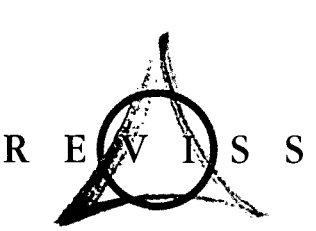

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3 June 2010

Attn: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and safeguards
US Nuclear Regulatory Commission
Washington, D.C. 20555-0001

RE: Docket Number 71-0930

Sir,

REVISS Services is resubmitting our QA program after verifying all changes were appropriately made.

In Section 4 on page 7 of 15, the references to ISO 9001-2000 was changed to ISO 9001-2008 to reflect the current issue of our ISO certification

A complete review was conducted on the document to ensure there were no additional places where the revisions were omitted.

If you need further information to support your review, please do not hesitate to let us know. Thank you.

Sincerely,

John L. Schrader
Radiation Safety Officer

NMSS01

REVISS Services UK Limited

APPLICATION TO US NUCLEAR REGULATORY COMMISSION FOR APPROVAL OF QUALITY ASSURANCE (QA) PROGRAM APPLICABLE TO DESIGN, FABRICATION, ASSEMBLY, TESTING, MAINTENANCE, REPAIR, MODIFICATION AND USE OF PACKAGING USED IN THE TRANSPORT OF RADIOACTIVE MATERIAL

Purpose and Scope

The purpose of this document is to describe the QA Program operated by REVISS Services UK Limited (REVISS) to manage all activities associated with the R7008 and R7021 package used for the transportation of ^{60}Co and ^{137}Cs radioactive materials.

The scope of this document includes those aspects of the QA Program associated with design, fabrication, assembly, testing, maintenance, repair, modification and use of this specific package. The REVISS R7008 and R7021 packages conform to the criteria for type B(U) packaging as specified in IAEA TS-R-1.

Structure

This application is structured around the eighteen clauses of the United States Code of Federal Regulations 10 Part 71, subpart H – Quality Assurance and as further described in the US Nuclear Regulatory Commission Regulatory Guide No. 7.10 rev 2.
A description is provided of how each of the eighteen criteria is implemented within REVISS to control all work done on the R7008 and R7021 packages. Detailed implementation procedures are not referenced.

Contents

1. Quality Assurance Organization

REVISS is responsible for managing all aspects of the QA program described in this document. Work is performed across three organizational elements, all reporting to the senior management team in the Company

- Quality Management
- Design Management
- Operations Management

Further detail on each of the organizational elements is as follows:

Managing Director (MD)
Responsible for:

- Approving the policies for Quality and Safety within the Company
- Ensuring the whole Company including the QA program is resourced with suitably qualified and experienced staff
- Formal appointment of managerial resources with responsibility for design, safety and quality management including QA and Quality Control (QC). This approval details the duties and qualifications associated with each role.
- Ensuring a suitably experienced and qualified Quality Manager is appointed that has the authority and organizational freedom to ensure that safety matters are not subordinate to cost and schedule at any time

Quality Manager (QM)
Responsible for:

- Ensuring the QA program addresses and is effective in controlling all activities related to the defined scope.
- Verifying implementation of the QA program through planned audits and management review
- Appointing suitably qualified and experienced staff as **Quality Representatives (Q Reps)** to act as signatory on all documentation relating to safety, e.g. specifications, purchase orders, acceptance of controlled goods into stock, non-conformity reports etc. Q Rep authorisations signify that the person is satisfied that the requirements of the REVISS QA program have been met and that the decision and associated documentation meets all known quality and regulatory requirements. Q Reps are independent from all other work that is carried out on packaging and have the organizational freedom to stop work to prevent non-conforming materials being used further.

Packaging Design Authority (PDA)
Responsible for:

- The technical accuracy and completeness of package designs. The DA also approves all specifications and approves the management of non-conforming product. Such

approvals signify that the DA is satisfied with the technical content of the decision and associated documentation.

