NRC FORM 591S PART 1 (8-2002) 10 CFR 2.201

U.S. NUCLEAR REGULATORY COMMISSION

SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. LICENSEE/CERTIFICATE HOLDER	2. NRC/REGIONAL OFFICE
QSA Global, Inc. 40 North Avenue Burlington, MA 01803 REPORT NUMBER: 71-0040/2009-201	Division of Spent Fuel Storage and Transportation U. S. NRC M/S EBB-3D-02M Washington, DC 20555-0001

3. LICENSEE/CERETIFICATE NUMBER(S)	4. INSPECTION LOCATION	5. DATE(S) OF INSPECTION
Various	Burlington, MA	September 9, 2009

The inspection was an examination of the activities conducted under your license as they relate to radiation safety and to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your license of Certificate of Compliance (CoC). The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

☒ 1. Based on the inspection findings, no violation or nonconformances were identified.

☒ 2. Previous violations(s) or nonconformance(s) closed.

☐ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, NUREG-1600, to exercise discretion, were satisfied.

_____ Non-Cited Violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

☐ 4 During this inspection certain of your activities, as described below and/or attached, were in violation of nonconformance of NRC requirements and are being cited. This for is a NOTICE OF VIOLATION OR NONCONFORMANCE, which may be subject to posting in accordance with 10 CFR19.11.

(Violations, Nonconformances, and Corrective Actions)

STATEMENT OF CORRECTIVE ACTIONS

☐ I hereby state that, within 30 days, the actions described by me to the inspector will be taken to correct the violations identified. This statement of corrective actions I made in accordance with the requirements of 10 CRF 2.201 (corrective steps already taken, corrective steps which will be taken date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested; OR

☐ Written Response requested in 30 days ☐ Yes ☐ No

TITLE	PRINTED NAME	SIGNATURE	DATE
LICENSEE	Cathleen Roughan	Cathleen Roughan	9/9/09
NRC INSPECTOR	Earl Love/Rob Temps	Earl C. Love Robert Temps	9/9/2009

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	QSA Global, Inc. 40 North Avenue Burlington, MA 01803
Licensee/Certificate Holder contact and phone number	Ms. Cathleen Roughan (781) 505-8210
Docket No.	071-00040
Inspection Report No.	071-0040/2009-201
Inspection Dates(s)	September 9, 2009
Inspection Location(s)	40 North Avenue Burlington, MA 01803
Inspectors	Earl Love, Team Leader, Safety Inspector Rob Temps, Senior Safety Inspector
Summary of Findings and Actions	The inspection was to assess QSA's response to Notice of Violations (NOVs) identified during the December 10-14, 2007 and May 6, 2008 inspections and to assess current activities associated with the transportation of radioactive material being performed by QSA Global, Inc. (QSA) to determine if these activities were being performed in compliance with the requirements of 10 CFR Parts 21, "Reporting of Defects and Noncompliance," and 71, "Packaging and Transportation of Radioactive Material," applicable Certificates of Compliance, and Safety Analysis Reports, and QSA's NRC-approved Quality Assurance (QA) program. The team reviewed all corrective actions resulting from the Notice of Violations (NOV) issued at the conclusion of the last NRC inspection, Report No.: 71-0040/2007-201 (ML081640461). Overall, no concerns were identified in the review of QSA's corrective actions to the six (6) examples cited in the NOV. The team did discuss the progress made by QSA in identifying and describing areas for corrective action as well as the fact that continued attention is required by QSA to ensure regulatory compliance and conformance to QSA's NRC-approved QA program and various Certificates of Compliance. The review of QSA's corrective actions was assessed to be adequate. No significant adverse findings were noted and no cited or non-cited violations were identified during this inspection.
Lead Inspector Signature/Date	Earl Love / Rob Temps
Inspector Notes Approval Section Chief Signature/Date	David W. Pstrak 10/09/09

INSPECTOR NOTES: SECTIONS 02.05 THROUGH 02.08 OF IP 86001 WERE PERFORMED AS APPLICABLE IN REGARD TO REVIEW OF QSA CORRECTIVE ACTIONS FROM A PREVIOUS INSPECTION. THE INSPECTION RESULTS ARE DOCUMENTED BELOW:

The team reviewed all corrective actions resulting from the Notice of Violations (NOV) issued at the conclusion of the last NRC inspection of QSA (December 10-14, 2007 and May 6, 2008) as documented in NRC Inspection Report (IR) 72-1015/2007-201.

