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Mr. Jim Pearson
Transportation and Storage Safety Inspector
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
11555 Rockville Pike
Rockville, MD 20852

7 October 2008

Dear Mr. Pearson:

Enclosed please find an affidavit to support our request to maintain QSA Global's Technical Report 110 as confidential information under 10 CFR 2.390.

Please let me know if you need any additional information.

Sincerely,

Cathleen Roughan

Cathleen Roughan
Director, Regulatory Affairs/Quality Assurance

IE07

QSA GLOBAL

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AFFIDAVIT OF INFORMATION CONFIDENTIALITY UNDER 10 CFR 2.390

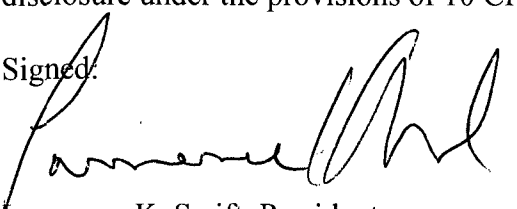
I hereby certify that the attached information in QSA Global Technical Report 110 contains information of a confidential and proprietary nature for the model 880 Type B package.

- This information is held confidential by QSA Global, Inc. and is intended for use only by QSA Global, Inc. Information related to the design of the model 880 Type B package is maintained confidential as this relates directly to QSA Global, Inc's ability to grow and maintain its business interests related to this product.

- The information attached to this affidavit is not available in any public sources, therefore, we request that the USNRC maintain the confidentiality of this information during the review of the 10 CFR 71 inspection report.

- The information was submitted to NRC as company confidential on 15 Feb 08.

- The information in Technical Report 110 is based on technical expertise and specific design basis information for the model 880. Release of this information to the general public could put QSA Global, Inc. at a competitive disadvantage from competitors, and therefore, I request that this information be withheld from public disclosure under the provisions of 10 CFR 2.390.

Signed:  Date: 7 OCT 2008

Lawrence K. Swift, President
QSA Global Inc.

NOTARIZATION

State of Massachusetts, County of Middlesex, ss. Subscribed and sworn to before me this 7th day of October, 2008.

Melissa J. Fortuna, Notary Public My Commission Expires 7-19-2013
Melissa J. Fortuna

QSA GLOBAL

40 North Ave
Burlington, MA 01803
781-272-2000

US Nuclear Regulatory Commission
Attn: Document Control Desk
Washington DC 20555-0001

9 July 2008

Re: NRC Inspection Report No. 71-00040-2007-201
Reply to a Notice of Violation

Dear Mr. Pstrak:

This letter responds to the audit findings and subsequent Notice of Violation issued on 9 Jun 2008 for the NRC QA audit performed at QSA Global Inc on 10-14 Dec 2007.

We have reviewed the audit report and have the following clarification in addition to the NOV response. Please note that many of the issues raised have been previously addressed as described in our letters dated 18 Dec 2007, 15 Feb 2008 and 1 May 2008 (copies of these letters are also enclosed with this letter for convenience).

The audit report (page 13, section 4.2.3) indicates that we continued manufacturing the model 680-OP after we discovered the discrepancies from the descriptive drawings. This is incorrect, once we discovered the discrepancies during an internal review and investigation, prior to the NRC audit we stopped the manufacture and entered the issue into our corrective action system. The immediate corrective action was to stop manufacturing and shipping the 680-OP until the NRC amendment was received.

Even though this action caused several months of delays in shipping customer orders, the inability of customers to perform some of their committed jobs, and in some cases the loss of an order, we felt it was important and necessary to maintain compliance with the Certificate of Compliance.

In addition to the specific actions taken in response to the NOV, QSA has also implemented many additional corrective actions to ensure a comprehensive approach to improving the QA program. These actions include:

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-Senior level management attention has been focused on the QA Program, which is continually re-emphasized to all personnel through their immediate management.

-A full detailed review of all the Type B packages is currently being performed. This includes a review of all the documentation to manufacture the Type B packages including production drawings, descriptive drawings, route cards and inspection instructions. This has been completed for all the Type B packages that are in active manufacture and appropriate corrective actions taken. For the remaining Type B packages that are not in full active manufacture we are continuing our review as we may supply replacement parts and are scheduled to complete this review by Oct 2008. All currently manufactured Type B packages are in full compliance with the descriptive drawings.

