

June 27, 2017

Docket Nos. 03036194

License No.: 52-25617-01 (expired)

EA-16-255

Frank Kolodziej Castro, M.D.
President and Owner
Somascan, Incorporated
Ashford Avenue 888 PH
San Juan, PR 00907

SUBJECT: ORDER IMPOSING CIVIL MONETARY PENALTY - \$7,000

Dear Dr. Kolodziej:

This refers to the Notice of Violation and Proposed Imposition of Civil Penalty (Notice) sent as an enclosure to our letter dated April 5, 2017, (ML17094A537)¹. Our letter and Notice described violations identified by the NRC through its review of Somascan's licensed activities.

To emphasize to Somascan the importance of compliance with NRC requirements and the obligation to decommission its facility and ensure proper transfer or disposal of licensed material in its possession and to secure from unauthorized removal or access of licensed material that is stored in an unrestricted area, a civil penalty of \$7,000 was proposed.

As of the date of this Order, Somascan has not responded to our letter dated April 5, 2017. Therefore, we have concluded that the violations occurred as stated and that the penalty proposed for the violations designated in the Notice should be imposed. In reaching this determination, the NRC staff considered that Somascan allowed its license to expire on April 30, 2013, and was previously informed that an expired license precluded Somascan from performing any licensed activities except those required for securing licensed radioactive material and decommissioning. Additionally, Somascan was informed of the need to properly dispose of its radioactive material and to request termination of the Somascan license. To date, Somascan has not acknowledged the Notice and has not taken any action to address the violations.

¹ Designation in parentheses refers to an Agency-wide Documents Access and Management System (ADAMS) accession number. Documents referenced in this letter are publicly-available using the accession number in ADAMS.

Accordingly, we hereby serve the enclosed Order on Somascan imposing a civil monetary penalty in the amount of \$7,000. Within 30 days from the date of the enclosed Order, you should either: (1) pay the civil penalty in accordance with Section IV of the Order, (2) request Alternative Dispute Resolution (ADR) as discussed below, or (3) request a hearing in accordance with Section V of the Order.

You may request ADR with the NRC in an attempt to resolve this issue. 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. Mediation is a voluntary, informal process in which a trained neutral (the "mediator") works with parties to help them reach resolution. If the parties agree to use ADR, they select a mutually agreeable 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's ADR program can be found 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's program as a neutral third party. If you are interested in pursuing this issue through the ADR program, please contact: (1) the ICR at (877) 733-9415; and (2) Mr. Jim Dwyer at (610) 337-5309 within 10 days of the date of this letter. You may also contact both ICR and Mr. Dwyer for additional information. Your submitted signed agreement to mediate will stay the 30-day time period for payment of the civil penalties, as identified in the enclosed Order, until the ADR process is completed.

We will review the effectiveness of your corrective actions during a subsequent inspection which typically would occur within six months from the issuance of the enclosed Order. At that time, we will also consider the need to impose additional civil penalties, including daily penalties, which would continue to be assessed until you address the violations.

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's document system (ADAMS), accessible from the NRC Web site 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.

The NRC also includes significant enforcement actions on its Web site (<http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/>).

Sincerely,

/RA/

Patricia K. Holahan
Director
Office of Enforcement

Enclosures:

1. Order Imposing Civil Monetary Penalty
2. NUREG/BR-0254 Payment Methods (Licensee only)

cc w/enclosures:

David M. Rhoe, Consultant
Ms. Elizabeth Zayas
Commonwealth of Puerto Rico

SUBJECT: NOTICE OF VIOLATION AND PROPOSED CIVIL PENALTY \$7,000

Distribution: see next page

ADAMS Package No.: ML17172A321
ADAMS ACCESSION No.: ML17172A322
ORDER Accession No.: ML17172A323

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*Concurrence on previous page

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DATE: June 27, 2017

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