

December 12, 2018

EA-18-163

Mr. Michael Fuller, Director
Regulatory Compliance Associates
QSA Global, Inc.
40 North Avenue
Burlington, MA 01803

SUBJECT: NOTICE OF VIOLATION – QSA GLOBAL, INC. RELATED TO FAILURE TO PROPERLY NOTIFY THE U.S. NUCLEAR REGULATORY COMMISSION IN ADVANCE OF IMPORT SHIPMENT

Dear Mr. Fuller:

This letter refers to the U.S. Nuclear Regulatory Commission's (NRC) review of information concerning the import of Category 2 quantity of selenium-75 (Se-75) by QSA Global, Inc. (QSA), from The Netherlands on or about October 9, 2018. The NRC initiated its review following an inquiry from the U.S. Customs and Border Protection (CBP) on October 15, 2018. Two members of my staff, Mr. Steve Baker and Ms. Jane Chimood, discussed the preliminary results of this review with Mr. Erik Okvist, QSA's Distribution Manager on October 18, 2018. A final exit briefing was conducted telephonically with both you and Mr. Okvist on November 30, 2018.

During this review, the NRC staff examined activities conducted under your NRC general license, which was granted under Title 10 *Code of Federal Regulations* (10 CFR) 110.27(a), "General license for imports," to ensure that activities were being performed in accordance with NRC rules and requirements and in a manner that ensured protection of public health and safety. Within these areas, the staff reviewed the Advanced Notification (Notification) submitted to the NRC on September 28, 2018, the amended Notification submitted on October 9, 2018, and the shipping document provided by the CBP on October 15, 2018.

Based on the results of this review, the NRC has determined that one Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy. The current Policy is located on the NRC's website at <https://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>. The violation is cited in the enclosed Notice of Violation (Notice), with a description of the circumstances surrounding the violation. The NRC is citing the violation in the Notice because the violation was identified by the NRC.

The violation concerned the licensee's failure to file a submittal containing the Notification with the NRC at least 7 days prior to the shipment of radioactive material listed in Appendix P to 10 CFR Part 110, as required by 10 CFR 110.50(c)(4).

QSA submitted emails, dated October 19, 2018 and November 30, 2018 (ADAMS Accession No. ML18301A002), in which QSA acknowledged that the failure of notifying the NRC of its import of Se-75 was an oversight. The shipment of Se-75 was scheduled separately from that of Ir-192, and that QSA was not aware the shipment would contain Se-75 at the time of

submitting Notification reference number 2018-022. As stated in its October 19 and November 30, 2018 emails, QSA's corrective actions to restore compliance and to prevent future reoccurrence included: (1) updating the Notification form to ensure it would have space available to include the additional isotope and activity; (2) revising QSA's procedure(s) to require QSA personnel to include a requirement to check the Se-75 production schedule prior to submitting the Notification; and (3) a commitment to provide training to employees on the revision in accordance with QSA's Quality Assurance Program.

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed on the docket in this letter. Therefore, you are not required to respond to this letter unless the description herein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter, its enclosures and your response 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 Website at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy or proprietary information so that it can be made available to the Public without redaction.

Please feel free to contact Ms. Jane Chimood at 301-287-9225 if you have any questions regarding this matter.

Sincerely,

/RA/

Peter J. Habighorst, Chief
Export Controls and Nonproliferation Branch
Office of International Programs

Enclosure:
Notice of Violation

cc:
Commonwealth of Massachusetts

SUBJECT: NOTICE OF VIOLATION - QSA GLOBAL, INC. RELATED TO FAILURE TO PROPERLY NOTIFY THE U.S. NUCLEAR REGULATORY COMMISSION IN ADVANCE OF IMPORT SHIPMENT: DATED DECEMBER 12, 2018

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| DATE | 12/11/18 | 11/05/18 | 11/30/18 | 12/12/18 |

OFFICIAL RECORD COPY

NOTICE OF VIOLATION

QSA Global, Inc.
Burlington, MA 01803

EA-18-163

During a U.S. Nuclear Regulatory Commission (NRC) review of information conducted between October 15 and November 30, 2018, one violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

Title 10 *Code of Federal Regulations* (10 CFR) 110.27(a) states, "Except as provided in paragraphs (b) and (c) of this section, a general license is issued to any person to import byproduct, source, or special nuclear material if the U.S. consignee is authorized to receive and possess the material under a general or specific NRC or Agreement State license issued by the Commission or a State with which the Commission has entered into an agreement under Section 274b. of the Atomic Energy Act."

10 CFR 110.50(c)(1) requires, in part, that a licensee authorized to export or import the radioactive material listed in Appendix P to this part is responsible for notifying NRC and, in cases of exports, the government of the importing country in advance of each shipment.

10 CFR 110.50(c)(4) requires, in part, that the import notification be received by the NRC at least 7 days in advance of each shipment.

Contrary to the above, QSA failed to notify the NRC at least 7 days prior to its import of 10 CFR 110 Appendix P radioactive material under its NRC general license. Specifically, on September 28, 2018, QSA notified the NRC of its intent to import a Category 1 quantity of iridium-192 (Ir-192) on October 8, 2018. On October 9, 2018, QSA submitted a revised notification to change the shipping date to October 9, 2018. On October 15, 2018, the U.S. Customs and Border Protection had questions about the October 9, 2018 import and forwarded the pertinent shipping documentation to the NRC for its review. The shipping document indicated that, in addition to the Category 1 quantity of Ir-192, QSA also imported a Category 2 quantity of selenium-75 (Se-75), which was not included in the notification. Therefore, QSA failed to notify the NRC of its import of Se-75 in a timely manner.

This is a Severity Level IV violation (NRC Enforcement Policy Section 6.15).

The NRC has concluded that information regarding the reason for the violation, the corrective actions taken and planned to correct the violation and prevent recurrence, and the date when full compliance was achieved is already adequately addressed in emails, dated October 19 and November 30, 2018 (ADAMS Accession No. ML18301A002). However, you are required to submit a written statement or explanation pursuant to the provisions of 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation (EA-18-163)," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Director, Office of International Programs, within 30 days of the date of the letter transmitting this Notice of Violation.

Enclosure

If you choose to respond, your response will be made available electronically for public inspection in the NRC Public Document Room or in the NRC's Agencywide Documents Access and Management System (ADAMS), accessible from the NRC Website at <http://www.nrc.gov/reading-rm/adams.html>. Therefore, 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.

Dated this 12th day of December 2018.