



UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

February 13, 2017

Docket No. 030-36194
EA-16-255

License No. 52-25617-01 (expired)

Frank Kolodziej Castro, M.D.
Somascan, Incorporated
Ashford Avenue 888 PH
San Juan, Puerto Rico 00907

SUBJECT: NRC INSPECTION REPORT NO. 03036194/2014001, SOMASCAN,
INCORPORATED, HATO REY, PUERTO RICO

Dear Dr. Kolodziej:

This letter refers to the routine, unannounced inspections conducted between December 10, 2014, and November 16, 2016; at your facilities located at Calle Jose Marti #56, Hato Rey; Torre Plaza, Suite 405; Plaza Las Americas, San Juan; and 1409 Ashford Avenue, Condado, Puerto Rico. This inspection examined activities conducted under your license as they relate to public health and safety, the common defense and security, and to confirm compliance with the U.S. Nuclear Regulatory Commission's (NRC's) rules and regulations and with the conditions of your license. Within these areas, the inspection consisted of an examination of selected procedures and representative records, observations of licensed activities, independent radiation measurements, and interviews with personnel. A final exit briefing was conducted telephonically with your consultant, David Rhoe, on January 30, 2017.

Based on the results of this inspection, three apparent violations were identified and are being considered for escalated enforcement action in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The apparent violations involved: (1) failure to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas; (2) the failure to notify the NRC in writing, within 60 days of the Somascan license expiring on April 30, 2013, and begin decommissioning; and (3) failure to complete decommissioning of the Somascan, Inc. facilities within 24 months. A more detailed description of the apparent violations and the circumstances surrounding the apparent violations may be found in the enclosed inspection report. Since the NRC has not made a final determination in this matter, a Notice of Violation is not being issued at this time. Please be advised that the number and characterization of the apparent violations described herein may change as a result of further NRC review.

Before the NRC makes its enforcement decision, we are providing you an opportunity to: (1) respond to the apparent violations in writing; (2) request a pre-decisional enforcement conference (PEC); or (3) request Alternative Dispute Resolution (ADR). Please contact Mr. James P. Dwyer, Chief, Medical Branch, at 610-337-5309 within **10** days of the date of this letter notifying the NRC whether you are interested in providing a written response, attending a PEC, or engaging in ADR.

If you choose to provide a written response, it should be sent to the NRC within 30 days of the date of this letter. Your response may reference or include previously docketed correspondence, if the correspondence adequately addresses the required response. You should clearly mark the response as a "Response to Apparent Violations in EA-16-255," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to the Regional Administrator, NRC Region I, 2100 Renaissance Boulevard, Suite 100, King of Prussia, PA 19406.

If you choose to request a PEC, the meeting should be held in our office in King of Prussia, PA, within 30 days of the date of this letter. The PEC will afford you the opportunity to provide your perspective on these matters and any other information that you believe the NRC should take into consideration before making an enforcement decision. The topics discussed during the PEC may include information to determine whether a violation occurred, information to determine the significance of a violation, information related to the identification of a violation, and information related to any corrective actions taken or planned. The time and date for the PEC would be publicly announced and open to the public for observation. The NRC will issue a press release to announce the conference time and date. Please note that the promptness and comprehensiveness of your corrective actions will be considered in assessing any civil penalty for the apparent violations. The guidance in the excerpt from NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," may be helpful. The guidance is included on NRC's Web site at <https://www.nrc.gov/docs/ML0728/ML072890794.pdf>.

In lieu of a PEC, you may request Alternative Dispute Resolution (ADR) with the NRC in an attempt to resolve these issues. 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; a voluntary, informal process in which a trained neutral 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 ADR program can be obtained 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 program as a neutral third party. Please contact ICR at 877-733-9415 within 10 days of the date of this letter if you are interested in pursuing resolution of this issue through ADR. The ADR mediation session should be held in our office in King of Prussia within 45 days of the date of this letter. The time and date for the ADR session would be publicly noticed but closed to the public for observation.

The NRC's primary interest in this matter is to ensure that the radioactive materials present in the Somascan facilities are immediately and properly disposed of, that the facilities can be released for unrestricted use, and that the Somascan license can be terminated.

Separately, you should be aware that your other NRC-licensed facility, International Cyclotron, Inc., remains in violation of NRC requirements for neither beginning nor completing site decommissioning within the timeframe required by 10 CFR 30.36(d). As a result, on August 30, 2016, the NRC issued to you a Notice of Violation and proposed Imposition of Civil Penalty. When you failed to address the violation or pay the civil penalty, on November 17, 2016, the NRC issued you an Order (EA-16-055) requiring that you pay the \$14,000 fine within 30 days. To date, you have not paid the fine and, more importantly, have still not taken steps to begin or complete site decommissioning.

