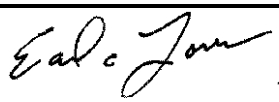
INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	QSA Global Inc. 30 & 40 North Avenue Burlington, Massachusetts 01803
Licensee/Certificate Holder contact and phone number	Michael Fuller Director, Regulatory Affairs/Quality Assurance Phone: 1-888-272-2242
Docket No.	071-00040
Inspection Report No.	071-00040/2019-201
Inspection Dates(s)	October 22-24, 2019
Inspection Location(s)	Burlington, MA
Inspectors	Earl Love, Team Leader, Senior Transportation and Storage Safety Inspector Marlone Davis, Senior Transportation & Storage Safety Inspector Jon Woodfield, Transportation and Storage Safety Inspector
Summary of Findings and Actions	On October 22-24, 2019, the U.S. Nuclear Regulatory Commission (NRC) performed an announced inspection of QSA Global, Inc.. The purpose of the inspection was to assess QSA's compliance with 10 CFR Parts 21 and 71, and to verify that the radioactive material packages for which QSA is the holder of the Certificate of Compliance (CoC), can be verified to comply with Part 71 in design, procurement, fabrication, repair, maintenance, and use requirements, as applicable. Based on the results of this inspection. The NRC determined that a Severity Level IV Violation of NRC requirements occurred. The violation is cited in NRC Form 591S as a non-cited violation (NCV) and the circumstances surrounding it is described in detail in the inspector notes. Except for the NCV, the inspection team determined that the inspection was satisfactory in that activities were adequately being performed and that QSA's implementation of its NRC approved Quality Assurance Program (QAP) was adequate.
Lead Inspector Signature/Date	 12/03/2019
Inspector Notes Approval Branch Chief Signature/Date	Margie Kotzalas Via email 12/03/2019

Inspection Background

QSA was granted an NRC 10 CFR Part 71 Quality Assurance (QA) Program Approval as a prerequisite to its using Type B radioactive material packages. As of October 2019, NRC had QSA registered as the CoC holder of the following radioactive material packages:

Part 71 Model	Package ID#	Certificate	Revision	Expiration Date
702	USA/6613/B(U)-96	6613	20	02/28/2023
741-OP	USA/9027/B(U)-96	9027	22	10/31/2020
680-OP	USA/9035/B(U)-96	9035	23	10/31/2020
865	USA/9187/B(U)-96	9187	12	3/31/20204
650L	USA/9269/B(U)-96	9269	10	1/30/2020
880 Series	USA/9296/B(U)-96	9296	11	6/30/2021
976 Series	USA/9314/B(U)-96	9314	10	7/31/2024
SENTRY	USA/9357/B(U)-96	9357	6	7/31/2021
360	USA/9371/B(U)-96	9371	3	8/31/2023

Inspection History

On December 9-11, 2014, the NRC conducted its last programmatic inspection at QSA offices. The team identified a violation during its review of design controls. The team noted QSA has no procedure addressing the control of analytical computer programs used in packaging design development. QSA has no specific computer software verification procedure and documented process to evaluate error reports it receives from the vendors of the software QSA utilizes. QSA has no procedure process to document which technical reports/calculations utilized specific versions of an analytical software program to ensure evaluation of vendor error reports for possible affects that have safety implications on prior results. QSA wrote Condition Report 1764 to capture and address this issue in their corrective action program.

On September 9, 2009, the NRC conducted a programmatic inspection at QSA offices in Burlington, Massachusetts. The purpose of the inspection was to assess QSA's response to Notice of Violations (NOVs) identified during 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 to determine if these activities were being performed in compliance with the requirements of 10 CFR Parts 21 and 71, applicable CoCs, Safety Analysis Report Packagings (SARPs), and QSA's NRC approved Quality Assurance Program.

The team reviewed all corrective actions resulting from the NOVs issued at the end of the last NRC inspections in December 2007 and May 2008. No concerns were identified by the inspection team in the review of QSA's corrective actions addressing the six examples of findings cited in the NOVs. No additional significant adverse findings were noted and no cited or non-cited violations were identified during this inspection. The 591S inspection report form with attached inspector notes can be found in NRC's Agencywide Documents Access and Management System [ADAMS] Accession No. ML092820268.