- Defining the levels of control needed to ensure safety of packages across the scope from design to use and establishing operating and maintenance procedures
- Choosing and managing suppliers used for performing activities that fall within the scope of the QA Program and providing information so that the QRep can verify that subcontractors performing activities important to product safety and fitness for purpose have suitable quality assurance and quality control arrangements in place.
- Approving the technical content of purchase orders for containers, spares and related services
- Providing technical advice to the QRep in assessing the implementation of the defined QA program whether the work is carried out by REVISS staff or by suppliers (e.g. for fabrication, assembly and testing) or by customers (e.g. for routine use on customer's premises).

Operations Supervisor

Responsible for:

- Routine use of packages in accordance with written procedures defined by the PDA and approved by the Q Rep, including those for handling, storing, cleaning, shipping, inspection and maintenance
- Ensuring internal and external (e.g. customer) staff are trained to use and maintain the R7008 and the R7021 containers in line with approved procedures
- Maintaining tools and equipment for inspection and maintenance operations
- Maintenance of the container spares inventory

In addition, there is a general requirement on all managers to be responsible for:-

- Safety of operations,
- The quality of the work carried out by their staff.
- Ensuring that their staff are familiar with Company procedures and have ready access to them.
- Ensuring that their staff use only approved procedures, and that any necessary missing procedures are established, approved and implemented.
- Ensuring that their staff are adequately qualified, trained and experienced to perform their duties in a satisfactory manner.
- Motivating all staff to take responsibility for reporting non-conformances.

2. Quality Assurance Program

The REVISS QA Program is fully documented covering a scope that includes not only the control of the R7008 and R7021packages as described in this application, but also the design, manufacture and supply of other type B packages, sealed radiation sources and associated services. The QA Program is approved by the United Kingdom Competent Authority as well as being certified to ISO9001:2008 by a third party certification body.

Documented procedures exist covering all the work that is described in this application and changes to these are controlled as described in section 6. Similarly, evidence of the application of procedures is maintained as quality records as described in section 17.

3. Package Design Control

The PDA is responsible for the design process which includes creation, development, modification and review of the R7008 and R7021 design.

3.1 Control of the design process

The design process specifically takes into the account the following areas:

- The criticality of individual components and items with respect to safety. The categories outlined in NUREG/CR-6407 version published February 1996 are used to classify components and the results of these classification decisions are documented in the technical application. Classification of components is aligned with the REVISS method of classification described in section 7 of this application.

- The standards and requirements for document and drawing preparation and the requirements for managing changes to the documents and drawings detailed in Section 5 of this application.

3.2 Control of design input

The original design work for the R7008 was carried out by Amersham International, who had a USNRC approved QA program in place at the time. REVISS developed this design starting from that original Amersham International concept.

In taking over the design, requirements from company, user, manufacturer, quality assurance, safety and regulatory perspectives were reviewed and are documented in the design file. Verification that design outputs met design inputs and validation that the design met the requirement of the intended application were carried out based on the reviewed design inputs. Part of the step to detail design requirements included defining the stakeholders participating in the design review process and in design verification

activities such as peer review. The format of design output documentation is also planned at this stage, for example the preparation of test specifications or the operating and maintenance instructions. REVISS procedures define an internal hold point to approve the design requirements before proceeding into the detailed planning stage. Design plans explicitly detailed internal and external resources required to do the work, defined milestones for design reviews and key decisions, and the timing of verification and validation activities, regardless of the initial design work carried out by Amersham which complied with that organisation's procedures and design inputs.

A key design input is a statement detailing the required regulatory approvals.

3.3 Control of design verification and validation

A variety of design verification and validation techniques are used including reasoned argument, comparison with other similar approved designs, calculation, computer modelling, and physical testing. All such documentation is peer reviewed by suitably qualified and experienced engineers,

The test programme used to verify the adequacy of the design was in two parts as defined in detail in the technical application:

- Drop testing of a one-third scale model prototype in the most adverse design conditions
- Thermal, shielding, pressure, lifting and containment tests of the first and every subsequent container manufactured before first shipment.

