

September 11, 2009

EA-08-343

Ms. Cathleen Roughan  
Director, Regulatory Affairs/Quality Assurance  
QSA Global, Inc.  
40 North Avenue  
Burlington, MA 01803

SUBJECT: NOTICE OF VIOLATION - FAILURE TO CONFIRM FOREIGN RECIPIENT WAS AUTHORIZED TO POSSESS BYPRODUCT MATERIAL PRIOR TO EXPORT- VIOLATION OF 10 CFR 110.50(b)(4)

Dear Ms. Roughan:

This refers to an e-mail dated April 13, 2009, (enclosure 1) sent to the U.S. Nuclear Regulatory Commission (NRC) by Mr. Fuller of QSA Global Inc. (QSA), in which he acknowledged that QSA inadvertently authorized the release of two iridium-192 (Ir-192) sources for export to a customer located in Australia, for which the activity level of each Ir-192 source exceeded the possession limits for the customer. Specifically, on October 27, 2008, pursuant to 10 CFR Part 110.50(b)(4), QSA provided notification to the NRC that, on or about October 28, 2008, QSA would export two sealed sources, each of which contained approximately 1.78 TBq of Ir-192 to a customer in Australia. Along with that notification, QSA provided a copy of an authorization from the Australian government that specifically states the maximum activity in any radiography source container shall not exceed 1,200 GBq (1.2 TBq). Therefore, the stated activity level of the two sources QSA shipped to the customer exceeded the customer's possession authorization. This error was discovered by the NRC during its review of QSA's export notifications submitted in accordance with 10 CFR Part 110.50(b)(4). In this instance, QSA failed to provide documentation that demonstrated the customer was authorized to possess the sources. However, once the error was brought to QSA's attention, QSA was forthcoming with information and asked the Australian regulators if they would like QSA to have the sources returned to its facility in the U.S. The Australian regulator declined the offer to have the sources returned to QSA in the U.S.

Additionally, in the e-mail dated April 13, 2009, QSA stated that it believes that the Australian government's authorization limits only apply to sources installed in radiography cameras and not to sources in source changers. Using QSA's interpretation, QSA may ship to its customer in Australia any amount of Ir-192 so long as it is: (1) not shipped in a radiographic camera; or (2) shipped in a source changer and not installed in the radiographic camera for use until the source decays below the Australian authorization limit of 1.2 TBq. The NRC finds this interpretation is invalid, since the Australian authorization places limits on the source within a container that is used for the operation of radiographic equipment and is independent of whether the source is contained in either a radiographic camera or a source changer.

Based on the information provided by QSA, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. This violation was evaluated 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 violation is cited in the enclosed Notice of Violation (enclosure 2).

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. We have enclosed NRC Information Notice 96-28, "Suggested Guidance Relating to Development and Implementation of Corrective Action," (enclosure 3) for your consideration when responding to the Notice. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room and 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.

Sincerely,

*/RA/*

Cynthia A. Carpenter, Director  
Office of Enforcement

Enclosures:

1. Email disclosure from QSA dated April 13, 2009
2. Notice of Violation EA-08-343
3. NRC Information Notice 96-28

cc:

Customs & Border Protection, NTCC  
Attn: Christopher M. Baugues, MSc, Physical Scientist  
LSS Teleforensic Center  
12825 Worldgate Plaza III  
Herndon, Virginia 20170

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DISTRIBUTION:

M. Doane, OIP  
S. Dembek, OIP  
C. Carpenter, OE  
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**OE Case File EA-08-343**

S. Moore, OIP  
S. Baker, OIP  
D. Solorio, OE  
N. Hilton, OE  
OE Day File

DOCUMENT NAME:

S:\APPENDIX P\Appendix P - OE Case Writeups\EA-08-343-QSA\EA-08-343.QSA.to Australia.doc

**ADAMS ACCESSION NOS.:**  
**Letter (plus Encls #2 & 3) No.: ML092580578**

**Package No.: ML092580569**  
**Enclosure 3 No.: ML092580592**

\* See previous concurrence

\*\* Concurred via email

	<input checked="" type="checkbox"/> Publicly Available	<input type="checkbox"/> Non-Publicly Available	<input type="checkbox"/> Sensitive	<input checked="" type="checkbox"/> Non-Sensitive		
<b>OFFICE</b>	OIP/ECIO	OIP/ECIO:BC	OIP/DD	OGC	OE/EPPO	OE/D
<b>NAME</b>	S Baker	J Owens*	S Dembek for S Moore*	T Rothschild for G Kim*	R Summers	C Carpenter
<b>DATE</b>	9/10/09	8/12/09	8/18/09	8/19/09	9/11/09	9/11/09

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## NOTICE OF VIOLATION

QSA Global, LLC  
Burlington, MA

License No. CBP0011a-01  
EA-08-343

During the review of information submitted to the U.S. Nuclear Regulatory Commission (NRC) on October 27, 2008, (via the Headquarters Operations Officer) and April 13, 2009, a violation of NRC requirements was identified. In accordance with the NRC Enforcement Policy, the violation is listed below:

10 CFR 110.50(b)(4) states 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. Notifications must contain specified information, including a copy of the foreign recipient's authorization or confirmation of that authorization from the government of the importing country as required by 10 CFR 110.32(h).

