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 |
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| REVISS Services Inc.<br>1 Hawthorn Place<br>175 E. Hawthorn Parkway Suite 142<br>Vernon Hills, IL 60061<br><br>REPORT NUMBER(S) 71-0930/05-201 | US Nuclear Regulatory Commission<br>Spent Fuel Project Office<br>11555 Rockville Pike<br>Rockville, MD 20852-2738 |

| 3. LICENSEE/CERTIFICATE NUMBER(S) | 4. INSPECTION LOCATION | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 71-0930 | Chesham, England | 09/19 - 23/2005 |

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 or 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 violations or nonconformances were identified.

☐ 2. Previous violation(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 Action(s):

☐ 4. During this inspection certain of your activities, as described below and/or attached, were in violation or nonconformance of NRC requirements and are being cited. This form is a NOTICE OF VIOLATION OR NONCONFORMANCE, which may be subject to posting in accordance with 10 CFR 19.11.

(Violations, Nonconformances, and Corrective Actions)

* US mailing address; REVISS Services (UK) Limited was the inspected entity.

## 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 is made in accordance with the requirements of 10 CFR 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 | DAVID A. COPPELL | | 23/9/2005 |
| NRC INSPECTOR | Robert R. Temps | | 23-09-05 |

## INSPECTOR NOTES COVER SHEET

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| Licensee/Certificate Holder (name and address) | REVISS Services (UK) Ltd<br>c/o 1 Hawthorn Place<br>175 E. Hawthorn Parkway Suite 142<br>Vernon Hills, IL 60061 (US Mailing address) |
| Licensee/Certificate Holder contact and phone number | John Schrader<br>847-680-4522 (US contact) |
| Docket No. | 71-0930 |
| Inspection Report No. | 2005-201 |
| Inspection Date(s) | September 19 - 23, 2005 |
| Inspection Location(s) | REVISS Services (UK) Ltd office in Chesham, England |
| Inspectors | Robert Temps James Pearson Andrew Barto |
| Summary of Findings and Actions | This inspection involved a first time review of REVISS Services (UK) Ltd (REVISS) QA Program implementation at their office in Chesham, England and at their package maintenance facility at the Harwell facility. Inspection activities focused on management controls, design activities, fabrication controls, and maintenance controls, and how these activities are being controlled under the REVISS QA implementing procedures.<br><br>The team assessed that, overall, REVISS was implementing their NRC approved Part 71 QA program in an acceptable manner. The team did identify some areas where the REVISS QA program procedures need enhancement or changes to fully reflect some requirements of Part 71.<br><br>With respect to the packagings that REVISS has fabricated to date, and for which REVISS plans to seek an NRC Certificate of Compliance (CoC), the team reviewed fabrication records and noted that the fabrication process was quite detailed and well documented. Overall, the team concluded that the packagings were fabricated to quality standards equivalent to Part 71 requirements.<br><br>The attached inspector notes document several observations with regard to REVISS QA activities. Had these activities been performed on packagings with an NRC CoC, the observations would have been listed as violations for not meeting the requirements of 10 CFR Part 71, Subpart H. |
| Lead Inspector Signature/Date | Robert R. Temps 4 October, 2005 |
| Inspector Notes Approval Section Chief Signature/Date | Robert J. Lewis 5 October 2005 |

INSPECTOR NOTES: IP 86001WAS USED IN CONJUNCTION WITH APPLICABLE PARTS OF NUREG/CR 6314. INSPECTION RESULTS USING THE NUREG/CR 6314 NUMBERING FORMAT ARE DOCUMENTED BELOW:

**INSPECTION BACKGROUND:**

On March 8, 2005, REVISS Services (UK) Limited (REVISS) was granted an NRC 10 CFR Part 71 Quality Assurance (QA) Program Approval in association with their plans to submit a Type B radioactive material packaging design for which it will seek an NRC Certificate of Compliance (CoC). Consistent with the Spent Fuel Project Office Master Inspection Plan, REVISS, as a new QA program holder, was scheduled for an inspection in order to assess implementation of their NRC-approved QA program with respect to QA program management, packaging design, fabrication, and maintenance activities. Further, as packagings have already been fabricated by REVISS to the design as approved by the British Department for Transport (DfT) under United Kingdom (UK) Competent Authority approval GB/3750A/B(U)-96 [and have been currently authorized for import/export use, under U.S. Department of Transportation approval USA/0591/B(U)-96], the inspection included physical inspection of the 3750A packagings to determine equivalency of their as-built configurations to 10 CFR Part 71 QA requirements, particularly in the areas of fabrication and procurement controls.

An invitation to observe the inspection was offered to, and accepted by, Chris Pecover of the Radioactive Materials Transport Division of the British DfT.

