



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713

August 30, 2016

Docket Nos. 03037882
03037957

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

EA-16-055

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

SUBJECT: NOTICE OF VIOLATION AND PROPOSED CIVIL PENALTY \$14,000 –
INTERNATIONAL CYCLOTRON, INC.

Dear Dr. Kolodziej:

This letter is in reference to the continued failure by International Cyclotron, Inc. (International Cyclotron) to decommission its site in Hato Rey, Puerto Rico, as required by Title 10 of the Code of Federal Regulations Part 30.36 (10 CFR 30.36). Specifically, 10 CFR 30.36(d) requires, in part, 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. Additionally, 10 CFR 30.36(h) requires that decommissioning be completed within 24 months of initiation of decommissioning. In a letter dated March 22, 2014 (ML14093A157),¹ you provided the written notification that International Cyclotron would begin decommissioning before April 18, 2014. NRC staff have communicated with you in person, and via telephone calls, letters, and electronic mail messages about the need to decommission the facility. Based on these communications, including site visits and inspections, the NRC staff identified that International Cyclotron has not completed (or begun) decommissioning.

In a June 13, 2016, letter (ML16166A369), we informed you that the NRC was considering escalated enforcement action for the apparent violations related to International Cyclotron's failures to begin and complete decommissioning of the site. We requested that you participate in a pre-decisional enforcement conference (PEC) with us to discuss the apparent violations and your corrective actions. In lieu of a PEC, we provided you the opportunity to request Alternative Dispute Resolution (ADR) to resolve this matter. The letter requested that you

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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.

inform us within 10 days of the date of the letter of your decision to conduct either a PEC or ADR. Since then, members of my staff have spoken with you in person and on the telephone about this issue. However, to date, you have neither responded to the June 13, 2016, letter, nor given any indication that International Cyclotron intends to comply with NRC requirements. Therefore, based on the above, the NRC has concluded that International Cyclotron is in violation of NRC requirements and is proceeding with enforcement action. The violation, which is cited in the enclosed Notice of Violation and Proposed Imposition of Civil Penalty (Notice), involves International Cyclotron's failure to begin and complete decommissioning of its site. Although these failures are described as two separate apparent violations in the June 13, 2016, letter, we are citing them in the Notice as one violation in recognition of their cause and effect relationship.

In assessing the significance of this violation, the NRC considered that the decommissioning timeliness requirements are intended to reduce potential risk to the public and environment that may result from delayed decommissioning of inactive facilities and sites. However, International Cyclotron has taken no action to address this issue or engage in meaningful communication with us regarding plans to remediate its site. Additionally, International Cyclotron's continued failure to comply with these requirements and to communicate with the NRC has resulted in additional, unplanned site visits to the licensee's facility to verify the security of the site and the licensed material therein. Based on these considerations, the NRC has assessed this violation at Severity Level (SL) III, in accordance with the NRC Enforcement Policy.

In accordance with the NRC Enforcement Policy, a base civil penalty in the amount of \$14,000 is considered for a SL III violation. Because your facility has not been the subject of escalated enforcement actions within the last two inspections, 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. The NRC staff determined that credit for corrective action is not warranted because International Cyclotron has failed to address the violation or to communicate with the NRC. Therefore, to emphasize the importance of compliance with NRC requirements, I have been authorized, after consultation with the Director, Office of Enforcement, to issue the enclosed Notice and Proposed Imposition of Civil Penalty in the base amount of \$14,000. In addition, issuance of this Notice constitutes escalated enforcement action that may subject you to increased inspection effort.

The NRC's primary interest in this matter is to ensure that International Cyclotron meets its obligation to decommission its facility and ensure the proper transfer or disposal of licensed material in its possession. Accordingly, the NRC will not impose the \$14,000 civil penalty at this time if International Cyclotron completes the following actions:

1. Within 30 days of the date of this letter, properly dispose of or transfer all sealed radioactive sources possessed by International Cyclotron, and send the following information documenting that the material has been transferred or disposed of to the Regional Administrator, NRC Region I, 2100 Renaissance Blvd, King of Prussia, PA 19406: (a) a completed NRC Form 314 (enclosed); (b) a copy of the certification from the authorized recipient that the material has been received; and (c) a copy of the radiation survey performed in accordance with 10 CFR 30.36(j)(2).
2. Within 60 days of the date of this letter, submit to the Regional Administrator, NRC Region I, 2100 Renaissance Blvd, King of Prussia, PA 19406, a written description of the

planned activities to complete decommissioning of the International Cyclotron site and a schedule for their completion (i.e., a decommissioning plan).

If International Cyclotron completes the actions described above, the NRC will forgo imposition of any civil penalty at this time, and will hold the final enforcement action for this violation in abeyance. The NRC will monitor International Cyclotron's site decommissioning activities and after all such activities are complete, the NRC will re-evaluate this enforcement action.

However, if International Cyclotron does not complete the above actions, the NRC will impose the \$14,000 civil penalty and will consider the imposition of additional daily civil penalties that would continue to be assessed until International Cyclotron addresses the violation by taking action to decommission its site.

