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24 January 2012

United States Nuclear Regulatory Commission
Quality Assurance
11555 Rockville Pike
Rockville, MD 20852

Subject: **Robatel Technologies, LLC – Part 71 Quality Assurance Program Description**
Reference: Docket No. 71-0952

Please find enclosed the Robatel Technologies, LLC Part 71 Quality Assurance Program Description for your review.

Questions regarding this submittal may be directed to the following contact:

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Sincerely,

George C. Jobson

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QUALITY ASSURANCE PROGRAM DESCRIPTION 10 CFR 71 Subpart H for Packaging and Transportation of Radioactive Material

Approvals: Emily A. Mayhew Date: 01/16/2012

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QUALITY ASSURANCE PROGRAM DESCRIPTION

10 CFR 71 Subpart H

for

Packaging and Transportation of Radioactive Material

REVISIONS

Rev.	Date	Comments
0	January 15, 2012	Original Release

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0.0 INTRODUCTION

Robatel Technologies, LLC (Robatel) is located in Roanoke, Virginia and provides design engineering and fabrication services primarily in the areas of transport packages, hot cells, and waste processing systems.

This Quality Assurance Program Description (QAPD) provides the Quality Assurance (QA) requirements to be invoked by Robatel for purchase orders or contracts governed by 10 CFR 71, or that specifically require compliance to this QAPD. Each contract will be reviewed to determine regulated activities and the appropriate measures to be implemented.

This Robatel Quality Assurance Program Description (QAPD) has been generated to specifically establish the QA requirements to meet Subpart H of 10 CFR Part 71 with respect to designing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying packaging components important to safety.

Once reviewed and accepted by the Nuclear Regulatory Commission (NRC), Robatel will be approved to conduct 10 CFR Part 71 activities in accordance with this QAPD.

This Quality Assurance Program Description along with the QAP and implementing procedures meets and exceeds the requirements of:

- Title 10, U.S. Code of Federal Regulations, Subpart H to Part 71 (10 CFR 71) and,
- American Society of Mechanical Engineers (ASME) NQA-1-1994 and 2008 with 2009 Addenda

1.0 ORGANIZATION

The Robatel quality organizational structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality are defined within this QAPD and implementing documents.

The responsibilities and authorities are presented in the Robatel QA Program (QAP); the QAP provides an organization chart and corresponding job descriptions that define job titles as well as the respective duties and responsibilities.

The Chief Operations Officer has full authority over company functions and may delegate authority and responsibility for selected functions to other personnel or organizations.

The Quality Assurance Manager is vested with the authority and responsibility to ensure that activities affecting quality are performed and documented correctly to the established requirements.

The Quality Assurance Manager shall have sufficient expertise in the quality discipline to direct the quality functions as appropriate to the established requirements. The Quality Assurance Manager's responsibilities include the development, implementation and administration of the quality program and supporting procedures.

Qualified personnel perform monitoring activities and verification of regulatory, contractual, and/or technical requirements in accordance with controlled documents.

2.0 QUALITY ASSURANCE PROGRAM

Robatel has a hierarchy of documents used to implement the total quality system. The hierarchy includes the QAPD followed by the Quality Assurance Program and lastly the Quality Procedures used to implement the QAPD and QAP. These documents in toto define the requirements to effectively and efficiently implement the requirements of 10 CFR 71 Subpart H as related to meet codes, standards, regulatory and contract requirements.

Activities within the scope of this quality system include Robatel engineering, manufacturing, research, testing and development related to nuclear applications for design, packaging and transportation of radioactive material.

Together, the Robatel hierarchy of documents provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. Furthermore, this hierarchy provides for any special controls, processes, test equipment, tools, and skills to attain the required quality of activities and items and for verification of that quality. The Robatel organization shall establish and implement processes to detect and correct quality problems.

3.0 DESIGN CONTROL

Robatel assures the following activities: design characteristics are defined, controlled, verified, inspected, and tested; designs developed meet applicable regulatory requirements; and design activities are carried out in a planned, controlled, and orderly manner. The customer maintains design responsibility when Robatel works to customer drawings and specifications.

Robatel may subcontract design and fabrication activities to their affiliated company, Robatel Industries or other approved suppliers. In all cases of Level A or B procurement, the supplier performing the work must have an acceptable quality program to meet the required criteria of 10 CFR 71 Subpart H. Acceptability will be determined by Robatel audit and subsequently, the supplier placed on the Robatel Approved Supplier List. Subsequently, Robatel shall verify that design activities were conducted in accordance with the Robatel-approved QA Program for that specific supplier.

4.0 PROCUREMENT DOCUMENT CONTROL

Procurement activities are performed in accordance with approved procedures that implement the applicable requirements defined in the Robatel Program.

All suppliers of safety related products and services are supervised by means of adequate quality assurance measures. These include:

- evaluation of the quality capabilities of potential suppliers
- periodic evaluations of suppliers by onsite audits and/or surveillances

Procurement documents shall identify the scope of work, technical requirements, quality/safety program requirements, right of access, inspection and test requirements, special process requirements, documentation requirements, and reporting and disposition of nonconformances, as applicable to the item or service being procured.

Quality related purchase orders and request for quotes shall include requirements, as applicable, such as the following criteria:

- Identification of the quality requirements for inspection and control, acceptance and rejection criteria, program and/or customer requirements, and invoking standards and codes (i.e. 10 CFR 21, etc).
- Material information such as size, type or grade.
- Basic technical requirements such as specifications, drawings, codes, industrial standards, hold points, inspections or tests.
- Documentation requirements such as inspection records, test records or certification documents.
- A statement that allows QA personnel, or designee(s) to have the right of access to supplier facilities for source inspection and/or audit activities as appropriate.