On December 10-14, 2007, and on May 6, 2008, the NRC conducted a team inspection at QSA's facility in Burlington, MA. The team assessed that QSA had experienced a decrease in QA program implementation effectiveness since the previous NRC inspections in 2003 and 2004. Based on the results of the inspection, the NRC determined that three Severity Level IV

violations of NRC requirements occurred. The first violation was against regulatory requirement 10 CFR 71.107, Package Design Control. QSA failed to: a) initiate prompt action to correct a discrepancy between descriptive drawings referenced in the CoC and fabrication drawings; b) evaluate the safety significance of lubricant as well as material suitability and acceptance criteria at the time of receipt inspection and prior to use on safety related equipment; and c) define critical inspection characteristics and appropriate sampling method for a category A component at the time of receipt inspection and prior to use on safety related equipment. The second violation was against regulatory requirement 10 CFR 71.111, Instructions, procedures & drawings. QSA failed to: a) process Nonconformance Reports according to requirements set forth in the quality procedure; b) process Engineering Request Forms according to requirements set forth in the work instructions; and c) manufacture and assemble Transport Boxes in accordance with the latest configuration of the design and production drawings. The third violation was against regulatory requirement 10 CFR 71.133, Corrective action. QSA failed to initiate prompt action to correct a discrepancy between a descriptive drawing referenced in the CoC and a fabrication drawing identified on a NCR. The NRC notification letter to QSA with the attached inspection report and NOV can be found in ADAMS Accession No ML081640461.

4.1 Management Controls

Quality Assurance Policy

The team reviewed QSA's QA Program (Docket No. 71-0040) that include activities conducted regarding transportation packagings under applicable criteria of 10 CFR Part 71, Subpart H. Specifically, the team reviewed QSM-1, "Quality System Manual," Rev. 14, effective 11/27/2018. The team verified that the QSM as written adequately addressed the eighteen Subpart H Quality Assurance (QA) criteria of 10 CFR Part 71. The team noted that Section 1.0, assigns responsibility for the maintenance of the quality system and monitoring the implementation of the quality system provisions to the Director of Regulatory Affairs/Quality Assurance (RA/QA). Under Section 1.3, "Responsibilities/Organization," Section 1.3.2, "Management Representative," the President appoints the Director RA/QA as the management representative and Section 1.3.2 states that this position is independent from production schedules and reports directly to the President. The team also interviewed QSA's Quality Manager and determined the quality assurance (QA) organization had appropriate independence from cost, schedule, and production activities. The team determined that the inspection was satisfactory in that design, fabrication and maintenance activities were adequately being performed and that QSA's implementation of its NRC-approved QAP was adequate. The team verified that this relationship was represented in the QSA organization chart as shown in WI-G-1 002, "Organizational Chart," Rev. 23, dated 2/07/2019. No concerns were identified with QSA's Quality Assurance Policy.

Nonconformance and Corrective Action Controls

The team reviewed a sample of nonconformance records and interviewed selected personnel to evaluate how QSA implemented their nonconformance control program. The team reviewed completed nonconformance reports (NCRs) to evaluate if QSA identified nonconforming items concerning materials, parts or components in accordance with applicable requirements. The inspectors reviewed nonconformance and condition reports (CRs) from the previous five years. The team focused the review on use-as-is and repair type dispositions to evaluate how QSA technically justified the NCR. The team also discussed the NCRs and CRs with the QSA staff. The team used the following quality procedures and work instructions to review the NCRs and CRs:

-QMP-2100, “Control of Nonconforming Material,” Rev. 3
-WI-Q-2101, “Control of Nonconforming Items,” Rev. 11
-QMP-2200, “Corrective and Preventive Actions,” Rev. 1
-WI-G-2201, “Issue and Condition Management Process,” Rev. 18

The team assessed that QSA effectively implemented its nonconformance control and corrective and preventive action programs. The team also noted that QSA have adequate procedures in place to ensure compliance with the applicable regulations and approved QA Program requirements. However, the team identified in some cases that the technical justification for the use-as-is lacked a basis for acceptance as required in Section 3.2.4 of WI-Q-2101, “Control of Nonconforming Items.” The team noted this as example one of violation 10 CFR 71.111, "Instructions, procedures and drawings," which states, in part, that the certificate holder shall prescribe activities affecting quality by documented procedures of a type appropriate to the circumstances and shall require that these procedures be followed. QSA acknowledged the issue of concern and documented this issue in their corrective and preventive action program as CR number 2295, dated October 24, 2019 for resolution.