The NRC is considering the need to impose additional civil penalties, including daily penalties, which would continue to be assessed until you address the violations by taking action to decommission the site. The results of that determination will be provided in separate correspondence.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Ind, & Academic Uses**; then **Regulations, Guidance and Communications**. The current Enforcement Policy is included on the NRC's website at www.nrc.gov; select **About NRC, Organizations & Functions; Office of Enforcement; Enforcement documents**; then **Enforcement Policy (Under 'Related Information')**. 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 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>.

Sincerely,



James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03036194/2014001

cc w/Enclosure: David Rhoe, Consultant
Ms. Elizabeth Zayas
Commonwealth of Puerto Rico

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Sincerely,

/RA/

James M. Trapp, Director
Division of Nuclear Materials Safety

Enclosure:
Inspection Report No. 03036194/2014001

cc w/Enclosure: David Rhoe, Consultant
Ms. Elizabeth Zayas
Commonwealth of Puerto Rico

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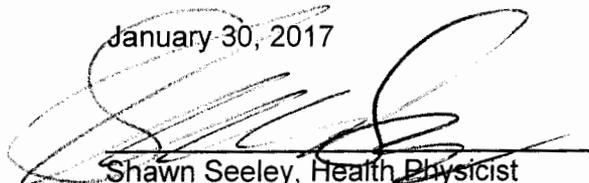
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REGION I

INSPECTION REPORT

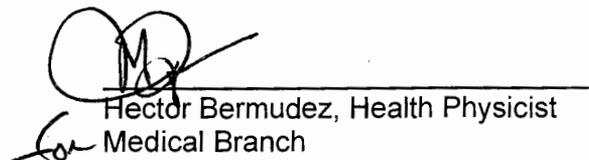
EA No.: EA-16-255
Inspection No.: 03036194/2014001
Docket No.: 03036194
License No.: 52-25617-01
Licensee: Somascan, Inc.
Location: Calle Jose Marti #56, Hato Rey, Puerto Rico 00918
Inspection Dates: December 10, 2014; August 8 and December 17, 2015; June 22 and November 16, 2016

Exit Meeting: January 30, 2017

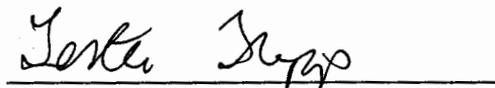
Inspectors:


Shawn Seeley, Health Physicist
Medical Branch
Division of Nuclear Materials Safety

1/30/17
date

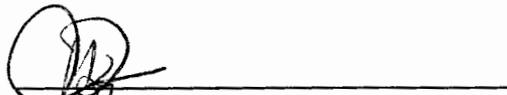

Hector Bermudez, Health Physicist
Medical Branch
Division of Nuclear Materials Safety

1/30/2017
date


Lester Tripp, Health Physicist
Medical Branch
Division of Nuclear Materials Safety

2/6/2017
date

Approved By:


James P. Dwyer, Chief
Medical Branch
Division of Nuclear Materials Safety

JANUARY 30, 2017
date

EXECUTIVE SUMMARY

Somascan, Inc.
NRC Inspection Report No. 03036194/2014001

Onsite inspections were conducted of the licensee's facilities on December 10, 2014; August 8 and December 17, 2015; and June 22 and November 16, 2016.

Three apparent violations were identified:

- Failure of the licensee to secure from unauthorized removal or access licensed materials that are 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, as of November 21, 2012, when an eviction order was finalized and issued by the building owner, Somascan has had no direct control over access to the facility. This is an apparent violation of 10 CFR 20.1801.
- Failure of the licensee to notify NRC in writing within 60 days of license expiration and begin decommissioning or submit, within 12 months of notification, a decommissioning plan. This is an apparent violation of 10 CFR 30.36(d).
- Failure of the licensee to complete decommissioning of facilities authorized for use under the Somascan, Incorporated license no later than 24 months following the expiration of its license. This is an apparent violation of 10 CFR 30.36(h).

A telephone Exit Meeting was held with the licensee's consultant on January 30, 2017.

REPORT DETAILS

1. Background

The Somascan, Inc. (Somascan) license was issued on April 16, 2003. Somascan was a private outpatient 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.

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 the importance of securing the licensed radioactive material and inquired about the licensee's plans for the future. 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.