The design process is not considered to be complete until the necessary regulatory approvals to use the design are in place.

4. Procurement Document Control

All purchases of goods or services are initiated with a purchase order that is prepared by the person controlling the purchase, in the case of packages the PDA.
All goods and services that can impact on safety, regulatory compliance and/or customers have purchase orders that are approved by the Q Rep as well as the budget holder. The Q Rep signatory confirms that goods/services are being ordered with reference to current versions of all applicable specifications. Identical procedures are used whether procuring parts for original fabrication or replacement parts.

Two types of specification exist for purchased items:

- Generic supply specifications - for example, requirements for quality assurance and quality control by suppliers, welding specifications or material specifications.
- Specific supply specifications for particular designs. Specifications may take the form of documented instructions, e.g. for special processes or testing and engineering drawings. Supply specifications detail all applicable "hold & witness" points in the process where a positive decision on the conformity of goods must be made. The

process for managing non-conforming goods at any stage in the process is also defined.

All specifications are uniquely identified and are approved by a DA (for packaging this is the PDA) and a Q Rep. Changes to specifications are controlled as described in section 6.

Through approval of suppliers, as described in section 7, purchasing of goods by suppliers for use on REVISS goods is controlled. Where this happens, the evidence of control of purchasing including review of all documentation is audited by REVISS.

With particular reference to the generic supply specification detailing requirements for quality assurance and quality control by suppliers, the following activities are contractually required:

- Access by REVISS staff to audit the appropriateness of processes and procedures and compliance with these on an ongoing basis
- Provision of documents with each supply to confirm all results and conformance with the suppliers QA program.

Although REVISS does not insist on a supplier having a quality program certified to ISO9001: 2008, nor assumes that a supplier having such a certification is suitable for supply of goods to REVISS this is the standard that audit of supplier processes is based upon. Accordingly, REVISS ensures that suppliers have a system that controls all of the requirements of ISO9001: 2008 and 10 CFR Part 71 including unique identification of physical items and documentation and control of the disposition of non-conforming materials.

5. Instructions, Procedures and Drawings

All instructions, procedures and drawings, collectively referred to as documents, within the REVISS QA Program are approved by at least two people; a person with responsibility for performing the work and a QRep. In addition, any document that refers in any way to the design of a particular item, or the control of a design related process is approved by a DA.

DA and QRep approval of design related documentation relating to the R7008 and R7021 ensures that:

- Documents prescribe activities important to quality and safety including all those required by Subpart H of 10 CFR Part 71,
- Documents prescribe the records that must be kept as documentary evidence that the instruction has been followed,
- Suitable hold points are established so that a positive review and approval is needed before the next stage in the process can be performed. The documented acceptance criteria and tolerances are specified so that the judgement by the QRep of whether the item conforms to requirements or not is objective

Manufacturing drawings conform to the current version of British Standard 308, Engineering Drawing Practice Parts 1, 2 and 3. Descriptive drawings, for 10 CFR Part 71 Package Approvals, conform to NUREG/CR-5502. The DA is responsible for ensuring that the manufacturing drawings remain compliant with the descriptive drawings. Both sets of drawings are listed on a controlled drawings list so the current issue of each drawing is clear.

6. Document Control

Version (configuration) control of all documentation including instructions, procedures, specifications, drawings and quality record proforma is established through a formal route so that the status of any document is clear at any time. All references to documents in instructions to third parties, for example purchase orders are issue specific. All acceptance activities at specific hold points are documented referencing issue specific documents.

Documents are authorized for use as described in Section 5. Controlled copies are then made available to users along with notification of the versions of documents that have been superseded. The process of Document Control is directly managed by the Quality Manager who maintains a master list of uniquely identified documents, their status and the relevant copy holders.