Corrective Actions Taken to Address the 2014 Inspection Violation of 10 CFR 71.111, "Instructions, Procedures, and Drawings"

During the 2014 inspection it was determined that QSA did not have prescriptive procedures for vendor supplied engineering analysis software verification testing, vendor error report tracking, and documentation of vendor error report evaluations on previously performed technical reports/calculations that utilized the version of the software with any reported errors. This was a violation of 10 CFR 71.111, "Instructions, procedures, and drawings." At the time of the 2014 inspection QSA wrote Condition Report CR-1764 to capture and address this issue in their corrective action program.

The team reviewed the corrective actions taken by QSA in CR-1764, which was closed. The main corrective action taken was to create work instruction procedure WI-R-1212, “Review for 3rd Party Software Used to Demonstrate Type B Package Compliance,” which at the time of the 2019 inspection was at revision 2. The team reviewed the procedure and the documentation of which transportation packagings utilized third party analysis calculations for their qualification with the software name and version recorded. The team also reviewed forms F-R-1212-1 and F-R-1212-2 which were created to evaluate and document third party software and the possible effects of software vendor error reports on previously performed computer calculations. The team determined that QSA currently has adequate procedures and a program in place to initially qualify third party analyses software, document the software and version used to analyze individual QSA transportation packagings, and document the evaluation of third party software error reports for any possible effects on previously performed calculations which utilized that software. The team determined the violation from the 2014 QSA inspection is now closed with adequate corrective actions taken by QSA to correct the QAP deficiencies.

Part 21 Requirements

The team reviewed the Part 21 work instruction WI-R-3129, “Part 21 Reporting,” Revision 5, to evaluate if provisions were in place for evaluating deviations that could cause a substantial safety hazard and if the required notification would be completed in a timely manner. The inspectors requested a list of Part 21 evaluations and notifications associated with any of the transportation packages and interviewed personnel to verify if they were familiar with the

implementing procedure WI-R-3129. The team also reviewed QSA posting of Part 21 requirements in accordance with the 10 CFR 21.6, “Posting requirements”.

The team assessed that QSA has provisions in place for evaluating deviations and reporting defects, as required by 10 CFR Part 21. The team noted that QSA did not have any Part 21 reports within the last five years.

Documentation Controls

The team reviewed sections of QSM-1 Rev. 14, the QSA Quality Assurance Program Description, Quality Management Procedures (QMPs), Work Instructions (WIs), and Specification Sheets (SPS), specifically related to document control and quality records. The team specifically reviewed the following documents/procedures associated with document control and quality records:

-QSM-1, “Quality System Manual,” Rev. 14
-QMP-1300, “Control of Quality Documents,” Rev. 8
-QMP-2400, “Control of Quality Records,” Rev. 4
-WI-Q-1301, “Document Control Maintenance,” Rev. 14
-WI-E-1302, “Product Drawings,” Rev. 5
-WI-E-1303, “Descriptive Drawings,” Rev. 3
-WI-E-1305, “Prototype Drawings,” Rev. 2
-WI-I-1310, “Control of Electronic Documents,” Rev. 1
-WI-M-2401, “Records Processing,” Rev. 4
-SPS-E-1200-1, “ERF Approval Matrix,” Rev. 8
-SPS-Q-1301-4, “Document Approval Matrix,” Rev. 5
-SPS-QMP-2400-1, “Document & Records Retention,” Rev. 7
-SPS-QMP-2400-2, “Off-site Records Storage Requirements,” Rev. 1
-SPS-QMP-2400-3, “Records Media Storage & Protection Methods,” Rev. 3

