001 AND
03037957/2016002, INTERNATIONAL CYCLOTRON, INC., HATO REY,
PUERTO RICO SITE

Dear Dr. Kolodziej:

This refers to the results of the review of activities under the above-listed licenses at your facilities located in Hato Rey, Puerto Rico. The review covered the period of December 7, 2009, through March 4, 2016, and included records of site visits to the facilities, and letters and other correspondence during that period.

Based on the review, the NRC identified two apparent violations of NRC decommissioning requirements that are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current NRC Enforcement Policy is included on the NRC's Web site at www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html. The apparent violations are described in Enclosure 1 to this letter, and the circumstances leading to them are summarized below.

International Cyclotron, Inc. (International Cyclotron), located in Hato Rey, Puerto Rico, possesses a cyclotron which was used to produce fluorine-18 (F-18) for Positron Emission Tomography (PET) imaging studies, and also operated a radiopharmacy which distributed the F-18 materials to medical facilities authorized to perform PET imaging studies. These activities were not regulated by the NRC until the Energy Policy Act of 2005 (EPAAct) expanded the definition of byproduct material to include naturally occurring and accelerator-produced radioactive material (NARM), including the use of certain cyclotron activities and radioactive materials produced in cyclotrons for commercial purposes. As a result of the EPAAct, International Cyclotron was required to obtain a radiopharmacy license from the NRC to prepare and distribute F-18 radiopharmaceuticals and a manufacturing license from the NRC to operate the cyclotron. On August 20, 2009, the NRC issued License No. 52-31352-01MD to International Cyclotron for the company's radiopharmacy activities and License No. 52-31352-02 for the cyclotron activities.

In a December 7, 2009, letter (ML093430005)¹, the NRC informed you that in accordance with Title 10 *Code of Federal Regulations* (10 CFR) 30.35(b)(1), you were required to provide financial assurance and a decommissioning funding plan for the quantities of unsealed byproduct materials with half-lives greater than 120 days that International Cyclotron was authorized to possess under License No. 52-31352-02. Although the NRC communicated with you and with International Cyclotron's consultant Radiation Safety Officer (RSO) about this requirement on multiple occasions between December 7, 2009, and October 12, 2011, through letters, telephone calls, electronic mail messages, and in person, you did not submit the documentation required to demonstrate provision of financial assurance.

On August 30, 2011, you participated in a Pre-decisional Enforcement Conference (PEC) with the NRC to discuss this issue, and you committed to provide the required financial assurance. Although you submitted an acceptable decommissioning funding plan with a decommissioning cost estimate on October 14, 2011 (non-public due to the inclusion of sensitive financial information), you did not provide a financial assurance instrument. As a result, on December 19, 2011, the NRC issued a letter with a Notice of Violation and an Order (ML11347A234) requiring International Cyclotron to provide financial assurance within 60 days or to shut down operations of the cyclotron and the radiopharmacy. On February 17, 2012, when no financial assurance was provided to the NRC by International Cyclotron, the Order became effective, and International Cyclotron ceased operations.

Since that time, the NRC has continued to communicate with you and the RSO by letter, telephone, and email, and has met with you and the RSO on multiple occasions including two site inspections and multiple site visits. The purpose of these communications has been to ascertain the status your efforts to obtain financial assurance, sell the cyclotron operation, or decommission the facility. The NRC notes that, to date, no progress has been made for any of these options.

NRC regulations in 10 CFR 30.36(d) require that, after 24 months without principal activities under the license being performed, licensees must, within 60 days, provide written notification to the NRC and either begin decommissioning the site or submit a decommissioning plan if one is required by NRC regulations. Further, as required by 10 CFR 30.36(h), decommissioning must be completed within 24 months of initiation of decommissioning. In a letter dated March 22, 2014 (ML14093A157), you provided the written notification and stated that International Cyclotron would begin decommissioning as soon as possible, but before April 18, 2014. However, as of the date of this letter, International Cyclotron has not conducted any physical decommissioning activities of the cyclotron.

Therefore, the NRC identified two apparent violations that are being considered for escalated enforcement action. The apparent violations involve International Cyclotron's failure to: A. begin decommissioning the cyclotron facility, as required by 10 CFR 30.36(d) and B. to complete the decommissioning within 24 months of initiation, as required by 10 CFR 30.36(h). Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. In addition, please be advised that the number and characterization of apparent violations described herein may change as a result of further NRC review.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Unless otherwise noted, documents referenced in this letter are publicly-available using the accession number in ADAMS.