Overall, no concerns were identified in the review of QSA's corrective actions to the six (6) examples cited in the NOVs. The team did discuss the progress made by QSA in identifying and describing areas for corrective action as well as the fact that continued attention is required by QSA to ensure regulatory compliance and conformance to QSA's NRC-approved QA program and various Certificates of Compliance. No significant concerns were noted and no cited or non-cited violations were identified during this inspection.

As cited in IR 71-00040/2007-201, the NOVs read as follows:

A. *10 CFR 71.111, "Instructions, Procedures, and Drawings," states in part, "The licensee, certificate holder, and applicant for a CoC shall prescribe activities affecting quality by documented instructions, procedures, or drawings of a type appropriate to the circumstances and shall require that these instructions, procedures, and drawings be followed. The instructions, procedures, and drawings must include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished."*

   Contrary to this requirement:

   1. *QSA procedure Q-2101, step 2.2.2, states, in part, "If the disposition is to "Use-As-Is" or "Repair," the basis and rationale must be documented on the NCR. "Use-As-Is" and "Repair" dispositions require concurrence from Regulatory Affairs." The NRC identified that NCRs 143305, 143908, 142684, and 143967, all dispositioned as Use-As-Is, did not have the required basis and rationale documented on them. Further, NCR 142684 was missing the required Regulatory Affairs concurrence signature.*

   2. *QSA Work Instruction, WI-R-3141, Revision 1, "Regulatory Processing of ERFs," describes the Regulatory review, sign-off and processing of Engineering review Forms affecting AEA Technology QSA, Inc., products. The NRC identified that QSA personnel failed to process ERFs according to requirements set forth in the work instructions. Specifically, the impact of the changes to affected documents was not evaluated.*

   3. *QSA Engineering Work Instruction, WI-E-1303, Revision 1, "Descriptive Drawings," covers the production, change, control, and storage of drawings used to submit to regulatory agency in support of submissions and requests for approvals. Further, Section 2.3, states, in part, "Deviations from descriptive drawing are not allowed. If a change is necessary, an ERF must be generated." The NRC identified that three separate manufactured packagings did not meet the NRC approved design as delineated in the CoC design drawings.*

B. *10 CFR 71.107, "Package Design Control," states, in part, "(a) The licensee, certificate holder, and applicant for a CoC shall establish measures to assure that applicable regulatory requirements and the package design, as specified in the license or CoC for those materials and components to which this section applies, are correctly translated into specifications, drawings, procedures, and instructions. These measures must include provisions to assure that appropriate quality standards are specified and included in design documents and that deviations from standards are controlled. Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety. (b) The licensee, certificate holder, and applicant for a CoC shall…apply design control measures to the following: (2) Compatibility of materials; and (5) Delineation of acceptance criteria for inspections and tests. (c) The licensee, certificate holder, and applicant for a CoC shall subject design changes, including field changes, to design control measures commensurate with those applied to the original design. Changes in the conditions specified in the CoC require prior NRC approval."*

Contrary to this requirement:

1. *QSA failed to initiate prompt action to correct a discrepancy between descriptive drawings referenced in the CoC and fabrication drawings.*

2. *QSA failed to evaluate the safety significance of lubricant as well as material suitability and acceptance criteria.*

3. *QSA failed to define critical inspection characteristics and an appropriate inspection sampling method of security screws that have been classified as Category A.*

02.05: Review selected drawings, procedures and records, and observe selected activities being performed to determine that design & maintenance activities meet SARP design requirements documented in the CoC.

Violation (A)(3): QSA Engineering Work Instruction, WI-E-1303, Revision 1, "Descriptive Drawings," covers the production, change, control, and storage of drawings used to submit to regulatory agency in support of submissions and requests for approvals. Further, Section 2.3, states that "Deviations from descriptive drawing are not allowed. If a change is necessary, an ERF must be generated." The NRC identified that three separate manufactured packagings did not meet the NRC approved design as delineated in the CoC design drawings.