QSA has separate document controls for its quality procedures/instructions, its engineering drawings/design documents, its material group procurement and fabrication quality records, and its regulatory affairs documents. Therefore, the QSA Quality Assurance Department functions as document control for procedures/instructions but does not actually control any of the final engineering design documents developed in accordance with the design/engineering procedures it does control. Similarly, although responsible for the procedures, the QSA QA department does not control any of the quality documents produced by the materials group or regulatory affairs. The procedure/instruction QA document control group controls new and revisions to engineering design procedures, procurement procedures, fabrication procedures, and regulatory procedures but does not control their products such as drawings, SARPs, calculations, project plans, design basis, test plans, test reports, purchase orders, receipt inspections, fabrication routing cards, etc.

The document control of design/engineering documents is performed by the QSA design engineering department. The QSA QA department, design/engineering department, materials department, and regulatory affairs document control departments are all electronic, eliminating the need for paper copies of documents if a computer screen is available. However, the QA document control does maintain one controlled hardcopy of quality procedures/instructions. The one controlled copy is identified by red lettering on each page stating controlled copy. All other printed hardcopies of documents are considered uncontrolled.

The quality procedures, engineering documents, materials documents, and regulatory affairs documents are user-controlled systems where the user of an electronic copy must verify the latest revision to that document from the electronic master list. Users of the electronic system do have the ability to print hardcopies of procedures and engineering, materials, and regulatory affairs documents. However, all printed copies are considered uncontrolled. Therefore, it is extremely important for the user of a printed hardcopy to continuously check the electronic master document list for current revisions.

Historically, QSA required hand written signatures on all its quality documents for initiator, reviewer(s), and approver(s), but is currently in the process of migrating to an electronic signature system with signature password controls in place.

SPS-Q-1301-4 and SPS-E-1200-1 are matrix documents that the team reviewed. The matrixes show the required signature levels to initially issue or revise a QA procedure/instruction or design/engineering document, respectively.

The final issuing of procedures is by an issuing authority. All new and revised procedures go through the initiation, review, and approval signature process and then are sent to the issuing authority. The issuing authority is one individual that controls the master procedure electronic data base. The issuing authority individual is one of only a few QSA staff that can make changes in the electronic procedure system. The change access to the system is password protected. All other employees have read only access in the computer system.

The issuing authority individual goes through a reviewing process before adding the revised or new procedure/instruction to the electronic system and showing it current on the master electronic document list. There is an isolated remote computer backup system in place by the QSA Information Technology (IT) staff should the main master document electronic system go down or become damaged for any reason. The issuing authority notifies QSA functional managers and supervisors electronically of new and revised procedures/instructions, whom in turn inform their staff. The team interviewed the issuing authority individual and was given a demonstration of the whole electronic work flow of new and revised procedures. The team determined that adequate procedure/instruction document control management exists at QSA.

Although the procedures that describe the process flow of how engineering documents are developed, controlled, and issued are controlled by the procedures/instructions QA document control; the issuing of the actual engineering documents is performed by the engineering document control system. For engineering documents, the final issuing authority is the project engineer (aka Design Engineer at QSA) for the engineering product; such as drawings, calculations, specifications, design basis, project plans, test plans, test reports, etc. As was the case for procedures/instructions; the initiation, review, and approval of engineering documents is performed on a hardcopy with original signatures or with an electronic copy with electronic signatures as QSA transitions to all electronic signatures. The individual project/design engineers are responsible for scanning engineering documents into the engineering department's electronic document system when needed.

For engineering documents, the project/design engineer for the document is the issuing authority. After final approval, the engineering document is sent back to the project/design engineer to place the document in the controlled document data base, update the master document list, and supersede/void any previous revisions. As was the case for procedures, QSA employees (other than the engineering staff) have read only access to the engineering documents. It is the project/design engineer's responsibility to notify other employees

electronically of a new or revised engineering document. This process is explained in the design engineering procedures and instructions. The team determined for the engineering product document control system and, just like the procedure document control system, there is a remote isolated computer backup system in place should the main engineering document electronic system go down or become damaged for any reason.