-Three QSA employees attended the Argonne National Lab course on "Quality Assurance for Radioactive Material Packaging" in Jun 2008.

-As many of the drawing discrepancies were directly related to weld symbol applications and interpretations, we have retained an outside welding consultant. This consultant will train Engineering, Manufacturing, Regulatory and QA/QC personnel. In addition they will also review welding procedures and drawing references for accuracy and correct implementation of welding codes.

-We will have an external audit of the Type B QA program performed in late 2008 to assess our performance.

Many of the examples cited in the audit directly related to the level of detail on the descriptive drawings and the expectations of the NRC reviewers and QSA's interpretation of what is critical to safety. We learned from NRC license reviewers during the inspection, that their interpretation was that even non-safety critical parts should be listed on the descriptive drawing. We had not always included non critical parts (ie lubrication, non essential foam and screws) on the drawing as they could change without affecting the package but if described on the drawing it would require an amendment. To help clarify the expectations on what level of detail should be on the descriptive drawings, we believe it would be beneficial to have a meeting with NRC on this particular subject.

The violation for inadequate regulatory response, specifically our failure to remove packagings in questions from service and notifying customers of discrepant licensing conditions, is primarily addressed under our letter dated 1 May 2008 which includes the justifications for continued use of these affected packages based on the discrepancies impact on package safety and integrity. In all cases where a package deviation could have existed on packaging in use for transport at that time, the impact of the deviation had no significant safety impact on the packages' ability to maintain its integrity during transport. Since no safety impact existed, notification of package users to cease transport

of the packaging was not considered necessary as continued use of the package for shipment remained safe.

We have been comprehensively addressing these issues and are working aggressively to complete all necessary corrective actions in order to continue to assure we have a thorough and robust QA program for the manufacture of Type B packages. We are committed to keeping our Quality Assurance program in full compliance with 10 CFR Part 71 and in making continuous improvements.

We greatly appreciate all the efforts made by your staff during this process.

Sincerely,

Cathleen Roughan
Director, Regulatory Affairs/Quality Assurance

for Lawrence Swift via email
President

cc: David Pstrak, Chief
Rules, Inspections and Operations Branch
Division of Spent Fuel Storage and Transportation
Mail Stop 6003 3 D-02M

Enclosures:

Letters dated 18 Dec 2007, 15 Feb 2008 and 1 May 2008

Reply to a Notice of Violation

NRC Finding

A. 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.

QSA Response

A.1

1) When QSA became aware of a discrepancy between the descriptive drawings and the fabrication drawings, we initiated a review to determine extent of the condition and then submitted as needed an amendment request. This is documented in our attached letter dated concerning 71.95 reports dated 1 May 2008. We did not make notifications to customers using the packages as the corrections were primarily administrative corrections and did not affect the package itself.

2) It has been clearly communicated to all affected staff that any discrepancy between the package and the descriptive drawings is a non-compliance, even if only a typographical error or a clarification. A detailed review of all Type B packages has been completed for all actively manufactured packages and the appropriate corrections made with the NRC amendments received.

3) QSA will not manufacture any Type B package that may potentially be non compliant with the descriptive drawing until either the drawing is changed or there has been discussion with NRC about the apparent discrepancy, (ie typographical error or necessary level of detail) and resolved.

4) Completed Dec 2007.

A.2

1) The use of Never Seez lubricant on SCR 154 (the screw used on the endplates of the model 880 package) was not indicated on the drawing for the 880 although it was being used. There was no documented assessment of the compatibility of the Never Seez with the model 880, although the Never Seez being used was specifically made for the stainless steel. Personnel had been made aware of its requirement for use during on the job training and had been appropriately applying it to the 880 since the original design.

2) An assessment on the compatibility has been documented in Technical Basis Document No. 110, and the drawing for the 880 has been revised to indicate the use of Never Seez and a secondary optional lubricant.

3) All use of lubricants and/or other miscellaneous components (ie non critical screws) will be assessed as needed and documented as part of the design history file.

4) Technical report was completed on 15 Feb 08, drawings were approved 4 Jan 08.

A.3

1) Although the QSA procedures did address the process of commercial grade dedication, they did not include sufficient detail on sampling methods or identification of the critical inspection characteristics.