**INSPECTION FINDINGS AND OBSERVATIONS**

4.1.1 Quality Assurance Policy

At the inspection entrance meeting, the REVISS Quality and Regulatory Manager briefly described the sections of the REVISS Quality Manual to help familiarize the NRC inspection team with the Quality Manual.

The team reviewed the draft REVISS Organizational Chart and discussed the organization with the REVISS Quality and Regulatory Manager. The team determined that the independence shown on the chart was clear and acceptable for the size of the REVISS organization. The REVISS Quality and Regulatory Manager described the Chart layout and provided names of the employees filling the upper level positions and many of the mid-level positions. The quality policy of REVISS, provided within their QA Manual as Section 3, clearly describes the quality objectives of the REVISS organization and is also clear in identifying that both safety and quality are the responsibility of all employees.

The team reviewed samples of REVISS Management Meeting Minutes against the requirements established for management oversight as provided in REVISS procedure SP110, issue 6, "Management Review and Performance Measures." It was noted that the management meetings have a prepared agenda as well as briefs on newly initiated Corrective Action Requests (CARs). The following meeting minutes, involving the review of different aspects of REVISS activities, were reviewed and assessed to be acceptable:

- Minutes for the July 26, 2005, meeting that included a review of "QA Policy," CAR status, quality auditing, staff training, and resources and continuous improvement initiatives.

- Minutes for the February 11, 2004, meeting that included a review of corrective and preventative actions that included a review of CARs (new and closed since last meeting), staff training, and resources and quality auditing.

4.1.2 Nonconformance Controls

The team reviewed procedure SP107, issue 7, "Corrective and Preventive Action," the problem identification and corrective action program guidance document used by REVISS. Discussions were held with QA personnel, and the team also reviewed selected CAR forms. REVISS' resolution of the issues documented in the various CARs was assessed to be appropriate to the nature and extent of the documented problems. No significant concerns were identified in this area. The team did identify, however, that guidance to CAR evaluators when signing the block for consideration of regulatory implications could be enhanced. In particular, the team noted that there is currently no guidance for REVISS staff on what this signoff means with respect to NRC regulatory requirements, such as 10 CFR Part 21 and 10 CFR 71.95 reporting requirements. REVISS management acknowledged the team's comment and stated they would review this, and other comments related to REVISS QA procedure enhancements, for incorporation into forthcoming guidance on various 10 CFR Part 71 requirements.

4.1.3 Documentation Controls

The team reviewed the REVISS QA procedures related to documentation controls, and interviewed personnel responsible for carrying out the related procedures. The team reviewed the following applicable procedures:

- SP101, "Document, Data, and Drawing Control"
- SP111, "Control of Quality Records"
- QS101, "Guidelines for Procedure Preparation"
- QS112, "Controlled Document List"
- QS116, "Controlled File Log"
- QS122, "Change Control Form"
- QS111, "Acknowledgment of Receipt/Withdrawal of Controlled Documents"

The team discussed these procedures with a REVISS Quality Representative who described and demonstrated how the above forms and procedures are used to control origination, storage, issuance, revision, and review of controlled documents, data, and drawings.

Overall, the team assessed that REVISS' documentation controls were adequate in addressing the applicable requirements of 10 CFR 71, Subpart H. The team had one comment related to form QS111; while the form provides space for personnel receiving controlled documents at various REVISS sites to indicate that they have reviewed the listed documents, it does not provide for identification of which personnel reviewed each document. In one example cited by the team, the form required nine personnel to review a document list, but it only provided seven

check-boxes to indicate that each document had been reviewed. REVISS personnel agreed to revise the form to more clearly indicate which personnel had reviewed which document.

As noted on the cover page, the term "observation" as used in this report means a non-conforming condition or activity that had it concerned packagings with an NRC CoC, the observation would have been a violation of the applicable requirement in 10 CFR Part 71. Observations have been listed in these inspector notes so that REVISS can take appropriate actions for these non-conformances consistent with their QA Program requirements.

The team identified an observation related to documentation control. While reviewing samples of form QS122, "Change Control Form," the team identified a form whose format differed from that of the officially controlled hardcopy. Further inspection identified several other instances where the incorrectly formatted form had been used. REVISS personnel suspected that an individual had incorrectly modified the previous issue of the form template and then repeatedly used the wrong form in documenting changes to controlled documents. REVISS generated a CAR to document this issue and indicated to the team that they would retrain staff as to the location of the official and most up-to-date versions of controlled forms, and would modify their computer system to prevent inadvertent use of incorrect form versions. The team assessed these initial corrective actions to be appropriate.

4.1.4 Audit Program

The team reviewed Internal and External Audit samples from REVISS Records Management files. The team also reviewed the 2005 audit schedules for internal and external audits. The schedules indicated that nine suppliers were listed on the external audit schedule. Eight audit dates had been identified and a total of thirteen audits were expected to be performed, with some of the suppliers being audited multiple times in 2005.

