

UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

In the Matter of:)	Docket No. 03036194
)	License No. 52-25617-01 (expired)
Somascan, Incorporated)	EA-16-255
San Juan, Puerto Rico)	
)	

ORDER IMPOSING CIVIL MONETARY PENALTY

I.

Somascan, Inc. (Somascan or the Licensee) is the holder of expired Materials License No. 52-25617-01 issued by the U.S. Nuclear Regulatory Commission (NRC or Commission) on April 16, 2003, pursuant to Part 30 of Title 10 of the *Code of Federal Regulations* (10 CFR). 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.

II.

Onsite inspections of Somascan's activities were conducted between December 10, 2014 and November 16, 2016. The results of these inspections indicated that Somascan had not conducted its activities in full compliance with NRC requirements, in that Somascan has neither begun nor completed decommissioning within the timeframes required by NRC regulations in 10 CFR 30.36(d) and 30.36(h) or secured from unauthorized removal or access

licensed material that is stored in an unrestricted area. As a result, on April 5, 2017, a written Notice of Violation and Proposed Imposition of Civil Penalty (Notice) was issued to Somascan (ADAMS Accession No. ML17094A537). The Notice states the nature of the violations, the provisions of the NRC's requirements that Somascan violated, and the amount of the civil penalty proposed for the violations. As of the date of this Order, Somascan has not responded to the Notice.

III.

The NRC staff has determined 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 its license. To date, Somascan has not acknowledged the Notice and has not taken any action to address the violations.

IV.

In view of the foregoing and pursuant to Section 234 of the Atomic Energy Act of 1954, as amended (Act), 42 U.S.C. 2282, and 10 CFR 2.205, IT IS HEREBY ORDERED THAT:

The Licensee shall pay a civil penalty in the amount of \$7,000 within 30 days of the issuance date of this Order, in accordance with NUREG/BR-0254, "Payment Methods" (see <http://www.nrc.gov/reading-rm/doc-collections/nuregs/brochures/br0254/>). In addition, at the

time payment is made, Somascan shall submit a statement indicating when and by what method payment was made, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, One White Flint North, 11555 Rockville Pike, Rockville, MD 20852-2738.

V.

In accordance with 10 CFR 2.205(d), Somascan and any other person adversely affected by this Order may request a hearing on this Order within 30 days of the issuance date of this Order. Where good cause is shown, consideration will be given to extending the time to answer or request a hearing. A request for extension of time must be directed to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, and include a statement of good cause for the extension.

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene (hereinafter "petition"), and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC E-Filing rule (72 FR 49139, August 28, 2007, as amended at 77 FR 46562, August 3, 2012). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Detailed guidance on making electronic submissions may be found in the Guidance for Electronic Submissions to the NRC and on the NRC Web site at <http://www.nrc.gov/site-help/esubmittals.html>. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten (10) days prior to the

filing deadline, the participant should contact the Office of the Secretary by e-mail at hearing.docket@nrc.gov, or by telephone at 301-415-1677, to (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's Public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit adjudicatory documents. Submissions must be in Portable Document Format (PDF). Additional guidance on PDF submissions is available on the NRC Public Web site at <http://www.nrc.gov/site-help/electronic-sub-ref-mat.html>. A filing is considered complete at the time the documents submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an e-mail notice confirming receipt of the document. The E-Filing system also distributes an e-mail notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed so that they can obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the "Contact Us" link located on the NRC's Public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by e-mail to MSHD.Resource@nrc.gov, or by a toll-free call to 1-866-672-7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) first class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, 11555 Rockville Pike, Rockville, Maryland, 20852, Attention: Rulemaking and Adjudications Staff. Participants filing adjudicatory document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is available to the public at <https://adams.nrc.gov/ehd/>, unless excluded

pursuant to an Order of the Commission or the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click “Cancel” when the link requests certificates and you will be automatically directed to the NRC’s electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. For example, in some instances, individuals provide home addresses in order to demonstrate proximity to a facility or site. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

If a person other than Somascan requests a hearing, that person shall set forth with particularity the manner in which his interest is adversely affected by this Order and shall address the criteria set forth in 10 CFR 2.309(d) and (f). If a hearing is requested by Somascan or a person whose interest is adversely affected, the Commission will issue an Order designating the time and place of any hearings. If a hearing is held, the issue to be considered at such hearing shall be whether this Order should be sustained.

In the absence of any request for a hearing or alternative dispute resolution (ADR), or written approval of an extension of time in which to request a hearing or ADR, the provisions specified in Section IV above shall be final 30 days from the date of this Order without further order or proceedings. If an extension of time for requesting a hearing or ADR has been approved, the provisions specified in Section IV shall be final when the extension expires if a hearing or ADR request has not been received. If ADR is requested, the provisions specified in Section IV shall be final upon termination of an ADR process that did not result in issuance of an

Order. If payment has not been made by the time specified above, the matter may be referred to the Attorney General for collection.

Dated at Rockville, Maryland, this 27th day of June 2017

For the Nuclear Regulatory Commission

/RA/

Patricia K. Holahan,
Director, Office of Enforcement.