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 (UK) Ltd<br>6 Chiltern Court, Asheridge Road<br>Chesham, Buckinghamshire, England HP52PX<br><br>REPORT NUMBER(S) : 71-0930/2008-201 | Division of Spent Fuel Storage and Transportation<br>U. S. NRC<br>M/S EBB-3D-02M<br>Washington, DC 20555-0001 |

| 3. LICENSEE/CERETIFICATE NUMBER(S) | 4. INSPECTION LOCATION | 5. DATE(S) OF INSPECTION |
|---|---|---|
| 71-0930 | Chesham, England | May 13, 2008 |

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

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

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

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

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

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

(Violations, Nonconformances, and Corrective Actions)

## STATEMENT OF CORRECTIVE ACTIONS

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

☐ Written Response requested in 30 days ☐ Yes ☐ No

| TITLE | PRINTED NAME | SIGNATURE | DATE |
|---|---|---|---|
| LICENSEE | MICHAEL NIXON | Michael Nixon | 13/5/2008 |
| NRC INSPECTOR | Robert Temps | Robert R Temps | 13/05/08 |

## INSPECTOR NOTES COVER SHEET

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| Licensee/Certificate Holder (name and address) | REVISS Services (UK) Ltd (REVISS)<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. | 2008-201 |
| Inspection Date(s) | May 13, 2008 (additional information provided June 2, 2008) |
| Inspection Location(s) | REVISS Services (UK) Ltd office in Chesham, England |
| Inspectors | Robert Temps James Pearson Earl Love |
| Summary of Findings and Actions | This inspection involved a one-day follow-up visit to review REVISS' response to issues identified during the first time inspection of REVISS' QA Program implementation at their office in Chesham, England, in September 2005.<br><br>The team assessed that, overall, REVISS had satisfactorily addressed the issues identified in the 2005 NRC inspection. One minor issue was identified for further follow-up as described in the enclosed inspector notes. |
| Lead Inspector Signature/Date | Robert R. Temps 06/13/08 |
| Inspector Notes Approval Branch Chief Signature/Date | David W. Pstrak 6/16/08 |

## INSPECTION METHODOLOGY

IP 86001 was used in conjunction with the 2005 inspection report and applicable portions of NUREG/CR 6314. Observations and comments from the 2005 inspection report (reference ML052840094) were extracted and are repeated below in italics. This is followed by a description and/or assessment, non-italicized, of the actions REVISS took in response to the observation or comment. The NUREG/CR 6314 numbering format, as used in the 2005 inspection report, is used below for consistency. 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.

## INSPECTION BACKGROUND:

In March 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 planned to seek an NRC Certificate of Compliance (CoC). REVISS, as a new Part 71 QA program holder, was inspected in September 2005 in order to assess implementation of their NRC-approved QA program with respect to QA program management, packaging design, fabrication, and maintenance activities. Overall, the inspection results were satisfactory, although several observations and findings were identified. The May 13, 2008, inspection was a one day follow-up inspection to assess REVISS' actions in addressing the 2005 inspection issues, and to determine REVISS' plans to modify its NRC-approved QA Program to address REVISS' plans to submit a different packaging design for certification by the NRC than the one originally described in their initial QA Program description submittal.

An invitation to observe the inspection was offered to, and accepted by, Ian Barlow of the Radioactive Materials Transport Division of the British Department for Transport (DfT).

## INSPECTION FINDINGS AND OBSERVATIONS

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.*

The team determined that REVISS had not enhanced applicable procedures to address the above comment. However, after further discussion about the original basis of the NRC's comment in the 2005 inspection report, REVISS personnel stated they would review the issue

once more to see if a practical guidance document could be developed to address all regulatory reporting requirements, not just NRC requirements.