Through a process of training and through the formal notifications when documents are revised and up-issued, REVISS staff are responsible for ensuring that they are working to the current and correct version of any document. Staff are particularly encouraged to raise problems with any documentation with the Quality Manager so that the current versions of documents always reflect accurate and safe practices in enough detail to maintain control of the activity. Changes to documents are explicitly shown in the document and justified on a separate change control form. Document approvers are responsible for understanding the history and justification for document changes.

7. Control of purchased material, equipment and services

REVISS Services procures all goods and services through a controlled process.
In the first instance goods and services are assessed according to their importance for safety and quality and then categorised as either **Controlled** (important for safety and quality) or **Ancillary** (irrelevant to safety and quality). Controlled purchases are then further categorised dependent on the level of risk and degree of control required. The USNRC classification of components according to importance to safety (NUREG/CR-6407) is taken into consideration when deciding on the REVISS category of controlled goods. All container purchases are controlled goods and the categories shown below take into account the USNRC safety classification. Individual components of a sub-assembly or an assembly may be graded separately.

Category 1:
Commercially available goods, with the exception of key safety related items such as fasteners and fixings, which meet an industry, a national or an International standard and are not modified in any way to meet specific REVISS requirements.
Category 2:
Reviss designed items for which it is possible to determine compliance on the basis of post manufacture inspection/testing and supply of documentation.
Category 3:
Reviss designed items for which it is necessary to approve key aspects of the production process in advance and if necessary implement hold and/or witness points.
Services:
Products where neither material nor manufacturing process(es) are involved

All controlled goods and services must be purchased from Approved Suppliers.
The supplier approval route includes three levels of approval:

Witnessed Status – for new suppliers of Category 2 or 3 goods e.g. fabrication or container prototype testing. Every key activity performed is witnessed by either a REVISS technical authority (DA) or a quality authority (QRep)

Approved Status – for suppliers of Category 2 or 3 goods where their processes and controls have been approved by REVISS. Pre-delivery assessment is performed before goods are approved for shipment to REVISS and accepted into stock. Approved Status also applies for Category 1 goods or for controlled services.

Preferred Status – for suppliers of Category 2 or 3 goods where their processes and controls are approved by REVISS, and where they have sufficient track record of supplying conforming product that they are allowed to ship without pre-delivery assessment and where acceptance into stock is done on the basis of audit of the accompanying documentation and some physical inspection of goods as appropriate and defined by the DA.

Potential suppliers are identified by the PDA and their appropriateness to supply to REVISS is initially reviewed with a follow-up audit of QA/QC arrangements by a QRep prior to deciding on the supplier status. Supplier status reports document the current status of the supplier for a particular scope of supply, hence a single supplier may have a different status for supply of some goods than others.

REVISS performs an inspection of all components and repairs and a review of all supplier documentation, either as part of hold and witness points, pre-delivery assessment or on receipt of goods, often at all of these. Where irregularities are found, a corrective action request is raised to:

- Identify the cause(s) of the problem
- Decide how to deal with any non-conforming goods and document this on a concession form(s)
- Identify actions to prevent future recurrence

Only when the QRep is satisfied that the goods and accompanying documentation meet REVISS requirements are the goods formally accepted. This process of acceptance is controlled through a procedural route and audit records of every acceptance decision are created and retained.

8. Identification and Control of Materials, Parts and Components

Unique identification of documentation is established and maintained as described in Section 6. and issue specific control of documentation is maintained with third parties through the process for procurement document control described in Section 4.

Materials, parts and components will be traceable to the documentation to which the item has been created.

Wherever possible and practicable, items carry a physical marking of unique identification that identifies the BU certificate type and the container serial number, e.g. 3750/02. Where such a physical unique identification is not possible or practicable, then the parts are stored in the REVISS bonded store in a container (typically the original packaging) that shows the unique identification of the parts within.

No components for the R7008 or R7021 containers have a shelf life of fixed duration, however "O" rings and gaskets are stored in opaque containers to prevent UV degradation.

Records of stock-holding and the disposition of each component are maintained and goods are only released from the bonded store to operators to perform a specific activity such as container turn-round maintenance.