2) QSA performed a review of their existing procedures and the available EPRI and NRC guidance on commercial grade dedication and has implemented a stand alone commercial grade dedication procedure incorporating applicable EPRI guidance. This procedure is WI-G-1401 and was completed on 8 Feb 08.

   A Part 21 evaluation for the specific screw (SCR 154) identified in the audit was performed and it was concluded that the screws meet the required technical requirements and were safe for continued use. This evaluation is in included in Technical Report no. 110 completed on 15 Feb 08.

3) We also performed a safety class assessment of all the hardware based on guidance in NUREG CR 6407 under Technical Report No. 116, so that appropriate sampling and inspection could be performed on all commercially procured Class A parts in accordance with WI-G-1401.

4) Technical Report completed 24 Apr 08.

NRC Finding

B. 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 ERF's," 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.

QSA Response

General Response for B.1 - B.3

During an internal audit conducted by QSA in 2007, a similar observation concerning adherence to procedures and lack of attention to detail was found. As a result several actions were taken:

1) To address the issue of attention to detail we have added Regulatory as an additional approval signatures for many of the manufacturing documents (route cards and inspection instructions), assuring any regulatory commitments are addressed.

2) We specifically trained employees in the importance of following procedures and emphasized why they were important as part of our regulatory commitments. It was also emphasized that if there is a discrepancy between any of the documentation they were working to, they must stop work and notify their management for appropriate action.

3) We have taken disciplinary action with employees as appropriate for not following procedures up to and including termination.

B.1

1) The Material Review Board (MRB) that reviews and signs off the NCRs is aware of the requirement to document the rationale for a Use As Is disposition and the QC supervisor at the time was typically very diligent in assuring this was done. The examples found were most likely due to oversight or to lack of attention to detail at that specific time.

2) To improve the compliance to this procedure, the need for this documented basis was emphasized with relevant personnel and the reviewers/signatories on the NCRs are now diligent to assure the NCR is not signed off until this is completed.

3) To prevent recurrence, the MRBs are now run by the QA Supervisor, giving more management attention and discipline to the process.

4) Completed February 2008.

B.2

1) This occurred due to some personnel not following the procedure.

2) Disciplinary action was taken against personnel that did not follow procedures.

3) All personnel retrained in the requirements for adhering to procedures and identifying any discrepancies.

4) Retraining completed in Nov 2007.

B.3

See response to B.2.

NRC Finding

C. 10 CFR 71.133, "Corrective Action," states, in part, "The licensee shall establish measures to assure that conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected."

Contrary to this requirement, QSA failed to initiate prompt action to correct a discrepancy between descriptive drawing referenced in the CoC and fabrication drawing, identified on NCR No. 143900, dated 10 September 2007.

QSA Response

1) During the audit the inspectors noted a discrepancy in the shield weight for the 880 Type B package, during a review of NCR 143900. The descriptive drawing listed the weight as maximum 34 pounds and shields had been accepted up to 34.36 pounds . The long standing interpretation by QSA and codified in QC inspection procedure (WI-Q-1813) was that standard rounding could be used and the weights were rounded down to 34 pounds therefore meeting the requirements of the drawing. A discussion with NRC license review staff determined that their interpretation was that "maximum" was a hard maximum and no rounding could be applied. QSA did initiate prompt corrective action, once it was aware that the NRC considered that the shield weights were specified differently on the descriptive than on the production drawings as identified during the audit.

Background

In March 2002, drawing 88001 for the shield was changed to Rev E where the shield weight tolerance was changed and was listed as 33.8 ± 0.5 pounds to deliberately put it in compliance with the descriptive drawing (ERF 197- attached). The descriptive drawing in place at the time was Rev C and described a weight on sheet 1 as 34 pounds for the shield and the individual shield drawing, sheet 5 indicated a maximum weight of 34 pounds. This ERF was signed off and approved by Engineering, Regulatory and Quality Control based on the understanding that the standard practice of rounding would take place when the shields were weighed. The production drawing would allow for a weight of 34.3 pounds being acceptable and using rounding would meet the descriptive drawing limit of 34 pounds as 34.3 would be rounded to 34 pounds.

In Jun 2002, WI-Q1813 was revised to clearly describe and document the methods used by QC to record measurements. This allowed for rounding of the recorded value to the same number of significant digits as the number of the significant digits specified on the drawing.