10 CFR 110.32(h) states in part, that for proposed exports of material listed in Table 1 of Appendix P to this part, pertinent documentation that the recipient of the material has the necessary authorization under the laws and regulations of the importing country to receive and possess the material. Pertinent documentation shall consist of a copy of the recipient's authorization to receive and possess the material to be exported or a confirmation from the government of the importing country that the recipient is so authorized.

Contrary to the above, on October 28, 2008, QSA Global, Inc., (QSA) exported two sealed sources, each containing an amount of Ir-192 listed in 10 CFR 110 Appendix P, Table 1, without providing the necessary documentation to show that the recipient is authorized to receive and possess the sources. Specifically, in the notification submission for this export, dated October 27, 2008, QSA stated the activity levels of the two Ir-192 sources were 1.78 TBq each. This same notification also included a copy of the recipient authorization issued by the Australian regulator that indicated the end user in Australia was only authorized to receive sealed sources of Ir-192, with a maximum radioactivity level not to exceed 1.2 TBq for each source. Therefore, QSA failed to provide an adequate recipient authorization that proved the end user was authorized to receive the relevant radionuclides and radioactivity being imported or that the recipient is authorized to receive and possess the sources.

This is a Severity Level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, QSA is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Director, Office of International Programs, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation; EA-08-343" and should include: (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) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be 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, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or

## Notice of Violation

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, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room and 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, it should not include any personal privacy, proprietary, or safeguards 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, then 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 material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the basis 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). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

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

Dated this 11<sup>th</sup> day of September 2009

UNITED STATES NUCLEAR REGULATORY COMMISSION  
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS  
WASHINGTON, D.C. 20555

May 1, 1996

NRC INFORMATION NOTICE 96-28: SUGGESTED GUIDANCE RELATING TO  
DEVELOPMENT AND IMPLEMENTATION OF  
CORRECTIVE ACTION

#### Addressees

All material and fuel cycle licensees.

#### Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this information notice to provide addressees with guidance relating to development and implementation of corrective actions that should be considered after identification of violation(s) of NRC requirements. It is expected that recipients will review this information for applicability to their facilities and consider actions, as appropriate, to avoid similar problems. However, suggestions contained in this information notice are not new NRC requirements; therefore, no specific action or written response is required.

#### Background

On June 30, 1995, NRC revised its Enforcement Policy (NUREG-1600) 60 FR 34381, to clarify the enforcement program's focus by, in part, emphasizing the importance of identifying problems before events occur, and of taking prompt, comprehensive corrective action when problems are identified. Consistent with the revised Enforcement Policy, NRC encourages and expects identification and prompt, comprehensive correction of violations.

In many cases, licensees who identify and promptly correct non-recurring Severity Level IV violations, without NRC involvement, will not be subject to formal enforcement action. Such violations will be characterized as "non-cited" violations as provided in Section VII.B.1 of the Enforcement Policy. Minor violations are not subject to formal enforcement action. Nevertheless, the root cause(s) of minor violations must be identified and appropriate corrective action must be taken to prevent recurrence.

If violations of more than a minor concern are identified by the NRC during an inspection, licensees will be subject to a Notice of Violation and may need to provide a written response, as required by 10 CFR 2.201, addressing the causes of the violations and corrective actions taken to prevent recurrence. In some cases, such violations are documented on Form 591 (for materials licensees) which constitutes a notice of violation that requires corrective action but does not require a written response. If a significant violation is involved, a predecisional enforcement conference may be held to discuss those actions. The quality of a licensee's root cause analysis and plans for corrective actions may affect the NRC's decision regarding both the need to hold a predecisional enforcement conference with the licensee and the level of sanction proposed or imposed.

#### Discussion

Comprehensive corrective action is required for all violations. In most cases, NRC does not

propose imposition of a civil penalty where the licensee promptly identifies and comprehensively corrects violations. However, a Severity Level III violation will almost always result in a civil penalty if a licensee does not take prompt and comprehensive corrective actions to address the violation.

It is important for licensees, upon identification of a violation, to take the necessary corrective action to address the noncompliant condition and to prevent recurrence of the violation and the occurrence of similar violations. Prompt comprehensive action to improve safety is not only in the public interest, but is also in the interest of licensees and their employees. In addition, it will lessen the likelihood of receiving a civil penalty. Comprehensive corrective action cannot be developed without a full understanding of the root causes of the violation.

Therefore, to assist licensees, the NRC staff has prepared the following guidance, that may be used for developing and implementing corrective action. Corrective action should be appropriately comprehensive to not only prevent recurrence of the violation at issue, but also to prevent occurrence of similar violations. The guidance should help in focusing corrective actions broadly to the general area of concern rather than narrowly to the specific violations. The actions that need to be taken are dependent on the facts and circumstances of the particular case.