9. Control of Special Processes

All processes that are required to design, fabricate, assemble, test, maintain, repair and use the R7008 and R7021 packages are documented and controlled within the REVISS QA Program. If it becomes apparent that a new process is needed, the PDA will create documentation to control that new process and, following review and approval, this will become a part of the standard QA Program for use, when required, in future.

REVISS requirements for welding, heat treating and non-destructive testing are specified in a supply specification and passed on to suppliers performing such work on the purchase order.

10 and 11. Internal Inspection and Test Control

Formally approved and controlled test procedures exist for the following operations relevant to the R7008 and R7021 containers:

- Manufacturing shielding test procedure
- Manufacturing leak test procedures
- Manufacturing thermal test procedure
- R7008 and R7021 specific turn-round inspection and maintenance procedure
- R7008 and R7021 specific scheduled inspection and maintenance procedure

REVISS staff are authorised to perform inspections and maintenance of transport containers by the Operations Supervisor and records are kept to document that training has taken place. When changes are made to procedures, all operators must formally record that they are familiar with the changes and can comply with the new procedures. Problems and concerns must be highlighted to the Operations Supervisor and PDA.

In all cases, checklists are used to prompt action and record evidence of completion of all test procedures. If any inspection is unsatisfactory the container is quarantined and the details reported to the PDA with the exception of routinely replaced components, e.g.: seals and fixings. Items in quarantine may not be released until returned to compliance with the design specification. The PDA assesses each case and decides and manages what, if any, remedial work is necessary and what inspection and test criteria need be employed to verify compliance.

In all cases, test procedures outline as a minimum:

- Equipment required
- Safety and operational notes
- Description of the test
- Acceptance criteria
- Requirements to keep records

Tests that are required to be performed by subcontractors, for example as part of fabrication are specified in the relevant supply specification or manufacturing drawing as described in section 4 of this document.

12. Control of Measuring and Test Equipment

All equipment, including measuring instruments, gauges, reference standards and radiological instruments, that is used for any inspection, measuring or test activity is indelibly and uniquely identified and marked to show calibration status in one of the following ways:

- Label showing last calibration date
- Label showing "calibrate before use"

- Label stating "out of calibration, do not use"

Periodicity of calibration, next calibration due dates and required accuracy of equipment is defined depending on the equipment type.

Calibration of equipment is subcontracted to a suitably approved calibration service. In the UK this will always be a laboratory accredited by the UK Accreditation Service (UKAS).

New equipment is purchased with a suitable calibration certificate or sent for independent calibration prior to first use.

Equipment used for inspection is checked for accuracy prior to use using approved reference standards. The identity of reference standards used is recorded on the relevant inspection report. This practice ensures that inaccurate equipment is not used to disposition components or assemblies.

13. Handling, Storing and Shipping Control

Documentation is approved and controlled to provide operators with the information they need to handle, load, unload, ship and maintain the R7008 And R7021 transport containers safely and in compliance with the license conditions. Specific and general safety precautions and warnings are detailed along with instructions covering:

- Loading
- Preparation for despatch (loaded)
- Carrier information
- Receipt and unloading
- Preparation for despatch (empty)
- Turn-round inspection
- Scheduled inspection and maintenance

All documentation must be approved by the PDA who in the role of DA ensures that all operations are specified within the constraints of the design requirements. It is the responsibility of the operator carrying out an approved procedure to report all problems to the PDA who will decide what further action to take.

In addition to documentation controlling the use of the transport container itself, documentation is also approved and controlled detailing the requirements for preparing shipping papers to accompany the container.

14. Inspection, Test and Operating Status

The maintenance status of each package is shown on the maintenance plate. The turn-round maintenance procedure gives specific instructions to operators on how to prepare

the package for use to ensure its compliance with all relevant regulations. For shipments despatched by REVISS, the despatch release procedure verifies that turn-round maintenance has been completed by a trained person. For other users of the package, details of how to perform turn-round maintenance is specified in the operating and maintenance procedure.