The number on the descriptive drawing was listed as a whole number with two significant digits. Normal rounding techniques allows for rounding up or down to the same number of significant digits. This is supported in ASTM E 29-06b (ref 1) and Australian standard AS2706-2003 (ref 2). The SAR (Section 1.2) lists the shield weight as approximately 34 pounds.

As the shields were weighed and measured in accordance with WI Q-1813 and the weight on the descriptive drawing allowed 34 pounds, shields that weighed more than 34.3 but were no greater than 34.44 pounds were reviewed under non-conformance reports and were be rounded down to 34 pounds IAW WI Q-1813 and accepted.

With these two factors, we felt we were in full compliance with the weight requirement on the descriptive drawing and did not make attempts to revise the descriptive even when additional amendment requests went in for other changes on the 880 after Mar 2002.

During the NRC QA audit in Dec 2007, it was noted that NRC considers a maximum weight to be absolute, ie no rounding in accordance with standard industry practices. As QSA did not believe it was out of compliance at the time the NCR was written (10 Sep 2007), there was no effort made to initiate corrective action. Once the NRC interpretation was made known to QSA, QSA took immediate corrective action by submitting an amendment to the drawing to clarify the intent of the "maximum" weight.

Ref 1: ASTM E29-06b "Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specification"

Ref 2: AS 2706-2003 "Numerical Values – rounding and interpretation of limiting values"

2) The immediate corrective action was to amend the descriptive drawings, this was completed by 19 Dec 2007. The amended NRC certificate of compliance was received on 6 Jun 08.

3) In addition, all other Type B packages were reviewed to determine if there were any similar interpretations in the use of maximum and determined that no other packages were affected. The QC procedure WW-Q-1813 was revised to specifically address the use of "maximum" and minimum" values when listed on a drawing.

4) Action completed 19 Dec 07.

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Mr. Jim Pearson
Transportation and Storage Safety Inspector
US Nuclear Regulatory Commission
Mail Stop 6003 3 D-02M
Washington DC 20555-0001

18 December 2007

Dear Mr. Pearson:

We are currently reviewing our methods for commercial grade dedication for robustness of the program based on your team's comments during the audit last week. Based on some of the questions you raised on SCR 154, we have specifically reviewed the commercial grade dedication process we used on SCR154 (which secures the locking assembly of the 880 Type B package) and confirm that the screws used on all the current 880's meet the quality requirements and are safe for continued use.

History

The SCR154 was originally designated a Class "B" item based on an engineering assessment completed in 2000 when the 880 was initially designed. This assessment assumed that all four screws would have to fail to create a safety hazard. To retain confinement of the radioactive source only one screw needs to be present. The four test units that were used during the Type B package testing utilized Class "B" commercially available screws and did not have any material analysis testing performed on them. These successfully passed all required Type B testing.

During a recent investigation into a complaint from a customer that the screw had some visual defects in the head of the screw, we re-assessed the safety class of the bolt using NUREG/CR-6407 guidance. At this point (May 2007) we conservatively made the bolt a Class "A" part based on the possibility that all four bolts might simultaneously fail and required that a chemical analysis be performed to assure it met the specification for 18-8 stainless steel. As a detailed risk analysis of the possibility of all four bolts failing simultaneously was not done at this time, we defaulted to the recommendation given in NUREG CR-6407.

We are currently reviewing the quality classification on SCR 154 to assure it is appropriate.

Supplier Information

We have received these screws from Fasteners and Metals since Jan 05 and have not rejected any lots. Prior to that, they were obtained from another supplier also without rejecting any lots. Fasteners and Metals has provided a Certificate of Compliance for these parts once the Quality Class was changed from "B" to "A", which includes their lot number. They have confirmed that their lot number is one heat number from the manufacturer and that they do not mix parts from different heat numbers in the bins at their facility. . Upon receipt in Burlington, the lot from Fasteners and Metals was assigned an internal lot number by QC and therefore material traceability has been maintained for this lot of screws. Based on this, we are confident that lot identity has been maintained throughout the process and that the lots we have received are not mixed lots with different heats. As the screws are now labeled as Class "A" the lot identity and traceability is maintained throughout the processing in accordance with standard procedures at QSA Global.

We have received 4 lots from Fasteners and Metals since the Quality class was changed, each one of these lots was then sent to Luvak, a Quality Class "A" test house. All four lots were chemically tested against the required material specification (MAT 076) and were found acceptable prior to putting the lots into production. Each of these material analysis tests were performed on one bolt from the individual lot.