The team reviewed the Internal Audit of the Operations Group at Harwell, dated May 5, 2005, and verified that the auditor's qualification to perform the audit was acceptable. The scope of the Operations Group audit covered container management, storage and preservation, calibration, training, and quality records.

The team reviewed the external audit records of two suppliers. REVISS auditor qualifications were determined to be acceptable. The team noted that while the audits were acceptable and met REVISS procedural requirements, the level of detail was minimal. The team discussed with REVISS management the fact that including more detail in audit reports provides for a more informative audit and provides a better planning tool for future audits.

The team reviewed REVISS procedure SP108, "Auditing," which invokes procedure SP400, "Supplier Control," for the actual performance of supplier audits. The team noted that both procedures provided little detail about audit planning and that they rely more on the auditor's experience, which in REVISS's case, has provided for acceptable completion of the audit process. The team identified this as an area that REVISS should consider for procedure enhancement.

The team also reviewed the REVISS Approved Suppliers Listing (ASL). The team reviewed the supplier records for suppliers of health physics services, material suppliers for spare parts and

components, and a sample of suppliers identified in the completed fabrication records that were reviewed. During this review the team identified that one supplier's audit record was missing from the records management manuals. The supplier had provided stainless steel materials for the fabricated 3750A packagings. REVISS Services was unable to locate the record before the end of the inspection and issued a CAR to address this issue. The team noted that the quality of the materials supplied was not in question and that the missing audit file was a records control issue.

With respect to procedural controls in the above areas, the team noted that consistent procedural guidance was lacking for determinations regarding the generation of quality-related records and their retention periods. Enhancement of procedures, particularly with respect to 10 CFR Part 71 quality records retention requirements, was discussed with REVISS management for their consideration.

With respect to employee training and records, the team reviewed applicable portions of the REVISS Quality Manual and noted that it provides for the training and development of all REVISS staff. The team reviewed selected portions of procedure SP109, "Training," issue 6, and QS109, "REVISS Services Training Form." The team discussed the current application of a systematic approach to training (SAT) process that is being applied by REVISS to their training programs. The job and task analysis portion of the SAT process, completed for personnel at the REVISS Harwell facility, was discussed with the team by the Harwell Operations Manager and Harwell Site Manager during the team's visit to that facility. REVISS indicated to the team that they plan to apply the SAT process to activities at the Chesham office as well. The team considered this to be a noteworthy effort by REVISS management due to the extensive time and effort required to develop an SAT based approach to employee training.

The REVISS Harwell Site Operations Manager described the performance by REVISS personnel of the annual appraisal of training needs as identified in SP109. The procedure requires a documented evaluation to determine training needs through the use of Form QS109. The team noted that this form also captures qualification and experience already possessed by the employee under evaluation. The team noted the implementation of this evaluation in the review of selected training documents for the following REVISS positions: (personnel filling the last two positions were also determined by the team to be acceptably qualified auditors)

- Operation Technician
- Transport and Safety Manager
- Installations Team Leader
- Operations Engineer
- Operations and Quality Manager
- Quality & Regulatory Manager
- Quality & Technical Engineer

4.2.2 Modifications (Design Changes)

The team reviewed REVISS' QA procedures related to design development and modification, and interviewed personnel responsible for carrying out such procedures. The team reviewed the following procedures in this area:

- SP200, "Design Control and Management"
- QS226, "Design Requirements Specification Record"
- QS201, "Design Brief Form"
- QS217, "Design Review Record"

The team discussed the procedures with a REVISS Quality Representative who demonstrated how the above forms and procedures are used to control design initiation and modification activities.

Overall, the team assessed that REVISS' procedures related to design development and modification were adequate in addressing related requirements of 10 CFR 71, Subpart H. The team had one comment, however, related to procedure SP200, in that the procedure does not address the determination of whether or not a design initiation or modification requires regulatory approval. While the related form, QS226, provides an area for the determination of compliance with various regulations (such as DfT, U.S. NRC or DOT) it does not specify what criteria of the proposed design should trigger a regulatory review. The team identified this as an area needing procedure enhancement and REVISS management indicated that they would consider revising procedure SP200 to include detailed guidance for determination of when a regulatory review is required.

The team also reviewed the licensing drawings referenced in the UK Competent Authority approval for the GB/3750A transportation packaging, and took several sample measurements of actual packagings located at the REVISS Harwell facility. The team verified that the physical dimensions of the package complied with the dimensions given in the appropriate licensing drawings. No concerns were identified.