The team determined that the materials department and regulatory affairs departments control their documents very similar to the engineering department.

Quality manufacturing records, such as original hand signed routing cards, are not currently scanned electronically. The quality records developed by the fabrication shop are accumulated until turned over to the materials department to be sent for off-site storage. QSA uses a third-party storage company to store these quality records that is on their Approved Supplier List and meets the requirements of SPS-QMP-2400-2. QSA is taking a business risk for not being able to use/sell the products manufactured during the document accumulation period should anything happen to the quality records prior to being sent to permanent off-site storage.

The team determined that adequate document control and records management exists at QSA. Overall, no concerns were identified by the team in the QSA documentation control or quality records areas.

Audit Program

The team reviewed selected audits and interviewed personnel to verify that QSA effectively implemented an audit program in accordance with 10 CFR part 71 requirements. The inspectors assess whether QSA scheduled and performed internal QA audits in accordance with approved procedures or checklists to all applicable eighteen criteria identified in Subpart H of 10 CFR Part 71. The team reviewed WI-Q-2501, "Internal Audits," Rev. 10, dated 9/11/2018. The team selected a sample of internal audits issued in FY2019 to determine if QSA identified and assigned appropriate corrective actions for negative findings. Additionally, the team assessed the quality and depth of the audits. The team noted that QSA performed adequate internal audits. Overall, the team concluded that the reviewed internal audit reports were satisfactory in meeting Part 71 requirements.

The team reviewed the following internal audit reports:
1-19-001, Procurement of Materials & Services, dated 8/23/2019
Internal Audit Assessment specific to ISO 9001:2015, dated 9/11-12/2019

4.2 Design Control

Design Development

The team reviewed the QSA procedures specifically related to design development/control and modification activities and held discussions with QSA design, engineering analysis, and licensing staff. The team focused its review on QSA design activities related to revision 9 to the SARP and revision 10 of CoC 9314 for the 976 series Part 71 transportation packaging.

The team reviewed the design control section of the QSA Quality Assurance Program Description, QSM-1 Rev. 14, and specifically reviewed the following QSA procedures/work instructions associated with design control to verify they are being properly implemented:

-QMP-1200, “Design Control,” Rev. 5
-QMP-3000, “Project Management,” Rev. 3
-WI-E-1200, “Engineering Request Form (ERF) Process Overview,” Rev. 0
-WI-E-1201, “Technical Reports,” Rev. 4
-WI-E-1202, “Design Development Plans,” Rev. 2
-WI-E-1203, “Quality Classification,” Rev. 1
-WI-E-1204, “Design History Files,” Rev. 2
-WI-E-1205, “Design Reviews,” Rev. 4
-WI-E-1207, “Engineering Request Form (ERF) Submittal Process,” Rev. 1
-WI-E-1208, “Engineering ERF Processing,” Rev. 2
-WI-E-1211, “New Product Development Process,” Rev. 2
-WI-E-1302, “Product Drawings,” Rev. 5
-WI-E-1303, “Descriptive Drawings,” Rev. 3
-WI-E-1305, “Prototype Drawings,” Rev. 2
-WI-Q-1307, “Quality Assurance Review of Documents,” Rev. 2
-WI-G-3001, “Classification & Project Management Process Flow,” Rev. 1
-WI-R-3141, “Regulatory Processing of ERF’s and Regulatory Holds,” Rev. 6

QSA’s system for the initiation, review, and approval of design documents is based on hard copy or electronic reviews with design documents receiving hand written or electronic signatures. QSA is trying to move to all electronic signatures on its design documents in the future.

The team reviewed the design development for a modification to the model 976 (CoC 9314) packaging as that was the only significant engineering work performed on the packagings for which QSA is the CoC holder with the NRC since the 2014 inspection. The team interviewed the QSA 976 design engineer and reviewed the list below of design documents associated with the modification. By procedure, QSA creates and maintains an individual Design History File for all QSA designed products. The 976 design engineer demonstrated to the team on the QSA computer system the electronic filing and folder structure of the 976 Design History File. Although the following documents were provided in hard copy to the team, the 976 design engineer demonstrated how they could be easily retrieved from the 976 Design History File.