Using one sample from the lot (all screws from same heat) demonstrates that based on the Chemical analysis, all screws in the lot also meet the material requirements. This is supported by the EPRI document, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process", TR-017218-R1, Final Report, January 1999.

Inspection/Manufacturing Information

Upon receipt, the bolts are physically inspected against an approved AQL and then sent for material testing as described above. Once fully accepted they go into stock and are re-issued as part of a work order to build 880s. The assembly department builds the packages and torques the bolts as required to 110 ± 5 inch pounds. This torque value is approximately 75-80% of the screw minimum yield strength. We have never had a screw fail during the manufacturing and/or torquing process. There have been no unusual problems with the installation of the screws during the manufacturing process.

Likelihood of Failure of 880 Fasteners Due to a Defect

In the specific case in question the fasteners secure the rear plate assembly to the 880 body. This assembly retains the source in the device, and is credited for both conditions of normal use and accident conditions. The consequences of failure are the source leaving the shielded position and exposing personnel. For this to occur all four fasteners would have to fail at the same time.

Engineering has indicated only one fastener is necessary to prevent loss of control of the source. Let us assume we need two fasteners to provide insurance against a common mode failure. The component supplier has an excellent track record at 95 + acceptance at incoming inspection. Let us assume we receive a lot of 3000 fasteners with 10% defects to be conservative.

If we assume the 300 defects are distributed randomly in the lot the probability of acceptance of the lot and the probability of more than two defects in any one assembly can be calculated, and therefore the risk of a field failure.

Since the sample size for inspection and the quantity per assembly are small the binomial distribution is used to determine the probabilities.

Formula: $P(r,n) = n! / r! (n-r)! \times p^r \times q^{(n-r)}$ where: n = number of trials
p = percent defects in lot
n = 4 trials
r = no. of defectives in n trials
q = 1-p

	Lot Percent Defective				
r	Lot 5%	Lot 10%	Lot 15%	Lot 20%	Lot 25%
0	0.8145	0.6561	0.5220	0.4096	0.3164
1	0.1715	0.2916	0.3685	0.4096	0.4219
2	0.0135	0.0486	0.0975	0.1536	0.2109
3	0.0005	0.0036	0.0115	0.0256	0.0469
4	0.0000	0.0001	0.0005	0.0016	0.0039
Sum	1.0000	1.0000	1.0000	1.0000	1.0000

At a lot percent defective level of 10% the probability that exactly four fasteners selected at random from the lot would be defective is 0.0001, or 0.01%. At a lot percent defective of 25% (1 in four) the probability is 0.0039, or 0.39%.

The performance history of the supplier is much better than 10%; therefore, the likelihood of an assembly with more than two defectives is remote.

Field Use History

The model 880 serves as both a radiography exposure device (ISO 3999 and ANSI N432) and a Type B transport package subsequently it is designed and manufactured to withstand severe environmental conditions and physical abuse. The 880 has been in use for almost 7 years with approximately 3400 in the field. Several of these have been inadvertently dropped from heights as high as 60 feet, with no significant damage. There have been no reports of a failure of SCR 154 in the operational history of the 880.

Conclusion

With all of these facts, we believe that SCR 154 meets all the material and quality specifications necessary to ensure continued field use of the 880s will remain safe, posing no significant safety hazard to users or transporters of these packages.

I hope this answers some of the questions your audit team had during the audit last week. We will continue to work on this and the other issues identified last week. Please let me know if you would like any additional information, you can contact me at 781-505-8210. Thank you.

Sincerely,

Cathleen Roughan
Director, Regulatory Affairs and Quality Assurance

QSA GLOBAL

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Mr. Jim Pearson
Transportation and Storage Safety Inspector
US Nuclear Regulatory Commission
Mail Stop 6003 3 D-02M
Washington DC 20555-0001

15 February 2008

Dear Mr. Pearson:

This letter is providing additional information to our letter dated 18 Dec 2007 and formally documents discussions in our recent conference calls.

As a result of the NRC QA inspection of our Type B program, several issues were raised that required further investigation. We have been comprehensively addressing these issues in order to continue to assure we have a thorough and robust QA program for the manufacture of Type B packages.

Commercial Grade Dedication

Although the QSA procedures did address the process of commercial grade dedication, the NRC inspectors questioned the robustness of the process.

