



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

July 16, 2020

EA-16-255
EA-16-055

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

SUBJECT: TERMINATION OF NRC LICENSES - SOMASCAN, INC. AND
INTERNATIONAL CYCLOTRON INC., NRC INSPECTION REPORT NOS.
03036194/2018001 AND 03037882/2018001

Dear Dr. Kolodziej:

This letter refers to announced inspections conducted between February 13, 2018, and May 29, 2020, to evaluate the status of your decommissioning activities for Somascan, Inc. and International Cyclotron, Inc.

Specifically, pertaining to Somascan, NRC License No. 52-25617-01 expired on April 30, 2013. As such, you were required to provide notification to the NRC in writing and begin decommissioning the site so that it would be suitable for release within 24 months following the initiation of decommissioning. Because you did not complete these actions, the NRC issued you a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) on April 5, 2017 (ML17094A537), requiring you to dispose of or transfer all licensed material or pay a \$7,000.00 civil penalty. After you failed to dispose of or transfer your licensed material or pay the fine, the NRC issued, on June 27, 2017, an Order imposing the civil penalty (ML17172A322) and requiring payment within 30 days. When you failed to pay, the debt was transferred, on June 26, 2018, to the US Department of the Treasury for collection.

Pertaining to International Cyclotron (NRC License Nos. 52-31352-01MD & 52-31352-02), you informed the NRC on March 22, 2014, that no principal activities under the licenses had been conducted for a period of 24 months and that decommissioning would begin as soon as possible and before April 18, 2014. Because you did not complete decommissioning within 24 months following the initiation of decommissioning, the NRC issued you a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) on August 30, 2016 (ML16238A071), requiring you to dispose of or transfer all licensed material or pay a \$14,000 civil penalty. After you failed to dispose of or transfer your licensed material or pay the fine, the NRC issued, on November 17, 2016, an Order imposing the civil penalty (ML16294A515). On August 21, 2017, your NRC licenses were also revoked for nonpayment of fees (ML17223A053). When you continued to fail to pay the owed fees and civil penalty, the debt was transferred, on June 26, 2018, to the US Department of the Treasury for collection.

During this time, NRC staff have continued to inspect the Somascan and International Cyclotron facilities to verify the security of any radioactive material and have continued to communicate with you and your Radiation Safety Officer regarding the need to complete decommissioning activities. In April 2019, the Conference of Radiation Control Program Directors (CRCPD) sponsored a collection of unused sealed radioactive sources in Puerto Rico under the Source Collection and Threat Reduction (SCATR) Program. The NRC verified, during an onsite inspection on July 30, 2019, that all sealed sources possessed under the Somascan and International Cyclotron licenses were properly disposed of as part of the SCATR event. Currently, the only remaining licensed material you possess is the material limited to NRC License No. 52-31352-02, related to the cyclotron. On May 23, 2019, you submitted NRC Form 314, Certificate of Disposition of Materials, and requested termination of NRC License Nos. 52-25617-01 and 52-31352-01MD.

The NRC has determined that all decommissioning activities required for the Somascan license and for International Cyclotron's medical distribution license have been completed. Although you did not comply with the prior enforcement actions related to failure to complete timely decommissioning, with the assistance of the Conference of Radiation Control Program Director's Source Collection and Threat Reduction (SCATR) program, compliance was restored, and the unpaid fees and fines are being addressed through debt collection. Accordingly, the NRC has determined to terminate the licenses and to not pursue further investigation or enforcement proceedings for this matter. The terminated licenses are enclosed.

No further action or response is necessary on your part pertaining to NRC License Nos. 52-25617-01 and 52-31352-01MD. However, you remain responsible for the licensed material possessed under NRC License No. 52-31352-02, related to the cyclotron and are required to maintain the security of the material (including preventing unauthorized access) and to complete all necessary decommissioning activities. Additionally, should you apply for another NRC license in the future, you may be asked to address the reason for the failure to complete timely decommissioning and your actions to prevent reoccurrence. The NRC expects licensee management to provide adequate oversight and compliance with all applicable regulatory requirements.

