



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

February 15, 2011

U.S. Nuclear Regulatory Commission
Document Control Desk
Region I
475 Allendale Road
King of Prussia, PA 19406

RE: Reply to a Notice of Violation
Inspection Report No. 03037882/2010001 & 03037957/2010001

2011 FEB -2 AM 11: 29

RECEIVED

This is the information that you requested in response to the "Notice of Violation" that we received on December 24, 2010.

Violation B – Licensee did not adequately supervise personnel in preparing radioactive drugs.

1. The violation is accepted as stated.
2. The reason for the violation is attributed to the supervisor of the individual preparing the doses. This individual received the directions directly from the RSO not to dispense any doses. The individual, by their own choice chose to dispense the doses, thereby directly disregarding the RSO directions. This individual is no longer working for the International Cyclotron, Inc.
3. Corrective action was to remove the individual from employment.
4. Date of full compliance was March 2010.

Violation C – Not properly perform test on dose measuring equipment after a power surge.

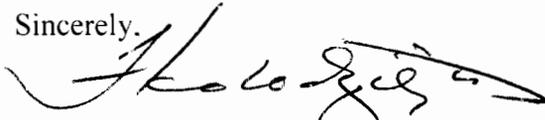
1. The violation is accepted as stated.
2. The reason for the violation is attributed to the supervisor of the individual preparing the doses. This individual received the directions directly from the RSO not to dispense any doses. The individual, by their own choice chose to dispense the doses, thereby directly disregarding the RSO directions. This individual is no longer working for the International Cyclotron, Inc.
3. Corrective action was to remove the individual from employment.
4. Date of full compliance was March 2010.

Violation E – Failure to conduct your program in accordance with the statements or representations contained in the letter dated January 28, 2009.

1. All employees working in the production and distribution of radiopharmaceuticals have been instructed to following the RSO directions.
2. Any individual witnessing the RSO instructions are not being following will immediately stop the production and notify the RSO immediately.
3. Willfully disobeying the RSO instructions will result in immediate dismissal.

If you have any questions or need any further information, please feel free to contact me at the address above.

Sincerely,

A handwritten signature in black ink, appearing to read "Frank Kolodziej Castro". The signature is fluid and cursive, with a long horizontal stroke at the end.

Frank Kolodziej Castro, MD
President



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION
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.

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