QSA performed a review of their existing procedures and the available EPRI and NRC guidance on commercial grade dedication and has drafted a stand alone commercial grade dedication procedure incorporating applicable EPRI guidance. This is currently being implemented using the SCR 154 as a test case and has a completion date of 29 Feb 08.

The Part 21 evaluation for SCR 154 is included as Technical Report no 114. Thisconcludes that the screws used on the 880's meet the required technical requirements and are safe for continued use.

We also identified four additional Class A items that go into a Type B package and that were commercially procured. We have assessed to determine impact on quality and the appropriate safety classification. In all four cases the safety class of the items was re-assessed as a "B" based on guidance in NUREG CR 6407.

Discrepancies in the 680 overpack

We had identified some discrepancies between the descriptive drawings and the production drawings and had entered this issue into our corrective action system. Although the discrepancies were minor in nature and had no safety significance, the manufacture of the 680 overpack was suspended until the necessary amendment could be made to the Type B certificate. We also learned from NRC license reviewers during the inspection, that their interpretation was that even non-safety critical parts should be listed on the descriptive drawing. We had not always included non critical parts on the drawing as they could change without affecting the package but if described on the drawing it would require an amendment. We completed our investigation on 25 Jan 08 and are currently finalizing the action plan to implement corrective actions.

Two of the key actions include:

1) A detailed review of all the manufacturing documentation was performed for the 680-OP package, and an amendment to the Type B certificate was prepared and sent into NRC on 11 Jan 08. This amendment request included clarification on some of the weld symbols and included non safety critical items that had not been on the drawings previously. All the changes requested were administrative in nature and did not have any safety significance. Action complete

2) A detailed review of all the documentation to manufacture the remaining Type B packages including production drawings, descriptive drawings, route cards and inspection instructions is being undertaken to find and correct any potential discrepancies. At this time we have not found any discrepancies that are of concern. This action will be complete 30 Apr 08.

Shield weight of the 880

During the audit the inspectors noted a discrepancy in the shield weight for the 880 Type B package. The descriptive drawing listed the weight as maximum 34 pounds and shields had been accepted up to 34.36 pounds . The long standing interpretation by QSA and codified in QC inspection procedure (WI-Q-1813) was that standard rounding could be used and the weights were rounded down to 34 pounds therefore meeting the requirements of the drawing. In addition, the SAR for the 880 indicates a shield weight of "approximately" 34 pounds. A discussion with NRC license review staff determined that their interpretation was that "maximum" was a hard maximum and no rounding could be applied.

QSA submitted an amendment to the drawing to clarify the intent of the "maximum" weight. In addition, all other Type B packages were reviewed to determine if there were any similar interpretations in the use of maximum and determined that no other packages were affected. Action completed 19 Dec 07.

Compatibility of materials

The use of Never Seez lubricant on SCR 154 (the screw used on the endplates of the model 880 package) was not indicated on the drawing for the 880 although it was being used. There was no documented assessment of the compatibility of the Never Seez and the SCR 154 or 880, although the Never Seez being used was specifically made for the stainless steel. Personnel had been made aware of its requirement for use during on the job training and had been appropriately applying it to SCR 154 since the original design.

An assessment on it compatibility has been documented in Technical Basis Document 110, and the drawing for the 880 now indicates the use of Never Seez and a secondary optional lubricant..

Adherence to procedures

The NRC inspectors found a few instances where it appeared the procedures had not been completely adhered to, specifically there were a couple of examples of NCRs (non conformance reports) that did not have a documented basis for a "use as is" as required by procedure. The need for this documented basis was emphasized with relevant personnel and the reviewers/signatories on the NCRs will be diligent to assure the NCR is not signed off until this is completed.

During an internal audit conducted by QSA in 2007, a similar observation concerning procedures and lack of attention to detail was found. As a result several actions were taken:

1) To address the issue of attention to detail we have added Regulatory as an additional approval signatures for many of the manufacturing documents (route cards and inspection instructions), assuring any regulatory commitments are addressed.

2) We specifically trained employees in the importance of following procedures and emphasized why they were important as part of our regulatory commitments. It was also emphasized that if there is a discrepancy between any of the documentation they were working to, they must stop work and notify their management for appropriate action.

3) We have taken disciplinary action as appropriate for not following procedures up to and including termination.