If you disagree with this enforcement sanction, you may deny the violation, as described in the Notice, or you may request 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. Mediation is a voluntary, informal process in which a trained neutral (the "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's ADR program can be found 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's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Blake Welling, Chief, Commercial, Industrial, R&D, and Academic Branch at 610-337-5205 within 10 days of the date of this letter. You may also contact both ICR and Mr. Welling for additional information. Your submitted signed agreement to mediate using the NRC ADR program will stay the 60-day time period for payment of the civil penalties and the required written response, as identified in the enclosed notice, until the ADR process is completed.

You are required to respond to this letter and to follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements. In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosure, and your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agency-wide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

F. Kolodziej Castro, M.D.

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The NRC also includes significant enforcement actions on its Web site at <http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

Enclosures:

1. Notice of Violation and Proposed Imposition of Civil Penalty
2. NUREG/BR-0254, "Payment Methods"
3. NRC Form 314, "Certificate of Disposition of Materials"

cc w/enclosures:

David M. Rho, Radiation Safety Officer
Commonwealth of Puerto Rico

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Sincerely,

/RA/

Daniel H. Dorman
Regional Administrator

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cc w/enclosures:

David M. Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

Distribution: see next page

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NAME	M Burgess via email	NLO by E Monteith via email		J Trapp/	D Dorman/
DATE	8/17/16	8/16/16		8/24/16	8/24/16

* See previous concurrence page

Letter to Frank Kolodziej Castro, M.D. from Daniel H. Dorman dated August 30, 2016

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ENCLOSURE

NOTICE OF VIOLATION
AND
PROPOSED IMPOSITION OF CIVIL PENALTY

International Cyclotron, Inc.
Hato Rey, Puerto Rico

Docket Nos. 03037882 & 03037957
License Nos. 52-31352-01MD & 52-31352-02
EA-13-059

During a review of International Cyclotron, Inc.'s licensed activities, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the NRC proposes to impose a civil penalty pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205. The particular violation and associated civil penalty are set forth below:

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.

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, although the licensee notified the NRC on March 22, 2014, 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; as of August 30, 2016, the licensee has neither begun decommissioning its site nor submitted a decommissioning plan; and has not completed decommissioning.

This is a Severity Level III violation (Enforcement Policy Section 6.3)
Civil Penalty - \$14,000

Pursuant to the provisions of 10 CFR 2.201, International Cyclotron, Inc. (Licensee) is hereby required to submit a written statement or explanation to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, with a copy to the Document Control Desk, Washington, DC 20555-0001, within 30 days of the date of this Notice of Violation and Proposed Imposition of Civil Penalty (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; (EA-16-055)" and should include for each alleged violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken; and (4) the date when full compliance will be achieved.

Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, the NRC may issue an order or a Demand for Information requiring you to explain why your license should not be modified, suspended, or revoked or why the NRC should not take other action as may be proper. Consideration may be given to extending the response time for good cause shown.

The Licensee may pay the civil penalty proposed above in accordance with NUREG/BR-0254 and by submitting to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, a statement indicating when and by what method payment was made, or may protest imposition of the civil penalty in whole or in part, by a written answer addressed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, within 30 days of the date of this Notice. Should the Licensee fail to answer within 30 days of the date of this Notice, the NRC will issue an order imposing the civil penalty. Should the Licensee elect to file an answer in accordance with 10 CFR 2.205 protesting the civil penalty, in whole or in part, such answer should be clearly marked as an "Answer to a Notice of Violation" and may: (1) deny the violation listed in this Notice, in whole or in part; (2) demonstrate extenuating circumstances; (3) show error in this Notice; (4) submit a written description of the decommissioning activities and planned schedule for completion as described in the letter enclosing this Notice, or (5) show other reasons why the penalty should not be imposed. In addition to protesting the civil penalty in whole or in part, such answer may request remission or mitigation of the penalty.

In requesting mitigation of the proposed penalty, the response should address the factors addressed in Section 2.3.4 of the Enforcement Policy. Any written answer addressing these factors pursuant to 10 CFR 2.205 should be set forth separately from the statement or explanation provided pursuant to 10 CFR 2.201, but may incorporate parts of the 10 CFR 2.201 reply by specific reference (e.g., citing page and paragraph numbers) to avoid repetition. The attention of the Licensee is directed to the other provisions of 10 CFR 2.205 regarding the procedure for imposing a civil penalty.

Upon failure to pay any civil penalty which subsequently has been determined in accordance with the applicable provisions of 10 CFR 2.205 to be due, this matter may be referred to the Attorney General, and the penalty, unless compromised, remitted, or mitigated, may be collected by civil action pursuant to Section 234c of the Act, 42 U.S.C. 2282c. Additionally, if, after 30 days, International Cyclotron, Inc. continues to remain in violation of the Order, the NRC will consider imposing additional daily civil penalties, as described in the letter enclosing this Notice.

The responses noted above, i.e., Reply to Notice of Violation, Statement as to payment of civil penalty, and Answer to a Notice of Violation, should be addressed to: Patricia Holahan, Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738, with a copy to the Regional Administrator, U.S. Nuclear Regulatory Commission, Region I, 2100 Renaissance Boulevard, King of Prussia, PA, 19406, and the Document Control Center, Washington, DC 20555-0001.

In accordance with 10 CFR 19.11, you may be required to post this Notice within two working days of receipt.

Dated this 30th day of August, 2016