- Engineering Request Form (ERF) 3659 to modify the Model 976 clamp band and to have quality classifications and product development drawings performed.
- The prototype drawings developed for the 976 with the new clamp band.
- The physical drop test plan development for the new 976 prototype.
- The drop test results report for the prototype 976.
- The quality classifications performed for the 976 components.
- The 976 product development drawings.
- The new or revised descriptive drawings for inclusion into the 976 SARP.
- The changes to sections of the 976 SARP affected by the modification.

The team found all the above design documents to be developed, processed, reviewed, and approved in accordance with all applicable QSA procedures. In all cases, the required proper forms per procedure were utilized. The 976 packaging was physically tested for compliance with Part 71 regulations so there were no new QSA Technical Reports (calculations) associated with the modified design. The team also reviewed the routing cards (travelers) associated with the fabrication of the test prototype and found all the steps signed off by the craft and QC.

The team reviewed the training records for the QSA design engineer with the least experience with QSA. The team found the training records to be quite extensive and indicated that the individual was current on all the latest QSA procedures with no concerns.

The team assessed that overall, QSA was effectively implementing its design control procedures currently in place. The team found that prototype/design/licensing/fabrication drawings, test plans, test reports, quality classifications, SARP changes, routing cards, and ERFs were developed and processed in accordance with the applicable procedures and received the proper independent verification reviews and approvals. No concerns were identified by the team in the design control area.

10 CFR 71.95 Reports

After the last QSA inspection in 2014, QSA sent the NRC individual 71.95 reports for several of its transportation packagings addressing the fact that as-built packagings did not agree with the licensing drawings provided in the various SARPs and listed on the associated CoCs. The team sampled reviewed three corrective action reports associated with three of the 71.95s submitted. CR-1902 addressed the Model 880 Series (CoC 9296) as-built issues, CR-1916 addressed the Sentry Series (CoC 9357) as-built issues, and CR-1924 addressed the 865 Series (CoC 9187) as-built issues. In general, the corrective actions for all three packaging models were to submit to the NRC an amendment for each to revise the licensing (QSA descriptive) drawings and/or revise the fabrication (QSA production) drawings. The NRC approved all three CoC/SARP amendments by issuing a separate Safety Evaluation Report (SER) for each. The team determined that the corrective actions taken by QSA to address the licensing/as-built drawing issues were adequate for all three models.

The team also reviewed the two most recent 71.95 reports submitted to the NRC by QSA and the associated single CAR. On August 8, 2018, QSA submitted two separate 71.95 reports to the NRC, one for the Model 702 packaging (CoC 6613) and one for the Model 976 Series packaging (CoC 9314). Since the two different packagings had the same hardware material issues, only CR-2161 was written. The issue was that the licensing drawings and fabrication drawings did not both call out on their materials list the requirement for various hardware parts to meet the requirements of ASME B18. As discussed above, the corrective actions were again to submit to the NRC an amendment to revise the licensing drawings and/or revise the fabrication drawings for each model. The NRC approved the CoC/SARP amendments by issuing a SER in both cases. The team also determined for these two 71.95 reports the CR-2161 corrective actions taken by QSA to address the licensing/fabrication drawing issues were adequate.

Modifications

The team reviewed the only modification since the last inspection as discussed above. The team reviewed all the forms and procedures associated with the QSA Engineering Request Form process. The team verified that through the ERF process, a QSA regulatory review will be performed to determine if NRC approval is required prior to implementing a proposed change to or deviation from a Part 71 packaging SARP. An amendment was submitted to the NRC for the 976 clamp band modification and it receive NRC approval by SER. The use of the new clamp band is currently a 976 model production option.