We greatly appreciate the opportunity to provide our actions to date and are working aggressively to complete any necessary corrective actions. We are committed to keeping our Quality Assurance program in full compliance with 10 CFR Part 71 and in making continuous improvements.

Sincerely,

Cathleen Roughan
Director, Regulatory Affairs/Quality Assurance

Lawrence Swift
President

QSA GLOBAL

Technical Report No. 114

QSA GLOBAL, Inc.
Regulatory Department
Technical Report

Title: 10 CFR Part 21 Evaluation for SCR 154 in the model 880

Prepared by: Cathleen Rongone Date: 15 Feb 08

Checked by: [signature] Date: 15 Feb 08

Engineering Approval: [signature] Date: 15 Feb 08

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1.0 Purpose

The purpose of the technical report is to perform a 10 CFR Part 21 evaluation to assess if there a substantial safety hazard with the use of SCR 154 as a Class B part being commercially procured. It also addresses the impact of the commercial grade dedication process that was used on the commercially procured screw when it was re-classified as a Class A part.

2.0 Evaluation

History

The SCR154 was originally designated a Class "B" item based on an engineering assessment completed in 2000 when the 880 was initially designed. This assessment assumed that all four screws would have to fail to create a safety hazard. To retain confinement of the radioactive source only one screw needs to be present. The four test units that were used during the Type B package testing utilized Class "B" commercially available screws and did not have any material analysis testing performed on them. These successfully passed all required Type B testing.

During a recent investigation into a complaint from an internal service technician that the screw had some visual defects in the head of the screw, we re-assessed the safety class of the bolt using NUREG/CR-6407 guidance. At this point (May 2007) we conservatively made the bolt a Class "A" part based on the possibility that all four bolts might simultaneously fail and required that a chemical analysis be performed to assure it met the specification for 18-8 stainless steel. As a detailed risk analysis of the possibility of all four bolts failing simultaneously was not done at this time, we defaulted to the recommendation given in NUREG CR-6407.

The engineering evaluation on safety classification is given in Technical Basis Document number 110.

Supplier Information

We have received these screws from Fasteners and Metals Products Corp. since Jan 05 and have not rejected any lots. Prior to that, they were obtained from another supplier also without rejecting any lots. Fasteners and Metals Products Corp, have confirmed that their lot number is one heat number from the manufacturer and that they do not mix parts from different heat numbers in the bins at their facility. We performed a QA audit on Fasteners and Metals Product Corp. on 26 Dec 2007 which confirmed they maintained excellent heat number and lot control traceability. Based on this, we are confident that lot identity from the supplier has been maintained throughout the process and that the lots we have received are not mixed lots with different heats. Upon receipt in Burlington, the lot from Fasteners and Metals Product Corp. was assigned an internal lot number by QC and therefore material traceability has been maintained for this lot of screws. As the screws are now labeled as Class "A" the lot identity and traceability is maintained throughout the processing in accordance with standard procedures at QSA Global.

We have received 4 lots from Fasteners and Metals since the Quality class was changed, each one of these lots was then sent to Luvak, a Quality Class "A" test house. All four lots were chemically tested against the required material specification for 18-8 steel and were found acceptable prior to putting the lots into production. Each of these material analysis tests were performed on one bolt from the individual lot.

Using one sample from the lot (all screws from same heat) provides reasonable assurance that based on the Chemical analysis, all screws in the lot also meet the material requirements. This is supported by the EPRI document, "Guideline for Sampling in the Commercial-Grade Item Acceptance Process", TR-017218-R1, Final Report, January 1999.

Additional samples of SCR 154 (in accordance with the draft commercial grade dedication procedures) were sent in for chemical analysis and met all required material specifications for 18-8 stainless steel.

Inspection/Manufacturing Information

Upon receipt, the bolts are physically inspected against an approved AQL and then sent for material testing as described above. Once fully accepted they go into stock and are re-issued as part of a work order to build 880s. The assembly department builds the packages and torques the bolts as required to 110 ± 5 inch pounds. This torque value is approximately 75-80% of the screw minimum yield strength. We have never had a screw fail during the manufacturing and/or torquing process. There have been no unusual problems with the installation of the screws during the manufacturing process.