Before the NRC makes its enforcement decision, we would like to discuss the apparent violations and International Cyclotron's corrective actions at a PEC. The decision to hold a PEC does not mean that the NRC has determined that violations have occurred or that enforcement action will be taken. Rather, this conference will be held to obtain information to assist the NRC in making an enforcement decision. This may include information to determine whether the violations occurred, information to determine the significance of the violations, information related to the identification of the violations, and information related to any corrective actions taken or planned. The conference will also include an opportunity for you to provide your perspective on these matters and any other information that you believe the NRC should take into consideration in making an enforcement decision. In presenting your corrective actions, you should be aware that the promptness and comprehensiveness of your actions will be considered in assessing any potential civil penalty for the apparent violations. The guidance in Enclosure 2, an excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. The PEC will be open for public observation and the NRC will issue a press release to announce the conference time and date.

In lieu of a PEC, you may also request alternative dispute resolution (ADR) with the NRC in an attempt to resolve this issue. ADR is a general term encompassing various techniques for resolving conflicts using a neutral third party. The technique that the NRC has decided to employ is mediation; a voluntary, informal process in which a trained neutral mediator works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable neutral mediator who has no stake in the outcome and no power to make decisions. Mediation gives parties an opportunity to discuss issues, clear up misunderstandings, be creative, find areas of agreement, and reach a final resolution of the issues. Additional information concerning the NRC ADR program can be obtained at <http://www.nrc.gov/about-nrc/regulatory/enforcement/adr.html>. The Institute on Conflict Resolution (ICR) at Cornell University has agreed to facilitate the NRC program as a neutral third party. Please contact ICR at 877-733-9415 within **10** days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session will be closed to public observation, but the time and date of the ADR will be publicly announced.

Please contact Elizabeth Ullrich, Acting Chief, Commercial, Industrial, R&D, and Academic Branch, at 610-337-5040 within **10** days of the date of this letter to notify the NRC whether you will be attending a PEC or electing to engage in ADR, and to discuss when the meeting will occur. Either the PEC or ADR should be held in our office in King of Prussia, PA, within **30** days of the date of this letter.

Current NRC regulations and guidance are included on the NRC's Web site at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's Web site at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. 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 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

F. Kolodziej Castro

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In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosures will be made available electronically for public inspection in the NRC Public Document Room and from the NRC Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosures:

1. Apparent Violations Being Considered
for Escalated Enforcement Action
2. Excerpt From NRC Information Notice 96-28

cc w/Encls: David Rhoe, Radiation Safety Officer
Elizabeth Zayas
Roberto Otero, Attorney at Law
Commonwealth of Puerto Rico

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ENCLOSURE 1: APPARENT VIOLATIONS BEING CONSIDERED FOR ESCALATED ENFORCEMENT

- A. 10 CFR 30.36(d) requires in part that, within 60 days of no principal activities under a license having been conducted for a period of 24 months, a licensee shall provide notification to the NRC in writing of such occurrence and either begin decommissioning its site or submit within 12 months of the notification, a decommissioning plan if required by §30.36(g)(1), and begin decommissioning upon approval of that plan.

Contrary to the above, on March 22, 2014, the licensee appropriately notified the NRC that no principal activities under the license have been conducted for a period of 24 months and that decommissioning would begin as soon as possible and before April 18, 2014. However, as of June 13, 2016, the licensee has neither begun decommissioning its site nor submitted a decommissioning plan.

- B. 10 CFR 30.36(h) requires, in part, that a licensee complete decommissioning of its site as soon as practicable but no later than 24 months following the initiation of decommissioning, unless the NRC has approved an alternative decommissioning schedule.

Contrary to the above, the licensee did not complete decommissioning of its site within 24 months following the initiation of decommissioning. Specifically, the licensee notified the NRC on March 22, 2014, that decommissioning would begin as soon as possible and before April 18, 2014. However, as of June 13, 2016, (a period greater than 24 months), the licensee has not completed decommissioning, and the NRC has not approved an alternate decommissioning schedule.