

May 25, 2016

EA-16-081

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

SUBJECT: FAILURE TO SUBMIT COMPLETE AND ACCURATE INFORMATION IN  
ADVANCE OF IMPORT SHIPMENT AND NOTICE OF VIOLATION

Dear Mr. Fuller:

This letter refers to a review of QSA Global, Inc.'s (QSA) Advanced Notification associated with the import of a Category 2 quantity of iridium-192 (Ir-192). Title 10 of the *Code of Federal Regulations* (CFR) Section 110.7a(a) states, in part, that information required by statute or by the Commission's regulations, orders or license conditions shall be complete and accurate in all material respects. Section 110.50(c)(3)(ii)(D), states that import notifications must include the radionuclides and activity level in terabecquerel (TBq), both for single and aggregate shipments. Additionally, in accordance with Section 110.50(c)(3)(ii)(G), these import notifications must include the shipment date from the exporting facility and estimated arrival date at the end use location. A telephonic exit briefing was conducted with Ms. Stephanie Burgess of your organization on February 18, 2016.

On January 18, 2016, QSA submitted incomplete and inaccurate information on its Import Notification Form for a January 25, 2016, shipment from Maharashtra, India. Specifically, the January 18, 2016, import notification provided by QSA did not include the accurate activity level for ten Ir-192 sources. The import notification form that QSA submitted on January 18, 2016, indicated a 0.96 TBq activity level, when the actual activity level was 1.40 TBq. Additionally, the import notification form indicated an expected shipment and arrival date of October 22, 2015, and October 28, 2015, respectively. These dates had already passed approximately two months before QSA submitted the import notification. Therefore, the import notification provided by QSA was incomplete and inaccurate in that it did not include: (1) the correct activity level in TBq, both for single and aggregate shipments, and (2) the correct shipment date from the exporting facility and estimated arrival date at the end use location. On January 21, 2016, the U.S. Nuclear Regulatory Commission (NRC) staff contacted QSA regarding the inaccurate information.

On January 22, 2016, QSA submitted a revised notification, but on January 25<sup>th</sup>, reported to the NRC that the 1.40 TBq activity listed in the notification was inaccurate. According to QSA, the correct activity for the shipment was 0.96 TBq. However on January 29, 2016, QSA again contacted the NRC and stated that the 1.40 TBq activity listed on the January 22<sup>nd</sup> import

notification was accurate. As a result, QSA submitted a revised import notification on January 29<sup>th</sup>, indicating the correct activity of 1.40 TBq. However, this notification was not submitted at least 7 days in advance of the shipment, in accordance with 10 CFR 110.50©(4). Specifically, QSA submitted the correct information the same day that the shipment was expected to arrive at the end user's facility. QSA's failure to provide timely and accurate information did not allow the NRC sufficient time to perform its review, which could have had significant implications for public health and safety or common defense and security.

Based on the information identified during the review of this activity, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation involved a failure to provide complete and accurate information in accordance with 10 CFR 110.7a(a), when making the required advanced notification pursuant to 10 CFR 110.50(c). The violation was evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is available on the NRC Web site at <http://www.nrc.gov/about-nrc/regulatory/enforcement/enforce-pol.html>.

The violation is cited in the enclosed Notice of Violation (Notice) because all of the criteria in Section 2.3.2 of the NRC Enforcement Policy were not met in that QSA did not identify the violation. You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. If you have additional information that you believe the NRC should consider, you may provide it in your response. The NRC will use your response, in part, to determine whether or not further enforcement action is necessary to ensure compliance with regulatory requirements.

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 Public Document Room or from the NRC's document system Agencywide Documents Access and Management System 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. If personal privacy or proprietary information is necessary to provide an acceptable response, please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such information, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information).

M. Fuller

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Please contact Andrea R. Jones at (301) 415-2309, if you have any questions regarding this matter.

Sincerely,

***/RA/***

David L. Skeen, Deputy Director  
Office of International Programs

Enclosure:  
Sequence of Events  
Notice of Violation

cc: Commonwealth of Massachusetts

M. Fuller

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Please contact Andrea R. Jones at (301) 415-2309, if you have any questions regarding this matter.

