

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of:)
) Docket Nos. 03037882 and 03037957
) License Nos. 52-31352-01MD and
International Cyclotron, Inc.) 52-31352-02
Hato Rey, Puerto Rico) EA-16-055
)

ORDER IMPOSING CIVIL MONETARY PENALTY

I

International Cyclotron, Inc. (International Cyclotron or the Licensee) is the holder of Materials License Nos. 52-31352-01MD and 52-31352-02 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) on August 20, 2009, pursuant to Part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR). The licenses authorized the Licensee to prepare and distribute fluorine-18 (F-18) radiopharmaceuticals for Positron Emission Tomography (PET) imaging studies and to operate a cyclotron which was used to produce the F-18, in accordance with the conditions specified therein. 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.

In a December 7, 2009, letter (ADAMS Accession No. ML093430005), the NRC informed the Licensee that in accordance with 10 CFR 30.35(b)(1), it was 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 Licensee submitted an

acceptable decommissioning funding plan with a decommissioning cost estimate on October 14, 2011 (non-public due to proprietary, financial information contained therein), the Licensee did not provide a financial assurance instrument. As a result, on December 19, 2011, the NRC issued a letter with a Notice of Violation (ADAMS Accession No. ML11347A256) and an Order (ADAMS Accession No. ML11353A417) 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. In a letter dated March 22, 2014 (ADAMS Accession No. ML14093A157), the Licensee provided written notification that International Cyclotron would begin decommissioning as soon as possible, but before April 18, 2014.

II

The NRC has continued to communicate with International Cyclotron by letter, telephone, and email, and has met with the Licensee on multiple occasions, including two site inspections and multiple site visits, to ascertain the status of site decommissioning. The results of these reviews indicated that the Licensee had not conducted its activities in full compliance with NRC requirements, in that International Cyclotron has neither begun nor completed decommissioning within the timeframes required by NRC regulations in 10 CFR 30.36(d). A written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was served upon the Licensee by letter dated August 30, 2016 (ADAMS Accession No. ML16238A071). The Notice states the nature of the violation, the provisions of the NRC's requirements that the Licensee violated, and the amount of the civil penalty proposed for the violation.

In a letter dated September 13, 2016 (ADAMS Accession No. ML16266A337), a representative of the Licensee stated that his firm was assisting International Cyclotron with establishing a financial assurance instrument and with arranging for another company to operate or purchase the cyclotron. The Licensee representative stated that, with more time, an arrangement could be made.

III

After consideration of the letter from the Licensee's representative and the statements contained therein, the NRC staff has determined that the violation occurred as stated and that the penalty proposed for the violation designated in the Notice should be imposed. In reaching this determination, the NRC staff considered that the Licensee was informed of the requirement to obtain financial assurance nearly seven years ago, was issued the Order to cease operations more than four years ago, and was required to complete decommissioning of its site by April 18, 2016. During this timeframe, the Licensee has repeatedly informed the NRC that it was working to obtain financial assurance and was seeking to find an operator/buyer for the facility. However, neither of these actions have occurred and the Licensee has, to date, taken no actions towards site decommissioning.

IV

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee shall pay a civil penalty in the amount of \$14,000 within 30 days of the issuance date of this Order, in accordance with NUREG/BR-0254, "Payment Methods" (see <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0254/>). In addition, at the time payment is made, the Licensee shall submit a statement indicating when and by what method payment was made, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

V

In accordance with 10 CFR 2.205(d), International Cyclotron and any other person adversely affected by this Order may request a hearing on this Order within 30 days of the issuance date of this Order. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene (hereinafter "petition"), and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. System requirements for accessing the E-Submittal server are available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/adjudicatory-sub.html>. Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Electronic Filing Help Desk will not be able to offer assistance in using unlisted software.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a petition. Submissions should be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC's public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time

on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Electronic Filing Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call at 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 7 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the

document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a petition will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

The Commission will issue a notice or order granting or denying a hearing request or intervention petition, designating the issues for any hearing that will be held and designating the Presiding Officer. A notice granting a hearing will be published in the *Federal Register* and served on the parties to the hearing.

If a person other than International Cyclotron requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and

shall address the criteria set forth in 10 CFR 2.309(d) and (f).

If a hearing is requested by a licensee or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearing. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for a hearing or alternative dispute resolution (ADR), or written approval of an extension of time in which to request a hearing or ADR, the provisions specified in Section IV above shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing or ADR has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing or ADR request has not been received. If ADR is requested, the provisions specified in Section IV shall be final upon termination of an ADR process that did not result in issuance of an order. If payment has not been made by the time specified above, the matter may be referred to the Attorney General, for collection.

Dated at Rockville, Maryland, this 17th day of November 2016.

FOR THE NUCLEAR REGULATORY COMMISSION

/RA/

Patricia K. Holahan, Director,
Office of Enforcement