The team reviewed CR 889 that was issued by QSA to document this issue cited in the NOV. The team noted significant actions had been taken to maintain configuration control of production documents to be consistent with the approved designs. The team noted that QSA performed a comprehensive review of all design basis documentation which resulted in the identification of numerous corrections to descriptive drawings and production drawings resulting in reportable conditions under 10 CFR 71.95(c). The team noted a comprehensive assessment and actions taken to problems identified in the areas of Design; Procurement; and Instructions, Procedures and Drawings. Further, the team noted that actions taken included but were not limited to interim overchecks, ample reviews to assure compliance to Certificates of Compliance, and enhancements to numerous procedures and processes to preclude recurrence (i.e. production drawings, work instructions, inspection plans, assembly instructions, system controls for computer aided design (CAD) software, transition of design changes to production,

manufacturing instructions, implementing procedures, and training). The team reviewed a sample of Production drawings for conformance to the Descriptive drawings and NRC CoC for type B transportation packages. Further, in a letter dated May 1, 2008, QSA performed an extent of condition on four Type B packages and concluded that changes or discrepancies were minor in nature and did not affect the safety or integrity of the packages. In addition, the team noted adequate justifications for continued use of the existing packages where applicable and in all cases no Part 21 conditions. The team concluded that QSA's corrective actions were appropriate and effective in preventing recurrence.

The team verified that QSA had processed amendments for the packages in question as well as two (2) additional packages noted in QSA letters dated September 21, 2009 (after conclusion of this inspection) to the NRC Licensing Branch (LB) in which separate 10 CFR 71.95 reports had been submitted applicable to Model Nos. 680-OP (CoC 9035) and 741-OP (CoC 9027). The deficiencies noted in the reports were specific to the type of steel used to fabricate overpack boxes and were identified during QSA's process of completing routine quality inspections on incoming parts used in production of the overpack box assembly. QSA concluded as part of a Technical Report (No. 159), "use-as-is" justification of overpack boxes currently in service. Further, QSA concluded that the packages will continue to meet regulatory requirements and that no safety issues or part 21 conditions exist. The team considers actions taken were an extension of QSA's comprehensive review of design basis documentation and corrections to descriptive drawings and production drawings that result in reportable conditions under 10 CFR 71.95(c). The team verified implementation of the corrective actions and assessed that they were appropriate for the identified issue.

Violation (B)(1): QSA failed to initiate prompt action to correct a discrepancy between descriptive drawings referenced in the CoC and fabrication drawings.

The NRC had identified during the 2007 inspection that with regard to NCR No. 143900, dated 10 September 2007, that two depleted uranium (DU) shields specific to the Model No. 880 Delta radiographic camera, weighed 34.34 and 34.36 pounds, respectively. One shield was accepted for use, the other was rejected. The requirement specified on the NCR for acceptance was 33.8 ± 0.5 pounds. The team had questioned why one DU shield was accepted and the other rejected. QSA QA personnel had responded that by applying QSA-developed rounding methodologies, the DU shield measured as 34.34 pounds rounded to a value of 34.3 pounds, consistent with the number of significant digits in the acceptance value of 33.8 ± 0.5 pounds. Since 34.3 pounds is allowed by the upper acceptance limit, the DU shield was acceptable for use. The other DU shield, that weighed 34.36 pounds, rounded up to 34.4 pounds and therefore was above the upper acceptance value and therefore was rejected for use.

The team had noted that the acceptance range of 33.8 ± 0.5 pounds was listed on the fabrication drawing for the Model No. 880 Delta camera. However, the team pointed out to QSA personnel that the licensing drawing for the Model No. 880 Delta camera stated that the DU shield maximum weight is 34 pounds. QSA had responded that by applying their rounding practices to DU shield weights, a DU shield with a weight of 34.3 pounds would round down to 34 pounds and would therefore meet the licensing drawing specification. The team had informed QSA that this was an incorrect interpretation of the licensing drawing in that 34 pounds maximum weight means exactly that, 34 pounds maximum with no tolerance above that amount or consideration for rounding practices. This position was further emphasized by subsequent discussions with SFST Licensing Branch personnel.

The shield weight issue was documented in CR 891. Corrective actions included:

1. Submittal of an amendment request to the CoC to show a maximum weight of 34.4 pounds.
2. Review of other NRC CoC package designs to determine compliance without using rounding techniques
3. Revision of appropriate quality procedures stating to not apply rounding to dimensions or features that are specified as maximums or minimums to determine acceptance.

The team verified implementation of the corrective actions and assessed that they were appropriate for the identified issue.

02.06: Observe activities affecting safety aspects of the packaging (such as design changes, maintenance and testing) to verify that they are performed in accordance with approved methods, procedures, and Specifications.

Violation (A)(2): QSA Work Instruction, WI-R-3141, Revision 1, "Regulatory Processing of ERFs," describes the Regulatory review, sign-off and processing of Engineering Review Forms affecting AEA Technology QSA, Inc., products. The NRC identified that QSA personnel failed to process ERFs according to requirements set forth in the work instructions. Specifically, the impact of the changes to affected documents was not evaluated.