In accordance with 10 CFR 2.390, a copy of this letter and its enclosure will be available electronically for public inspection in the NRC Public Document Room or from 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>.

You are not required to respond to this letter. However, should you choose to respond, your response should be sent to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington DC 20555-0001, within 30 days of the date of this letter.

Please clearly mark your response as a "Reply to Letter dated July 7, 2020, EA-16-255/EA-16-055". In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room and from 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>.

If you have any questions, you may contact Shawn Seeley of my staff at (610) 337-5102, or via electronic mail at shawn.seeley@nrc.gov.

Thank you for your cooperation.

Sincerely,

Kevin Williams

Digitally signed by Kevin
Williams
Date: 2020.07.16 08:36:44
-04'00'

Kevin Williams, Acting Director
Division of Nuclear Materials Safety
Region I

License Nos. 52-25617-01
52-31352-01MD
Docket Nos. 03036194
03037882

Enclosure: NRC Inspection Report Nos. 03036194/2018001 and 03037882/2018001

cc: Commonwealth of Puerto Rico

TERMINATION OF NRC LICENSES - SOMASCAN, INC. AND INTERNATIONAL
CYCLOTRON INC., NRC INSPECTION REPORT NOS. 03036194/2018001 AND
03037882/2018001 DATED JULY 16, 2020

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U.S. NUCLEAR REGULATORY COMMISSION
REGION I

INSPECTION REPORT

EA Nos.: EA-16-255
EA-16-055

Inspection Nos.: 03036194/2018001
03037882/2018001

Docket Nos.: 03036194
03037882

License Nos.: 52-25617-01
52-31352-01MD

Licensee: Somascan, Inc.
International Cyclotron, Inc.

Location: Calle Jose Marti #56, Hato Rey, Puerto Rico 00918

Inspection Dates: February 13, 2018 – May 29, 2020

Exit Meeting: May 29, 2020

Inspector: **Shawn W. Seeley** 7/2/2020
Shawn Seeley, Health Physicist date
Medical Branch
Division of Nuclear Materials Safety

Approved By: **Donna M. Janda** 07/06/2020
Donna M. Janda, Chief date
Medical Branch
Division of Nuclear Materials Safety

EXECUTIVE SUMMARY

Somascan, Inc./International Cyclotron, Inc.
NRC Inspection Report Nos. 03036194/2018001 & 03037882/2018001

An onsite inspection was conducted of the licensee's facilities on February 13, 2018, February 25, 2019, and July 30, 2019, with continued in-office review until May 29, 2020.

Three violations were identified, each of which had been previously cited and yet continued to occur until April 2019:

1. Failure of Somascan, Inc. to secure from unauthorized removal or access licensed materials that was stored in controlled or unrestricted areas. Specifically, a 20 millicurie cesium-137 sealed source was stored inside of a PET/CT camera located within a Somascan facility and, from November 21, 2012, when an eviction order was finalized and issued by the building owner, until April 2019, when the source was removed for proper disposal, Somascan had no direct control over access to the facility.
2. Failure of Somascan, Inc. to notify the NRC in writing within 60 days of license expiration and begin decommissioning its site so that the site was suitable for release in accordance with NRC requirements and to complete decommissioning within 24 months following the initiation of decommissioning.
3. Failure of International Cyclotron, Inc. to begin decommissioning its site or submit a decommissioning plan; and to complete decommissioning within 24 months following the initiation of decommissioning.

A telephone Exit Meeting was held with Dr. Frank Kolodziej and David Rhoe on May 29, 2020.