The corrective action process should involve the following three steps:

1. Conduct a complete and thorough review of the circumstances that led to the violation. Typically, such reviews include:
  - a. Interviews with individuals who are either directly or indirectly involved in the violation, including management personnel and those responsible for training or procedure development/guidance. Particular attention should be paid to lines of communication between supervisors and workers.
  - b. Tours and observations of the area where the violation occurred particularly when those reviewing the incident do not have day-to-day contact with the operation under review. During the tour, individuals should look for items that may have contributed to the violation as well as those items that may result in future violations. Reenactments (without use of radiation sources, if they were involved in the original incident) may be warranted to better understand what actually occurred.
  - c. Review of programs, procedures, audits, and records that relate directly or indirectly to the violation. The program should be reviewed to ensure that its overall objectives and requirements are clearly stated and implemented. Procedures should be reviewed to determine whether they are complete, logical, understandable, and meet their objectives (i.e., they should ensure compliance with the current requirements). Records should be reviewed to determine whether there is sufficient documentation of necessary tasks to provide an auditable record and to determine whether similar violations have occurred previously. Particular attention should be paid to training and qualification records of individuals involved with the violation.
2. Identify the root cause of the violation.

Corrective action is not comprehensive unless it addresses the root cause(s) of the violation. It

is essential, therefore, that the root cause(s) of a violation be identified so that appropriate action can be taken to prevent further noncompliance in this area, as well as other potentially affected areas. Violations typically have direct and indirect cause(s). As each cause is identified, ask what other factors could have contributed to the cause. When it is no longer possible to identify other contributing factors, the root causes probably have been identified. For example, the direct cause of a violation may be a failure to follow procedures; the indirect causes may be inadequate training, lack of attention to detail, and inadequate time to carry out an activity. These factors may have been caused by a lack of staff resources that, in turn, are indicative of lack of management support. Each of these factors must be addressed before corrective action is considered to be comprehensive.

3. Take prompt and comprehensive corrective action that will address the immediate concerns and prevent recurrence of the violation.

It is important to take immediate corrective action to address the specific findings of the violation. For example, if the violation was issued because radioactive material was found in an unrestricted area, immediate corrective action must be taken to place the material under licensee control in authorized locations. After the immediate safety concerns have been addressed, timely action must be taken to prevent future recurrence of the violation. Corrective action is sufficiently comprehensive when corrective action is broad enough to reasonably prevent recurrence of the specific violation as well as prevent similar violations.

In evaluating the root causes of a violation and developing effective corrective action, consider the following:

1. Has management been informed of the violation(s)?
2. Have the programmatic implications of the cited violation(s) and the potential presence of similar weaknesses in other program areas been considered in formulating corrective actions so that both areas are adequately addressed?
3. Have precursor events been considered and factored into the corrective actions?
4. In the event of loss of radioactive material, should security of radioactive material be enhanced?
5. Has your staff been adequately trained on the applicable requirements?
6. Should personnel be re-tested to determine whether re-training should be emphasized for a given area? Is testing adequate to ensure understanding of requirements and procedures?
7. Has your staff been notified of the violation and of the applicable corrective action?
8. Are audits sufficiently detailed and frequently performed? Should the frequency of periodic audits be increased?
9. Is there a need for retaining an independent technical consultant to audit the area of concern or revise your procedures?
10. Are the procedures consistent with current NRC requirements, should they be clarified, or should new procedures be developed?

11. Is a system in place for keeping abreast of new or modified NRC requirements?
12. Does your staff appreciate the need to consider safety in approaching daily assignments?
13. Are resources adequate to perform, and maintain control over, the licensed activities? Has the radiation safety officer been provided sufficient time and resources to perform his or her oversight duties?
14. Have work hours affected the employees' ability to safely perform the job?
15. Should organizational changes be made (e.g., changing the reporting relationship of the radiation safety officer to provide increased independence)?
16. Are management and the radiation safety officer adequately involved in oversight and implementation of the licensed activities? Do supervisors adequately observe new employees and difficult, unique, or new operations?
17. Has management established a work environment that encourages employees to raise safety and compliance concerns?
18. Has management placed a premium on production over compliance and safety? Does management demonstrate a commitment to compliance and safety?
19. Has management communicated its expectations for safety and compliance?
20. Is there a published discipline policy for safety violations, and are employees aware of it? Is it being followed?

This information notice requires no specific action or written response. If you have any questions about the information in this notice, please contact one of the technical contacts listed below.

signed by

Elizabeth Q. Ten Eyck, Director  
 Division of Fuel Cycle Safety  
 and Safeguards  
 Office of Nuclear Material Safety  
 and Safeguards

signed by

Donald A. Cool, Director  
 Division of Industrial  
 and Medical Safety  
 Office of Nuclear Material Safety  
 and Safeguards

Technical contacts:

Nader L. Mamish, OE  
 (301) 415-2740  
 Internet:nlm@nrc.gov

Daniel J. Holody, RI  
 (610) 337-5312  
 Internet:djh@nrc.gov

Bruno Uryc, Jr., RII  
 (404) 331-5505  
 Internet:bxu@nrc.gov

Bruce L. Burgess, RIII  
 (708) 829-9666  
 Internet:blb@nrc.gov

Gary F. Sanborn, RIV  
 (817) 860-8222  
 Internet:gfs@nrc.gov