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

December 24, 2010

Docket Nos. 03037882
03037957

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

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

SUBJECT: NRC INSPECTION REPORT NOS. 03037882/2010001 & 03037957/2010001, INTERNATIONAL CYCLOTRON, INC, HATO REY, PUERTO RICO SITE AND NOTICE OF VIOLATION

Dear Dr. Kolodziej Castro:

On February 9-10 and October 26-27, 2010, Todd Jackson and Lester Tripp of this office conducted a safety inspection at the above address of activities authorized by the above listed NRC licenses. The inspection was an examination of your licensed activities as they relate to radiation safety and to compliance with the Commission's regulations and the license conditions. The inspection consisted of observations by the inspectors, interviews with personnel, and a selective examination of representative records. The findings of the inspection were discussed with you and David Rhoe of your organization at the conclusion of the inspection.

Based on the results of this inspection, and in accordance with the NRC Enforcement Policy, the NRC has determined that five Severity Level IV violations of NRC requirements occurred for activities conducted under NRC License No. 52-31352-01MD. At this time, no violations related to NRC License No. 52-31352-02 were cited as a result of this inspection; however, as discussed with you during our exit meeting, it is required for you to provide financial assurance for this license in accordance with 10 CFR 30.35(c). You were first informed of this requirement in a letter dated December 9, 2009; however, we have not received adequate financial assurance as of the date of this letter. Failure to provide financial assurance in accordance with 10 CFR 30.35(c) may result in additional violations.

During our inspection exit meeting on October 27, 2010, you acknowledged your understanding of the violations and the necessity of completing the actions required to establish financial assurance. Additional guidance to assist in satisfying financial assurance requirements can be found in NUREG-1757, “Consolidated NMSS Decommissioning Guidance”, Volume 3, “Financial Assurance, Recordkeeping, and Timeliness” (on the internet at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1757/v3/).

In accordance with 10 CFR 2.390 of the NRC’s "Rules of Practice," a copy of this letter, its enclosures, and your response, if you choose to provide one, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC document system (ADAMS), accessible from the NRC website at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement;** then **Enforcement Policy.** 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).

Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
David Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

Current NRC regulations are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Medical, Academic, and Industrial Uses of Nuclear Material;** then **Regulations, Guidance, and Communications Page.** The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC; How We Regulate; Enforcement;** then **Enforcement Policy.** 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).

Please contact Todd Jackson at 610-337-5308 if you have any questions regarding this matter.

Sincerely,

Original signed by James P. Dwyer

James P. Dwyer, Chief
Commercial and R&D Branch
Division of Nuclear Materials Safety

Enclosure:
Notice of Violation

cc:
David Rhoe, Radiation Safety Officer
Commonwealth of Puerto Rico

Distribution:
D. J. Holody, RI

DOCUMENT NAME: G:\WordDocs\Current\Insp Letter\L52-31352-01.2010001.doc

SUNSI Review Complete: TJackson

After declaring this document "An Official Agency Record" it **will** be released to the Public.

To receive a copy of this document, indicate in the box: "**C**" = Copy w/o attach/encl "**E**" = Copy w/ attach/encl "**N**" = No copy

OFFICE	DNMS/RI	N	DNMS/RI		DNMS/RI			
NAME	TJackson TJJ		LTripp TJJ FOR		JDwyer JDP			
DATE	12/23/2010		12/23/2010		12/24/2010			

ML103630004

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

International Cyclotron, Inc
Hato Rey, PR

Docket No. 03037882
License No. 52-31352-01MD

During an NRC inspection conducted on February 9-10 and October 26-27, 2010, five violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

A. Condition 21 of NRC Radioactive Materials License No. 52-31352-01MD requires that, except as specifically provided otherwise in the license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained, in part, in the application, including any enclosures, dated November 25, 2008, and the letter dated January 28, 2009. The application dated November 25, 2008 describes, in paragraph 10.12, sample labels stated to be representative of labels to be used by the licensee. Furthermore, the licensee commits in the letter dated January 28, 2009, that labels will contain the information required by 10 CFR 32.72(a)(4), including that a label will be affixed to each transport radiation shield of a radioactive drug to be transferred for commercial distribution, and the label must include the name of the radioactive drug or its abbreviation and the quantity of radioactivity at a specific date and time.

Contrary to the above, the licensee did not conduct certain activities in accordance with the statements or representations contained in the letter submitted the NRC dated January 28, 2009. Specifically, for the period January 14 through February 9, 2010, the licensee did not affix a label to the container or shield for radioactive drugs to be transferred for commercial distribution that included the quantity of radioactivity at a specific date and time, and on several occasions did not accurately identify the name of the radioactive drug contained in the container or shield. Labels of radioactive drugs containing Tc-99m shipped during this period did not include the time of assay or calibration for radioactivity. In addition, on several occasions during this period the label indicated a radioactivity quantity of less than 1/3 of the actual quantity shipped in the container on that date. On January 14 and 26, 2010, the licensee shipped containers with a particular radioactive drug (TcO_4) that were labeled as containing a different radioactive drug (sestamibi). On January 26, 2010, the mislabeled drug was administered to a patient, resulting in an incorrect diagnostic scan being performed.

This is a Severity Level IV violation (Enforcement Policy Section 6.8.d).