Likelihood of Failure of 880 Fasteners Due to a Defect

In the specific application in question the fasteners secure the rear plate assembly to the 880 body. This assembly retains the source in the device, and is credited for both conditions of normal use and accident conditions. The consequences of failure are the source leaving the shielded position and exposing personnel. For this to occur all four fasteners would have to fail at the same time.

Engineering has indicated only one fastener is necessary to prevent loss of control of the source. Let us assume we need two fasteners to provide insurance against a common mode failure. The component supplier has an excellent track record at 95 + acceptance at incoming inspection. Let us assume we receive a lot of 3000 fasteners with 10% defects to be conservative.

If we assume the 300 defects are distributed randomly in the lot the probability of acceptance of the lot and the probability of more than two defects in any one assembly can be calculated, and therefore the risk of a field failure.

Since the sample size for inspection and the quantity per assembly are small the binomial distribution is used to determine the probabilities.

Formula: $P(r,n) = n! / r!\,(n-r)! \times p^r \times q^{(n-r)}$ where: n = number of trials
p = percent defects in lot
n = 4 trials
r = no. of defectives in n trials
q = 1-p

	Lot Percent Defective				
r	Lot 5%	Lot 10%	Lot 15%	Lot 20%	Lot 25%
0	0.8145	0.6561	0.5220	0.4096	0.3164
1	0.1715	0.2916	0.3685	0.4096	0.4219
2	0.0135	0.0486	0.0975	0.1536	0.2109
3	0.0005	0.0036	0.0115	0.0256	0.0469
4	0.0000	0.0001	0.0005	0.0016	0.0039
Sum	1.0000	1.0000	1.0000	1.0000	1.0000

At a lot percent defective level of 10% the probability that exactly four fasteners selected at random from the lot would be defective is 0.0001, or 0.01%. At a lot percent defective of 25% (1 in four) the probability is 0.0039, or 0.39%.

The performance history of the supplier is much better than 10%; therefore, the likelihood of an assembly with more than two defectives is remote.

Test Data

Using the results from the hypothetical accident condition tests for the 880 as described in Technical Report No. 110 and below, it is clear that the 880 will withstand a 30 foot drop even if all the screws fail.

In a hypothetical accident condition, the screws are severely stressed. The testing performed under Test Plan #108 show the screws with thread lubricant applied and tightened to 110+/-5 inch-pounds met the hypothetical accident requirements for Type B transport. In fact, the test results show the body of the projector also provides additional insurance to prevent the rear plate assembly from detaching from the projector body.

The additional insurance comes from the fact that both the front and rear plate assemblies are recessed within the ends of the projector body. The thin wall body allows deformation to occur at the point of impact. The body deformation absorbs impact energy and provides a retaining feature to aid in securing the front and rear plate assemblies in the event impact damage causes the attachment screws to fail. The recessed location of the rear plate assembly prevents the assembly from shifting beyond the outside diameter of the welded body. The thin edges of the body will crimp over and retain the rear plate assembly should damage occur. This can be seen in the results of Type B transport testing under test plan #108.

The Model 880 projector was tested for compliance to Type B transport requirements under plan #108. Two of the 4 test units, TP108B and TP108G, were dropped in an orientation to attack the rear plate lock and its attachment screws. Test unit TP108G was tested with the plastic jacket while test unit TP108B was tested without the jacket.

All security screws remained completely intact on test unit TP108G (with jacket) after the test sequence. Three of the 4 screws remained in tact on TP108B (without jacket) after the same test sequence. A radiograph of the damage to TP108B revealed a thread fracture of the upper right screw. The other 3 screws appeared only slightly bent. The difference in results between the two test units is due to the impact energy absorption properties of the jacket.

Field Use History

The model 880 serves as both a radiography exposure device (ISO 3999 and ANSI N432) and a Type B transport package, subsequently it is designed and manufactured to withstand severe environmental conditions and physical abuse. The 880 has been in use for almost 7 years with approximately 3400 in the field. Several of these have been inadvertently dropped from heights as high as 60 feet, with no significant damage. These devices are routinely serviced and maintained, which requires removal and inspection of the screws There have been no reports of a failure of SCR 154 in the operational history of the 880.

3.0 Conclusion

With all of these facts, we conclude that SCR 154 meets all the material and quality specifications necessary to ensure continued field use of the 880s and will remain safe,

posing no safety hazard to users or transporters of these packages. As this evaluation concludes there is no substantial safety hazard, this is not 10 CFR Part 21 reportable.