The team reviewed CR 893 that was issued by QSA to document this issue cited in the NOV. QSA issued new procedures for controlling the ERF process. The procedures included the requirement that ERFs must include an engineering assessment (impact statement) for all changes to a regulated product (i.e., NRC CoC packagings) and that safety classification sheets be routed with the ERF and filed with the completed ERF. The team reviewed a sampling of recent EFRs and noted they were properly processed and that no examples of the issue were present. The team concluded that QSA's corrective actions were appropriate and effective in preventing recurrence.

Violation (B)(2): QSA failed to evaluate the safety significance of lubricant as well as material suitability and acceptance criteria.

With regard to the second issue in the above NOV, the NRC had identified during the 2007 inspection that QSA changed a series of production drawings to incorporate the addition of primer and thread locking compound to socket head cap and set screws. The team noted that the type of lubricant was not listed on the product drawing Bill of Material and that the safety classification and material suitability evaluation had not been performed. The team reviewed QSA Condition Report No. CR 892, that included Technical Report No. 117, "Type B Device Glue, Adhesive, Grease and Lubricant Material Compatibility Review." The review included an assessment of each manufacturer's recommended materials compatibility currently used on Type B containers. As part of the review, the team noted that the commercial component drawings for glues/adhesives and greases/lubricants classifications were revised with expanded descriptions and use information as supplied by the manufacturers. The team noted that the materials reviewed were determined to be compatible with the materials that they are used with and are within the manufacturers stated applications. The team reviewed Engineering request Form (ERF) No. 1815 dated 02/11/2008 which documented changes to production drawings on the Model 880 Projectors to allow use of thread lubricant. The team verified implementation of the corrective actions and assessed that they were appropriate for the identified issue.

02.07 Review selected drawings and records, and interview selected personnel, to verify that the procurement specifications for materials, equipment, and services received by the QA Program holder meet the design requirements.

Violation (B)(3): QSA failed to define critical inspection characteristics and an appropriate inspection sampling method of security screws that have been classified as Category A.

The NRC had identified during the 2007 inspection that QSA procured MAT076, Revision A, "18-8 Stainless Steel Quality Class A" screws as commercial grade through an unapproved distributor. The inspection team concluded that QSA failed to define the appropriate method to substantiate procurement of a Class 'A' component. In this case, the procurement process lacked appropriate selections of critical characteristics and basis of a sample plan expected of commercial grade item acceptance for use as a Safety Related component. The team reviewed Condition Report No. CR 890, which documents QSA's performance of an extensive investigation and cause determination as well as appropriate corrective actions. The team noted that a review of the dedication activities associated with twelve commercial grade items designated as quality class A was conducted and noted process implementation such as development of a more rigorous procedure for use of commercial grade items, training of personnel in the dedication process, changes to Work Instructions involved in the dedication of commercial grade items, clearly define critical characteristics and method of verification, and changes to Inspection Instruction records for all Class A components to conform with updated specifications and commercial grade dedication procedures. The team reviewed the results of QSA's review of acceptance history, changes to procedures, and implementation enhancements to the existing commercial grade dedication process and determined that QSA's dedication process is acceptable and that products previously manufactured are acceptable and do not present a substantial safety hazard. The team verified implementation of the corrective actions and assessed that they were appropriate for the identified issue.

02.08 Review selected records and interview selected personnel to verify that a nonconformance control program is effectively implemented, and that corrective actions for identified deficiencies are technically sound and completed in a timely manner.

Violation (A)(1): QSA procedure Q-2101, step 2.2.2, states, in part, "If the disposition is to "Use-As-Is" or "Repair," the basis and rationale must be documented on the NCR. "Use-As-Is" and "Repair" dispositions require concurrence from Regulatory Affairs." The NRC identified that NCRs 143305, 143908, 142684, and 143967, all dispositioned as Use-As-Is, did not have the required basis and rationale documented on them. Further, NCR 142684 was missing the required Regulatory Affairs concurrence signature.

The team reviewed CR 893 that was issued by QSA to document this issue cited in the NOV. Corrective actions for this issue included having a QA representative present during the conduct of Material Review Boards (where NCRs are reviewed) and to have this individual be responsible for assuring that all necessary signatures and justifications are obtained. The team noted that this action was not captured in any QA administrative procedure and QSA stated they would look at incorporating the expectations for the QA individual during MRBs into the appropriate procedure. The team reviewed a sampling of recent NCRs and noted they were properly processed and that no examples of the issue were present. The team concluded that QSA's corrective actions were appropriate and effective in preventing recurrence.