REPORT DETAILS

1. Background

The Somascan, Inc. license was issued on April 16, 2003. Somascan was a private practice medical licensee authorized to possess and use radiopharmaceuticals and sealed sources for diagnostic and therapeutic medical procedures permitted by 10 CFR 35.100, 35.200, 35.300, 35.400 and 35.500; and pre-packaged kits authorized by 10 CFR 31.11. The main Somascan facility in Hato Rey is co-located with the International Cyclotron facility and both licenses are owned by Frank Kolodziej, M.D. Somascan originally operated the facility in Hato Rey and a facility in Torre Plaza. In September 2007, Somascan amended the license to add a third facility in Condado and, in December 2008, Somascan amended the license to add a fourth facility in the Cardiovascular Hospital in San Juan. Documentation of inspections performed in April 2004, September 2005, May 2006, June 2007, and August 2008, indicated that Somascan always anticipated performing the wide range of medical procedures authorized by the license; however, they only ever possessed sealed sources for calibrating dose calibrators and operating PET cameras. Radioactive materials used to perform diagnostic PET procedures were received directly from the International Cyclotron radiopharmacy and were not licensed by NRC until enactment of the Energy Policy Act of 2005.

The International Cyclotron, Inc. (ICI) license was issued on August 20, 2009. ICI was a private radiopharmacy that serviced the Somascan, Inc. license at its various locations. As mentioned above, the radiopharmacy was co-located with Somascan at the Calle Jose Marti address in Hato Rey.

In June 2011, Somascan amended the license to remove the Torre Plaza facility. In granting the amendment, the license reviewer confirmed that the licensee transferred the sealed sources that were located at Torre Plaza to the International Cyclotron facility.

An inspection performed in February 2012 identified that no new licensed activities had occurred at the Hato Rey facility or the Cardiovascular Hospital facility but that the facilities were both secured. The inspector noted that the Condado facility was closed and it was not inspected. The inspector discussed with the owner the importance of securing the licensed radioactive material and inquired about the licensee's plan for future operations. The licensee acknowledged his responsibility for securing the facilities and the licensed materials located within the facilities. He also stated he had plans to reopen the facilities and stated he planned to renew the Somascan license prior to its expiration. A September 2012 inspection of the Hato Rey facility confirmed that radioactive materials located at that facility were secured.

The Somascan radioactive materials license expired on April 30, 2013, after the licensee failed to submit a license renewal application. ICI had their license revoked due to non-payment of fees on December 19, 2011. An inspection conducted in June 2013, identified there had been no licensed activities conducted at any of the Somascan/ICI facilities for approximately two years and that sealed sources from the Somascan facility located at the Cardiovascular Hospital and sealed sources from the Somascan facility in Condado had been transferred to the International Cyclotron facility in Hato Rey in May 2011. The inspector discussed with the licensee that the expired license precluded

Somascan from performing any licensed activities except those required for securing licensed radioactive material and decommissioning. The licensee was informed of the need to properly dispose of the sealed sources and request termination of the Somascan license.

2. Management Oversight

a. Inspection Scope

A routine, announced inspection was initiated at the Somascan, Inc. facility located in Hato Rey, Puerto Rico, on February 13, 2018, February 25, 2019, and July 30, 2019, with continued in-office review until May 29, 2020. The inspection was conducted to follow up on concerns identified during December 2015, June 2016, November 2016, and February 2018 inspections, that no new licensed activities had been conducted under the Somascan/ICI licenses since some time in 2011. Specifically, the licensee was required to complete decommissioning activities as required by an Order issued June 27, 2017. The inspection was performed in accordance with NRC Inspection Procedure 87130 with focus on management oversight, security and control of licensed radioactive materials, and sealed source inventories and leak tests. The inspectors toured facilities to evaluate security; spoke with the license owner, the licensee's consultant, and facility owners/managers; observed the storage of radioactive sealed sources; performed sealed source inventories; reviewed records of sealed source inventories and leak tests performed by the consultant; and reviewed disposal records.

b. Observations and Findings

The inspectors determined that all sealed sources possessed under the Somascan and ICI licenses were picked up by the Conference of Radiation Control Program Directors (CRCPD) sponsored collection of unused sealed radioactive sources in Puerto Rico under the Source Collection and Threat Reduction (SCATR) Program in April 2019. The inspectors surveyed the storage locations and the gamma camera and confirmed that no sealed sources remained. Additionally, the inspectors determined through a review of disposal records that all sources, including the one located at the Condado location, were received by Bionomics for disposal.