Somascan allowed their license to expire on April 30, 2013. An inspection conducted in June 2013, identified there had been no licensed activities conducted at any of the Somascan facilities for approximately 2 years and that most 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 the fact 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, unannounced inspection was initiated at the Somascan, Inc. facility located in Hato Rey, Puerto Rico on December 10, 2014. The inspection was conducted to follow up on a concern, identified during a June 2013 inspection, that no new licensed activities had been conducted under the Somascan license since some time in 2011. 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. Additional site visits were performed on August 8 and December 17, 2015, and on June 22 and November 16, 2016, at the Hato Rey facility, the Torre Plaza facility and the Condado facility. The inspectors toured facilities to evaluate security; spoke with the license owner when he was available to them, the licensee's spouse, the licensee's consultant, and facility owners/managers; observed the storage of radioactive sealed sources; performed sealed source inventories; and reviewed records of sealed source inventories and leak tests performed by the consultant.

b. Observations and Findings

The inspector who conducted the December 10, 2014, inspection at the Hato Rey facility confirmed that the sealed sources transferred from Somascan were secured at the International Cyclotron facility. The inspector learned that a single sealed source containing 20 millicuries of cesium-137 was still located at one of the Somascan facilities and it was secured inside of a PET/CT camera. The licensee's consultant told the inspector that in May 2014, he attempted to remove the cesium-137 source from the PET/CT camera so that it could be better secured at the International Cyclotron facility. The consultant said that the cesium-137 source could not be removed from the camera without special tools possessed only by the camera manufacturer and its service technicians. The inspector confirmed that the licensee's consultant performed inventories and leak tests of the Somascan sealed sources.

The inspector who conducted the December 17, 2015, inspection at the Hato Rey facility learned that an eviction order had been issued to Somascan for non-payment of rent at one of the facilities. The inspector contacted the manager of the facility and made certain the manager knew that the licensee was responsible for the sealed source that was located within the PET/CT camera and that the facility needed to be secured until the source could be removed and properly disposed of by Somascan. The facility manager said that he understood and would cooperate.

The inspector who conducted the June 22, 2016, inspection contacted the manager of the facility where the sealed source was located and attempted to gain access to the facility. Unfortunately, the facility manager was sick and a mutually convenient time for the site visit could not be arranged. The inspector reminded the facility manager of the licensee's responsibility for securing, inventorying and leak testing the cesium-137 sealed source located within the PET/CT camera. The inspector noted that the sealed sources transferred to

International Cyclotron were stored and shielded in the cyclotron hoods with two sources located in a PET scanner stored in a room adjacent to the dose preparation room.

The inspector who conducted the November 16, 2016, inspection made arrangements with the manager of the facility where the sealed source was located to access the facility. The inspector confirmed with a radiation survey instrument that the cesium-137 sealed source was secured inside of the PET/CT camera and that the facility containing the PET/CT camera was secured. The inspector reviewed with the manager the need to secure the facility until the sealed source inside of the PET/CT camera could be disposed of properly by Somascan. The inspector was provided with a copy of the eviction order which was finalized on November 21, 2012.

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, as of November 21, 2012, the licensee failed to secure from unauthorized removal or access licensed materials that are 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, since November 21, 2012, when an eviction order was finalized and issued, Somascan has had no direct control over access to the facility. This is an apparent violation of 10 CFR 20.1801.

10 CFR 30.36(d) requires, in part, that within 60 days of a license expiring, the licensee must begin decommissioning its site, or any separate building or outdoor area that contains residual radioactivity so that the building or outdoor area is suitable for release in accordance with NRC requirements.

Contrary to the above, as of June 29, 2013, Somascan did not provide written notification to the NRC that its license had expired and that they had begun decommissioning the site so that the site was suitable for release in accordance with NRC requirements. This is an apparent violation of 10 CFR 30.36(d).

10 CFR 30.36(h) requires, in part, that unless the Commission approves an alternate schedule for decommissioning of the site, the licensee must complete decommissioning of the site, or separate building, or outdoor area as soon as practicable but no later than 24 months following the initiation of decommissioning.

Contrary to the above, as of June 29, 2015, Somascan has not completed decommissioning of its site, within 24 months following the expiration of its license. Specifically, a 20 millicurie cesium-137 sealed source stored inside of a PET/CT camera located still remains at Somascan facility for which the licensee has not completed decommissioning and the licensee has no immediate plans for disposal of the sealed source. This is an apparent violation of 10 CFR 30.36(h).

c. Conclusions

Apparent violations of 10 CFR 20.1801, 10 CFR 30.36(d) and 10 CFR 30.36(h) were identified.

3. Exit Meeting

An exit meeting was held with the licensee's consultant by telephone on January 30, 2017. The inspection findings and the apparent violations were discussed. The licensee's consultant agreed to discuss the inspection results with the licensee when he was presented with the opportunity.

PARTIAL LIST OF PERSONS CONTACTED

Licensee

Frank Kolodziej, M.D., owner

Elizabeth Zayas, Dr. Kolodziej's spouse

+ David Rhoe, Consultant

Julio J. Guilliani, Facility Manager

+Attended telephonic exit meeting conducted on January 30, 2016