15. Nonconforming Materials, Parts or Components

The status of entire packages or components is identified as described in section 8 of this application.

Where any part of a package has been identified as non-conforming one of the following actions is followed:

1. The part is scrapped and replaced (fixings and seals)
2. The part is quarantined, recorded on the maintenance inspection report and labelled "do not use" pending a decision by the PDA on the disposition of the part

In the case of 2 a corrective action request is raised. This is the trigger for the PDA to consider the disposition of the part, identify the cause of the non-conformance and identify corrective action to prevent recurrence.

A corrective action request may also be raised where parts need to be routinely replaced on a more frequent basis than would normally be expected. This is to enable the root cause of the potential problem to be formally investigated.

16. Corrective Action

The process for managing corrective actions within REVISS is used to manage all problems, and potential problems that may be found by any person involved in a REVISS operation. Where a third party, for example a customer, supplier or regulator notes a problem, this is also managed using the corrective action system.

In all cases, the problem is formally recorded and a person, usually the DA for containers, allocated to take responsibility for finding out the root cause(s) of the problem and finding solutions that not only manage the immediate problem, e.g. putting the problem item in quarantine until a resolution is found but also finding long term solutions to the problem that prevent a recurrence wherever possible.

As part of the correction action process, concession requests are raised as a means of prompting a decision on ongoing disposition of non-conforming items. The DA recommends and justifies the disposition of non-conforming items and this is approved by the QRep. Regulatory approval is sought where the non-conformity contravenes the requirements of the license.

Records of all correction action requests are maintained in the design file for use during design review.

Corrective actions are formally closed out by the Quality Manager when they are satisfied that actions to prevent recurrence are adequate and have been implemented.

17. Quality Assurance Records

Records are created and maintained as documentary evidence of the implementation of documented procedures.

Records can either be completed by hand in ink, or electronically but must bear at least one signature of endorsement from a suitably qualified and experienced person. Electronic records are only considered official when an approved method is used to verify that the record has been approved by an authorised person. Amendments to paper records must be initialled and dated clearly with original entries struck through but still clearly visible. Changes to electronic records must be uniquely identified by creating a new version of the record.

The organization function responsible for creating of records is also responsible for storage, preservation and safe-keeping.

Storage of quality records must be in an environment that prevents damage or deterioration. Thermal fax paper is not an acceptable media and photocopies of such records must be taken prior to storage.

All records pertaining to design, fabrication, inspection and/or maintenance are retained for a minimum of 30 years and for at least 3 years after the item is in service for the last time.

Records relating to the training and qualifications of personnel are retained for a minimum of 5 years after the employment of the person ceases.

Records relating to the quality system such as calibration records or audit reports are retained for a minimum period of 3 years.

Quality records must not be removed from their storage area, copies are taken where these are required for reference outside the approved location of storage.

18. Audits

Procedures are approved and controlled covering the planning, preparation and performance of audits to verify compliance with requirements.

Suitably qualified auditors are assigned by the Quality Manager. The auditor then defines the scope and objectives of the audit and communicates these in writing to the auditee(s). Previous audit findings in the area are reviewed as part of audit preparation and verification of the effectiveness of corrective actions taken are built into the audit plans.

Product audits are carried out to accept and release manufactured items (components or finished products) for ongoing use. No controlled item can pass into REVISS stock from a supplier, or from REVISS stock to a user or customer without being approved through product audit. This applies to transport containers for radioactive materials as well as the radioactive materials themselves.

Process and quality system audits are planned in advance depending on one or more of the following:

- The supplier status for controlled goods
- The importance of the activity to be business
- The existing compliance status, e.g. more frequent audits are planned following a recurrence of a problem

Process and quality system audits of the internal REVISS operation and of current preferred suppliers are carried once every 12 months as a minimum.

Audit findings are reported in writing and maintained as quality records as described in section 17.

Non-conformities are reported and recorded using the Corrective Action system as described in section 16.