4.3 Fabrication Controls

Material Procurement

The team reviewed QSA work instructions associated with the procurement, commercial grade dedication, and receipt inspection of materials of various packages to verify if they are being properly implemented:

Q-1401, “Supplier Evaluation,” Rev. 8
M-1402, “Purchase Order Processing,” Rev. 16
M-1404, “Supplier Management,” Rev. 8
M-1406, “Procurement of Quality Related Services,” Rev. 3
G-1410, “Use of Commercial Grade Items and Services in Safety Related Applications,” Rev. 3

The team reviewed selected drawings, procurement documents and records associated with only Important to Safety (ITS) Category A material. The team verified that procurement specifications, commercial grade dedication plan and material chemical analyses met the design and applicable quality procedure requirements. The team reviewed the QSA’s commercial grade dedication of stainless-steel weld filler material ER308L. QSA’s dedication identified the material as the critical characteristic, which was found to be appropriate and in accordance with the applicable industry standard, American Welding Society (AWS) A 5.9. The Dedication Plan also identified the required material chemical characteristics of the weld filler material, which was verified by independent chemical analysis to be in accordance with AWS A5.9, QSA drawing WEL007, Rev. D, “Welding Wire Stainless Steel,” and G-1410, Rev. 3. The team then reviewed a sampling of material chemical analyses performed by Luvak Inc., who was verified to be on QSA’s Approved Suppliers List (ASL). However, the team noted Luvak’s approval was solely based on the International Laboratory Accreditation Cooperative (ILAC) Mutual Recognition Arrangement (MRA) accreditation process for material testing services. The team noted this as example two of violation 10 CFR 71.111, "Instructions, procedures and drawings," which states, in part, that the certificate holder shall prescribe activities affecting quality by documented procedures of a type appropriate to the circumstances and shall require that these procedures be followed. Contrary to this QSA adopted the ILAC MRA accreditation process for calibration and material testing services in lieu of performing a commercial-grade survey without meeting the requisite elements of NRC Regulatory Issues Summary 2016-01. The team noted the same applies for calibration services. QSA acknowledged the issue of concern and documented this issue in their corrective and preventive action program as CR number 2295, dated October 24, 2019 for resolution.

In addition to weld wire, the team reviewed QSA’s procurement of compression springs classified as ITS-A. The team noted that the material was procured as commercial grade as a dedicated item consistent with G-1410, Rev 3. However, the team noted that QSA’s purchase order to the commercial supplier invoked the springs as subject to 10CFR Part 21 as well as the suppliers QA program as audited and accepted by QSA. Contrary to this the springs were procured as commercial grade and therefore were not subject to the above conditions in part because it was QSA’s intent to complete the commercial grade dedication process. The team noted this as example three of violation of 10 CFR 71.111, "Instructions, procedures and drawings," which states, in part, that the certificate holder shall prescribe activities affecting quality by documented procedures of a type appropriate to the circumstances and shall require that these procedures be followed. Contrary to this, QSA’s procurement process for commercial-grade dedication lacked elements necessary to support dedication. QSA acknowledged the issue of concern and documented this issue in their corrective and preventive action program as CR number 2295, dated October 24, 2019 for resolution.

The team reviewed a sample of component purchase orders procured as ITS-A (e.g., shields, lock slide, and rear plate), as well as, a sampling of material chemical analyses performed by QSA. The team noted that procurement documents included purchase requisitions, purchase orders, drawings/specifications used to define requirements for purchase. The team noted that the vendors were listed on QSA's ASL as qualified suppliers of ITS-A components. In addition, the team noted ITS-A categorizations and the identification of QA criteria (i.e., 10CFR 71, Subpart H; ASME Code; 10CFR21) appropriate to the procurement and applicable vendor QA program as approved by QSA. The team assessed QSA's external audits and noted that audit reports and checklists primarily assessed vendor QA commercial programs (e.g., ISO) not specific to 10CFR 71 nor applicability to 10CFR 21. The team noted this as example three of violation 10 CFR 71.111, "Instructions, procedures and drawings," which states, in part, that the certificate holder shall prescribe activities affecting quality by documented procedures of a type appropriate to the circumstances and shall require that these procedures be followed. Contrary to this QSA's approved supplier process for ITS-A components lacked elements necessary to indicate supplier commitment to 10 CFR 71, Subpart H and 10 CFR 21, as applicable. QSA acknowledged the issue of concern and documented this issue in their corrective and preventive action program as CR number 2295, dated October 24, 2019 for resolution.