Sincerely,

**/RA/**

David L. Skeen, Deputy Director  
Office of International Programs

Enclosure:  
Sequence of Events  
Notice of Violation

cc: Commonwealth of Massachusetts

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**\*concurrence via e-mail**

<b>OFFICE</b>	OIP	OIP	BC:OIP/ECNP	OE	OIP
<b>NAME</b>	SBaker	AJones	BSmith	LSreenivas*	DSkeen
<b>DATE</b>	05/19/16	05/19/16	05/23/16	05/11/16	05/25/16

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Office of International Programs Sequence of Events  
May 3, 2016

Based on the information provided by QSA, the following is the sequence of events during January 2016:

- January 18     QSA submitted an import notification dated October 15, 2015, indicating an expected shipment date and expected arrival date of October 22, 2015, and October 28, 2015, respectively, for ten 1.40 terabecquerel (TBq) of iridium-192 (Ir-192) sources.
- January 21     The NRC Export Controls and Nonproliferation Branch licensing staff requested verification of October 2015 shipment and arrival dates.
- January 22     QSA responded with a revised import notification with corrected shipment and arrival dates.
- January 23     NRC Headquarters Operations Officer (HOO) contacted QSA, identifying a discrepancy in the activity level contained in the revised import notification and the email transmitting the notification. Specifically, the import notification listed an activity level of 0.96 TBq while the transmittal email listed an activity level of 1.4 TBq for the Ir-192 sources.
- January 25     QSA responded to the HOO, and indicated the 0.96 TBq activity shown on the revised import notification submitted on January 22<sup>nd</sup> was correct and the activity contained in the transmitting email was inaccurate.
- January 25     QSA shipped the Ir-192 sources.
- January 29     QSA contacted the HOO and revealed that the 0.96 TBq activity level contained in the January 22<sup>nd</sup> revised import notification was inaccurate and that the accurate activity was 1.40 TBq. A second revised import notification was submitted to the HOO. The shipment was expected to arrive at the end use facility on January 29<sup>th</sup>.

## NOTICE OF VIOLATION

QSA Global, Inc.  
Burlington, MA

EA-16-081

During a U.S. Nuclear Regulatory Commission (NRC) review completed on February 18, 2016, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 110.7a(a) requires, in part, that information required by the Commission's regulations shall be complete and accurate in all material respects.

10 CFR 110.50(c)(3)(ii)(D) requires that the import notification must contain the radionuclides and activity level in TBq, both for single and aggregate shipments.

10 CFR 110.50(c)(3)(ii)(G) requires that the import notification must contain the shipment date from the export facility and estimated arrival date at the end use location.

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

Contrary to the above, on January 18, 2016, QSA Global, Inc., (QSA) failed to submit information required by the Commission's regulations that was complete and accurate in all material respects. QSA failed to submit an import notification that contained the correct activity level in TBq, both for single and aggregate shipments, and the correct shipment date and estimated arrival date at the end use location. Also, the correct import notification was not received 7 days in advance of the shipment. Specifically, the January 18, 2016, import notification stated a shipment date from the exporting facility and estimated arrival date at the end use location of October 22, 2015, and October 28, 2015 respectively, instead of January 25, 2016, and January 29, 2016. The import notification provided by QSA indicated an activity of 0.96 TBq for the aggregate shipment instead of 1.40 TBq and no single activity level was provided. The corrected imported notification was received on January 29, 2016, 4 days after the January 25, 2016, shipment date.

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

Pursuant to the provisions of 10 CFR 2.201, QSA Global, Inc. is hereby required to submit a written statement or explanation to the Director, Office of International Programs, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, within 30 days of the date of this Notice of Violation. This reply should be clearly marked as a "Reply to a Notice of Violation (EA-16-081)" and should include for each violation: (1) the reason for the violation, or, if contested, the basis for disputing the violation or severity level; (2) the corrective steps that have been taken and the results achieved; (3) any additional corrective steps that will be taken; and (4) the date when full compliance will be or was achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified in this Notice, the NRC may issue an Order or a Demand for Information requiring you to explain why your

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license should not be modified, suspended, or revoked or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice," 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, proprietary, or safeguards information so that it can be made available to the public without redaction.

In accordance with 10 CFR 19.11, you may be required to post this Notice within 2 working days of receipt.

Dated this 25<sup>th</sup> day of May 2016.

**cc:**

Jack Priest, Director  
Department of Public Health  
Radiation Control Program  
Bureau of Environmental Health  
Schrafft Center, Suite 1M2A  
529 Main Street  
Charlestown, MA 02129