B. 10 CFR 32.72(b)(1) specifies that a licensee described by paragraph (a)(2)(iii) or (iv) of this section, may prepare radioactive drugs for medical use, as defined in 10 CFR 35.2, provided that the radioactive drug is prepared by either an authorized nuclear pharmacist, as specified in paragraph (b)(2) and (b)(4) of this section, or an individual under the supervision of an authorized nuclear pharmacist as specified in 10 CFR 35.27.

10 CFR 35.27(b) requires a licensee that permits the preparation of byproduct material for medical use by an individual under the supervision of an authorized nuclear

pharmacist or physician who is an authorized user, as allowed by § 35.11(b)(2), shall (1) in addition to the requirements in §19.12 of this chapter, instruct the supervised individual in the preparation of byproduct material for medical use, as appropriate to that individual's involvement with byproduct material; and (2) require the supervised individual to follow the instructions of the supervising authorized user or authorized nuclear pharmacist regarding the preparation of byproduct material for medical use, written radiation protection procedures established by the licensee, the regulations of this chapter, and license conditions.

Contrary to the above, from January 14 through February 9, 2010, the licensee allowed an individual to prepare radioactive drugs for medical use, as defined in 10 CFR 35.2; this individual was under the supervision of an authorized nuclear pharmacist, as specified in 10 CFR 35.27, but had not been adequately instructed by the licensee in the preparation of byproduct material for medical use. Specifically, the licensee did not adequately supervise the individual and did not instruct the individual in the licensee's procedures for preparation of these radioactive drugs for medical use. As a result, on several occasions including January 14 and 26, 2010, radioactive drugs were prepared and delivered to physicians for use which contained drugs different than what was ordered and which were incorrectly labeled regarding the drug contained, and which contained an amount of radioactivity different than what was ordered and what the container label indicated.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.d).

C. 10 CFR 32.72 (c) requires that a licensee possess and use instrumentation to measure the radioactivity of radioactive drugs. The licensee shall have procedures for use of the instrumentation. The licensee shall measure, by direct measurement or by combination of measurements and calculations, the amount of radioactivity in dosages of alpha-, beta-, or photon-emitting radioactive drugs prior to transfer for commercial distribution. In addition, the licensee shall (1) perform tests before initial use, periodically, and following repair, on each instrument for accuracy, linearity, and geometry dependence, as appropriate for the use of the instrument; and make adjustments when necessary.

Contrary to the above, on January 14, 2010, the licensee did not perform tests following the identified need for repair as appropriate for the use of the dose calibrator instrument. Specifically the licensee identified an electrical problem in the pharmacy that could have impacted the dose calibrator used for preparing Tc99m dosages distributed for commercial use. The Radiation Safety Officer identified and documented the necessity to check the instrument prior to distribution of drugs containing Tc-99m, however the licensee still distributed dosages on January 14, 2010, without appropriately verifying instrument performance following the electrical disturbance and customers did receive and use the dosages. Some of these dosages distributed on January 14, 2010 contained radioactivity that significantly exceeded the radioactivity content identified on the label.

This is a Severity Level IV violation (Enforcement Policy Section 6.7.d).

D. 10 CFR 71.5 requires each licensee who transports licensed material outside the site of usage as specified in the NRC license, or where transport is on public highways, or who delivers licensed material to a carrier for transport, shall comply with the applicable requirements of the DOT regulations in 49 CFR parts 107, 171 through 180, and 390 through 397, appropriate to the mode of transport.

49 CR 172.202(a)(5) requires the shipping description of a hazardous material on the shipping paper for radioactive material must indicate the total quantity of hazardous materials covered by the description (by mass or volume, or by activity for radioactive materials) and must include an indication of the applicable unit of measurement.

Contrary to the above, the licensee shipped packages containing radioactive Tc-99m with shipping papers that did not indicate the total quantity of radioactive materials contained within the package. Specifically, from January 14 through January 26, 2010, shipping papers sent with packages containing Tc-99m did not include a statement of total activity contained within the package.

This is a Severity Level IV violation (Enforcement Policy Section 6.8.d).

E. Condition 21 of NRC Radioactive Materials License No. 52-31352-01MD requires that, except as specifically provided otherwise in the license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained, in part, in the letter, including any enclosures, dated January 28, 2009. The letter dated January 28, 2009 describes, in paragraph 14, a table of maximum quantities of radioactivity that will be shipped per syringe and per package. For Tc-99m compounds, the table states the maximum activity to be shipped will be 100 milliCuries (mCi) per syringe, 40 mCi per unit dose pig, and 440 mCi per shipping bag.

Contrary to the above, the licensee did not conduct its program in accordance with the statements or representations contained in the letter dated January 28, 2009. Specifically, quantities of radioactivity shipped exceeded the stated maximum activity per syringe in shipments on January 14, 25, 26 and 27, 2010, and exceeded the stated maximum activity per bag on January 14, 2010.

This is a Severity Level IV violation (Enforcement Policy Section 6.3.).

Pursuant to the provisions of 10 CFR 2.201, International Cyclotron, Inc is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, 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, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001. Under the authority of Section 182 of the Act, 42 U.S.C. 2232, any response which contests an enforcement action shall be submitted under oath or affirmation.

Your response will be placed in the NRC Public Document Room (PDR) and on the NRC Web site. To the extent possible, it should, therefore, not include any personal privacy, proprietary, or safeguards information so that it can be made publically available without redaction. However, if you find it necessary to include such information, you should clearly indicate the specific information that you desire not to be placed in the PDR, and provide the legal basis to support your request for withholding the information from the public.

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

Dated This _24_ day of _December_2010