4.1.3 Documentation Controls

*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.*

The team reviewed recent records documenting employee acknowledgement of receipt or withdrawal of controlled documents. The team noted that the underlying procedure requirements were followed and that the use of check-boxes and signatures made it clear as to which documents personnel had acknowledged receipt of for action. The team assessed that REVISS' action in addressing the 2005 inspection comment was satisfactory.

*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.*

The team reviewed Corrective Action Report (CAR) No. 466 that REVISS had issued to document and address the 2005 inspection observation. The CAR documented that one individual had modified the format of an uncontrolled copy of QS122 so that it no longer matched the controlled copy. The team noted that the extent of condition, as described in the CAR, revealed no other instances of inappropriate use of uncontrolled files or forms. The team noted that specific measures were taken, such as employee training and the performance of an in-depth review, including protected electronic files, of other forms for compliance to related procedures. The team assessed REVISS' actions taken to address this issue to be satisfactory.

4.1.4 Audit Program

*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' 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 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 additional detail about planning for audits and supplier evaluation's but still rely somewhat on the auditor's/evaluator's experience, which in REVISS' case, has provided for acceptable completion of the audit process.

The team reviewed the last internal audit in the quality assurance area. The team also reviewed the REVISS lead auditor qualifications and determined them to be adequate. The team noted that while the reviewed audit was adequate and met REVISS procedural requirements, and the level of detail was improved over the last NRC inspection, it was evident that the level of detail could still be further improved. The team further discussed with REVISS management the basis for including more detail in audit reports. REVISS Management agreed with the team that some of the areas discussed could be improved.

The team also reviewed the REVISS Approved Suppliers Listing specifically in regard to the contracted lead auditor who performed the audit of the REVISS Quality Assurance area. The team interviewed the REVISS Quality Assurance Manager to determine the basis for acceptance of a contracted Lead Auditor used by REVISS. The team noted that while the REVISS database, which was noted by the team as the method/system used to track suppliers, listed the contractor (Lead Auditor) as an ancillary supplier, the Quality Assurance Manager was unable to explain discrepant dates contained in the database regarding the timeframe that the contractor was approved for use. Following the recent inspection, REVISS performed an investigation, and as documented in REVISSS CAR 711, identified "personnel error" as the reason for the discrepancy noted by the team.

*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.*

The team reviewed CAR 468, issued by REVISS in 2005, and noted that the corrective action section did not describe in detail the method used to assure that the missing record was indeed the only missing record. This issue of documenting the extent of condition methodology was

discussed with REVISS management personnel who discussed amongst themselves whether additional information was available for inclusion into the CAR.

*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.*

The team noted that a procedure revision to SP111, "Control of Quality Records" had occurred and now adequately addresses storage requirements from 10 CFR Part 71.

4.2.2 Modifications (Design Changes)

*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 reviewed the current versions of SP200, as well as SP204 and OP208, and assessed that there are adequate procedural controls in effect to ensure that new design initiations or modifications to existing designs will receive an appropriate regulatory review.

4.3 Fabrication Controls

*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.*

The team reviewed CAR 467 issued by REVISS to address the observation and assessed that corrective actions were appropriate. The team reviewed a recent inspection report to verify that proper recording of measuring equipment, utilized in the performance of a dimensional inspection, was performed. The team noted the proper recording of the equipment serial number used for the inspection. The team noted that while the report listed the equipment used, it did not include the equipment calibration due dates. The team discussed with REVISS management that they should consider also recording equipment calibration dates to facilitate proper traceability of any equipment discovered to be out of tolerance, when sent for calibration, and to facilitate the evaluation that such a situation may have on previously measured components. REVISS management indicated they will standardize the recording of calibration

information as part of the inspection reports. The team considers REVISS' actions to be satisfactory.

4.4.1 Maintenance Activities

*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.*

REVISS informed the team that a CAR was not issued for the observation as it did not constitute a breach of their procedures. The team discussed with REVISS management the basis of the observation and what specifically is meant by the term "internal inspection" and when it should be applied. REVISS management stated they would review the issue again for any needed changes in procedures.