4.3 Fabrication Controls

The team reviewed the fabrication records for two groups of previously fabricated 3750A packagings, the package design for which REVISS plans to submit a CoC application to the NRC. Fabrication records for units 2 through 7 and 17 through 22 were reviewed. The packagings were fabricated for REVISS at the Mayak facility located in Russia. The team noted that the documentation records were quite extensive as were the controls for the various fabrication processes. Detailed documentation of the following activities were included in the records:

- Quality Plans for special processes
- Concession forms associated with CARs for fabrication nonconformances
- Identification of customer (REVISS) hold and witness points
- Weld control documents including radiograph records
- Weld approval (inspection) documents
- Protocols for weld inspection approval
- Records of visual and dimensional control
- Records of various tests such as those for radiation shielding effectiveness, leakage testing, temperature testing, and excess pressure testing
- Lists of materials used including chemical analyses for certain materials
- Material and component certificates

The team noted that REVISS performed independent and redundant analyses of all metal products procured by Mayak for use in the package fabrication. Overall, the team concluded that the packagings were fabricated to quality standards equivalent to 10 CFR 71, Subpart H, requirements.

The team reviewed REVISS' controls for providers of services and materials. The team reviewed REVISS procedure SP400, "Supplier Control and Development," and the associated forms. The team questioned the REVISS Quality and Technical Engineer about the process for capturing the approved suppliers as a quality record and he acceptably described the process to the team. The team also reviewed several procurement records. As noted above in Section 4.1.4, the audit record for one supplier could not be located and a CAR was initiated for this issue by REVISS. The team also reviewed the procurement records for two contractors, one that provides health physics services at Harwell and one that performs welding and non-destructive examination services. The team verified that both contractors were listed on the REVISS Approved Suppliers Listing as an approved supplier of these types of service. No additional concerns were identified.

The team toured the REVISS bonded store area where spare/new parts and raw materials are kept. The team determined that materials stored in the area were appropriately secured, identified by labeling, and maintained for use. The team noted the area included a locked materials segregation area as well as a locked quarantine area. While touring the bonded store area, the team randomly picked a sample of materials currently in storage and reviewed their associated receipt inspection report records. All but one of the records reviewed were determined to be acceptable.

An observation was noted with regard to one inspection report reviewed, in that the associated Form QR407 was incomplete. Specifically, the maintenance and test equipment identity, used to measure the material inspected, was not included on the form as required by OP404, "Inspection Procedure for Non-Radioactive Goods." REVISS identified this issue on a CAR for resolution. The team noted that a recent internal audit noted a recommendation to review records for adequacy. The Quality and Technical Engineer explained that implementation of the audit's corrective action had not yet occurred due to the audit recent completion.

4.4.1 Maintenance Activities

The team reviewed REVISS' QA procedures related to package maintenance controls, and interviewed personnel responsible for carrying out such procedures. The team reviewed the following procedures:

- OP306, "Transport Container Maintenance Procedure"
- OP316, "Operating Instructions R7008 Transport Container (GB 3750A)"
- QR325, "3300A & 3750A Container Maintenance Checklist"

The team also interviewed the Harwell site Operations Technician in charge of 3750A package and turnaround maintenance. The Operations Technician demonstrated how the above forms and procedures are used to control package turnaround and annual maintenance activities. The team also observed the maintenance documentation process at the Harwell facility and sample reviewed several maintenance documents. One particular maintenance record noted

an irregularity in the closure head of the package that had caused the Operations Technician to quarantine the package for further examination. The team noted that this irregularity was documented in a CAR as required by procedure.

The team identified an observation with respect to the use of independent verification, including use of hold and witness points, as required by 10 CFR 71.121, "Internal inspection," when performing certain internal (to REVISS) inspection activities. Specifically, when reviewing package maintenance records, the team noted that there were no provisions for hold and witness points for independent verification of quality activities. The team discussed this observation with REVISS management and noted that REVISS already provides for the identification of hold and witness points for external processes, such as the fabrication controls noted for the 3750A package. The team stressed that REVISS will need to have internal controls in place at such time as the 3750A package CoC application is sent to the NRC.

4.4.2 Tools and Equipment

The team reviewed REVISS procedure SP114, "Control of Inspection, Measuring, and Test Equipment," and related calibration records for various tools and equipment at the REVISS Harwell facility. The team also interviewed the Harwell Site Operations Manager, who provided documentation related to equipment calibration.

All tools and equipment inspected by the team were found to have their identification number, calibration date, and calibration due date clearly identified. Calibration Record Cards, as well as test certificates where appropriate, were provided by REVISS personnel for each piece of equipment inspected by the team. REVISS personnel also provided a listing of the calibration status for each category of equipment identified in procedure SP114 (e.g., torque wrenches, vacuum gauges). The list provided the identification number, make and model, calibration date, and calibration due date for every piece of equipment in use at the Harwell facility.

Overall, the team assessed that REVISS' controls on tools and equipment were adequate in addressing the applicable requirements of 10 CFR 71, Subpart H. No significant concerns were identified.