Up until the transfer of the sealed source to Bionomics, the licensee remained in violation of the same violations as cited in previous Notices of Violation and Orders. Specifically,

- A. 10 CFR 20.1801 requires, in part, that the licensee secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.

Contrary to the above, from November 21, 2012, through April 2019, Somascan, Inc. (Somascan) failed to secure from unauthorized removal or access licensed materials that were stored in controlled or unrestricted areas. Specifically, a 20 millicurie cesium-137 sealed source was stored inside of a PET/CT camera located within a Somascan facility. From November 21,

2012, when an eviction order was finalized and issued, until April 2019 when the source was removed for proper disposal, Somascan had no direct control over access to the facility.

- B. 10 CFR 30.36(d) requires, in part, that within 60 days of license expiration 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 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, from June 29, 2013 through April 2019, Somascan, Inc. (Somascan) did not provide notification to the NRC in writing and begin decommissioning its site so that the site was suitable for release in accordance with NRC requirements and did not complete decommissioning within 24 months following the initiation of decommissioning. Specifically, Somascan's license expired on April 30, 2013, and Somascan did not notify the NRC in writing within 60 days of license expiration, or June 29, 2013, of its plan to decommission and begin decommissioning its site and did not complete decommissioning of the site until April 2019, a period greater than 24 months, and the Commission did not approve an alternate schedule for decommissioning of the site.

Because Somascan did not complete these actions, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) on April 5, 2017 (ML17094A537), requiring the licensee to dispose of or transfer all licensed material or pay a \$7,000.00 civil penalty. After Somascan failed to dispose of or transfer its licensed material or pay the fine, the NRC issued, on June 27, 2017, an Order imposing the civil penalty (ML17172A322) and requiring payment within 30 days. When the licensee failed to pay, the debt was transferred, on June 26, 2018, to the US Department of the Treasury for collection.

- C. 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 International Cyclotron, Inc. notified the NRC on March 22, 2014, that no principal activities under the license had been

conducted for a period of 24 months and that decommissioning would begin as soon as possible and before April 18, 2014; however the licensee did not complete decommissioning of the site until April 2019, a period greater than 24 months, and the Commission did not approve an alternate schedule for decommissioning of the site.

Because International Cyclotron, Inc. (ICI) did not complete decommissioning within 24 months following the initiation of decommissioning, the NRC issued a Notice of Violation and Proposed Imposition of Civil Penalty (Notice) on August 30, 2016 (ML16238A071), requiring the licensee to dispose of or transfer all licensed material or pay a \$14,000 civil penalty. After ICI failed to dispose of or transfer its licensed material or pay the fine, the NRC issued, on November 17, 2016, an Order imposing the civil penalty (ML16294A515). On September 27, 2017, the NRC licenses were also revoked for nonpayment of fees (ML17269A214 and ML17269A216). When the licensee continued to fail to pay the owed fees and civil penalty, the debt was transferred, on June 26, 2018, to the US Department of the Treasury for collection.

c. Conclusions

Continued violations of 10 CFR 20.1801, 10 CFR 30.36(d), 10 CFR 30.36(h) and the Orders were identified. The NRC has determined that all decommissioning activities required for the Somascan license and for International Cyclotron's medical distribution license have been completed. Although the licensee did not comply with the prior enforcement actions related to failure to complete timely decommissioning, with the assistance of the CRCPD's SCATR program, compliance has been restored and the unpaid fees and fines are being addressed through debt collection. Accordingly, the NRC has determined to terminate the licenses and to not pursue further investigation or enforcement proceedings for this matter. However, International Cyclotron remains responsible for the licensed material possessed under NRC License No. 52-31352-02, related to the cyclotron and is required to maintain the security of the material (including preventing unauthorized access) and to complete all necessary decommissioning activities.

3. **Exit Meeting**

An exit meeting was held with Dr. Frank Kolodziej and David Rhoe on May 29, 2020. The inspection findings, violations, and enforcement decisions were discussed.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

- + Frank Kolodziej, M.D., owner
- + David Rhoe, Consultant

+Attended telephonic exit meeting conducted on May 29, 2020