Fabrication, Assembly, Inspection and Test Controls

The team reviewed the Welding Procedure Specifications (WPS) and Welder Logs used in production welding of Model Nos. SENTRY 330, 360 and 880DELTA transportation subassembly packages. The team reviewed fabrication and inspection forms (including shielding profiles), as well as, material storage controls to verify that all phases of the fabrication, inspection and storage processes were properly controlled and implemented. Observations included a sample review of route cards, weld logs and inspection records to verify that fabrication and test activities were accomplished and appropriately documented according to controlled drawings, work instructions and quality procedures. QSA's implementation of fabrication and test controls including welding and examinations and material storage was assessed to be adequate.

The team interviewed QSA personnel to determine their familiarity with specified design, fabrication techniques, testing requirements, and quality controls. Familiarity with the required subject areas was adequate based on responses from the personnel interviewed and on the quality of the work performed and as witnessed by the team during the inspection. The team reviewed the certifications of the QSA non-destructive examination personnel and verified that they were qualified and certified. In addition, the team reviewed qualification and certification records of welders. For observed fabrication activities, the team determined that QSA personnel were trained, certified, or qualified to perform those fabrication activities based upon review of each individual's training records and certifications. The team noted that all the documents were found to be adequate.

Tools and Equipment

The team reviewed the control of measuring and test equipment (M&TE) procedure to evaluate how QSA identified, specified, and controlled tools and equipment in accordance with applicable standards and regulatory requirements. Specifically, the team reviewed QMP-1900, "Control of Measuring and Test Equipment," Revision 4 and WI-Q-1901, Measuring, Test & Key Process Equipment Control, Revision 9. The team selected a sample of the M&TE used during the fabrication and annual maintenance of the 880 series projectors and the Sentry 330. The

sample included a review of fabrication routers and maintenance procedures that identified one hanging scale (QSA-354), torque wrenches, a welder (LJ410713L), and digital caliper (05358267). The team also reviewed the calibration reports to verify calibration dates, testing standards, and traceability of the associated M&TE.

Overall, the team assessed that QSA established controls of M&TE in accordance with standards and regulatory requirements. The team verified that personnel used M&TE within their rated capacities and sensitivities as documented in the certification package documentation. The team found the M&TE program to be adequate with no concerns.

4.4 Maintenance Controls

The team reviewed selected records and interviewed personnel to verify that QSA effectively implemented a maintenance control program in accordance with their NRC approved QA Program, CoC conditions, and the requirements of 10 CFR Part 71 for the transportation of radioactive material. The team performed a review on maintenance activities related to selected QSA Type (B) transportation packages for a period of five years for the 880 Series (CoC 9296), and the Model Sentry Numbers 110 and 330 (CoC 9357). The team evaluated annual maintenance activities conducted at QSA. The evaluation included a review of maintenance requirements identified in the Safety Analysis Report (SAR) and CoC, inspection and maintenance procedures, specification sheets, completed maintenance records, and personnel and qualification training records.

The team reviewed the following quality and maintenance implementing procedures and specification sheets:

QMP, “Inspection and Testing” Rev. 3
WI-L-1715, “Leak Testing of Sealed Sources and Equipment,” Rev. 2
SPS-P-2701-9, “Maintenance of 880 series projectors,” Rev. 1
SPS-L1717-535 “Models Sentry 110 & Sentry 330,” Rev. 2

Based on a review of the maintenance records and procedures specifications the team assessed that QSA used appropriate maintenance materials, tools and equipment to conduct the annual maintenance activities for the model number 880 Series, and the Model Sentry 110 and 330 transport packages. The team verified that the inspections were comprehensive and met acceptance criteria for tests identified in the maintenance records and procedure specifications. The team assessed and verified the results of the visual weld inspection and leak testing of the sealed sources. The team also verified that maintenance personnel and technicians recorded the proper information on the applicable forms and data sheets as defined and required in the QSA quality and maintenance procedures. The team assessed that the maintenance tests satisfied the requirements identified in the 880 series and Sentry SARs and CoCs.