Quality related purchase orders and requests for quotes shall be reviewed prior to release by qualified management and QA personnel, or their respective designee(s), to assure compliance with the applicable section of the QA program and procedures.

Changes to procurement documents shall be subject to the same review and approval as the original documents.

5.0 INSTRUCTIONS, PROCEDURES AND DRAWINGS

Activities affecting quality shall be prescribed by and performed in accordance with documented instructions, procedures, or drawings of a type appropriate to the applicable contract services. These documents shall include (or reference) appropriate quantitative and qualitative acceptance criteria for determining that the prescribed activities have been satisfactorily accomplished.

The activity shall be described to a level of detail commensurate with the complexity of the activity and the need to assure consistent, acceptable results. The need for written procedures or instructions, as well as their level of detail, shall be determined based upon complexity of the task, significance of the item or activity, work environment, and worker proficiency and capability (education, training, experience).

Based on design drawings, production drawings will be prepared if no definitive production drawings were prepared with the safety report. These production drawings may be prepared by Robatel insofar as sufficient knowledge and experience concerning production processes and possibilities. If experience concerning production processes and possibilities is not sufficient, the manufacturer of the packaging may be entrusted with the development of the production documents.

Approved written procedures assure that all applicable documents conform to the appropriate specifications and pertinent regulations. Good engineering judgment is used when specific specifications or regulations do not exist.

All work activities are coordinated with QA personnel to ensure that the work-controlling documents incorporate appropriate inspection and hold points to verify that initial work, planned work, effective repairs, or rework have been performed satisfactorily.

6.0 DOCUMENT CONTROL

Robatel controls preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings in order to ensure that correct documents are being employed. Such documents, including changes thereto, shall be reviewed for adequacy and approved for release by authorized personnel, and subsequently, distributed and used at the location where the activity is performed.

7.0 CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

Robatel does not manufacture containers themselves; instead, Robatel utilizes selected manufacturers who are on the list of approved suppliers, or who are audited and approved before the order is placed.

In special cases, Robatel may place an order prior to audit/approval of a supplier; however, Robatel will audit/approve such supplier prior to supplier work start.

The procurement of material, equipment and services shall be controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection; evaluation of objective evidence of quality furnished by the supplier; source inspections; audit; and examination of services upon delivery or completion. Procurement procedures describe the procurement process leading to contract award for items and services, and they identify the responsible organizations.

8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS

The identification and control of materials, parts and components shall be in accordance with approved procedures, instructions and/or checklists to assure that identification is maintained (either on the item or records traceable to the item) to preclude use of incorrect or defective items.

When required by applicable specifications or customer requirements, the identification of materials, parts, and components shall be traceable to the appropriate documentation such as drawings, purchase orders, shop travelers, inspection documents, nonconformance reports and physical/chemical test reports.

The procedures shall identify the appropriate criteria and responsibilities in order to assure the correct identification of items is verified and documented in accordance with section 10.0 of the QAP and applicable implementing procedures.

Identification requirements shall be established when applicable during the generation of drawings and specifications to assure that the location and method of identification is not detrimental to the material, and does not affect the form, fit, function or quality of the item.

9.0 CONTROL OF SPECIAL PROCESSES

Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified requirements.

10.0 INTERNAL INSPECTION

Robatel performs inspections to verify conformance of an item/activity to specified requirements, or to verify continued acceptability of items already in-service. Characteristics subject to inspection and inspection methods shall be specified. Inspection results shall be documented. Inspection for acceptance shall be performed by qualified persons other than those who performed or directly supervised the work being inspected.

The manufacturer will develop the preliminary checking documents based on the manufacturer's specification and the drawings of the packaging to include the following criteria:

- List of materials,
- Fabrication and control follow-up plan (in part also named construction control follow-up plan, according to the manufacturer's choice),
- Welding plan, and
- If applicable, completion drawings (e.g. forging drawings).

The supervision of fabrication through Robatel is determined in the preliminary checking documents. The checking steps are carried out under the responsibility of the person responsible for acceptance appointed by Robatel Technologies. Implementation of the supervising steps is documented in the preliminary checking documents and, insofar as necessary, in the corresponding records.

11.0 TEST CONTROL

Robatel proof, acceptance and operational tests are controlled by approved written instructions, procedures, or drawings of a type appropriate to the activity.

Tests shall be planned and executed to collect data such as for siting or design input, verify conformance of an item or computer program to specified requirements, or demonstrate satisfactory performance. Characteristics to be tested and test methods to be employed shall be specified. Test results shall be documented and their conformance with test requirements and acceptance criteria shall be evaluated.

12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

Robatel assures tools, gages, instruments and other measuring and test equipment used in activities affecting quality are properly controlled, calibrated and adjusted to maintain accuracy within required limits.

13.0 HANDLING, STORAGE, AND SHIPPING CONTROL

In accordance with procedures and/or instructions and to prevent damage or deterioration, Robatel shall establish measures to control the handling, storage, shipping, cleaning, and preservation of materials/equipment to be used in packaging. Specific instructions must be provided as necessary for particular products and/or special protective environments (e.g., inert gas atmosphere, specific moisture content, and temperature levels).

14.0 INSPECTION, TEST, AND OPERATING STATUS

Procedures are established to ensure that the inspection, test, and operating status of materials, items, structures, systems and components throughout fabrication, installation,

operation and test are clearly indicated by suitable means (e.g., tags, labels, cards, form sheets, checklists, etc).

15.0 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

Procedures are established to control materials, parts, and components that do not conform to requirements in order to prevent their inadvertent use in manufacturing operations or during service.

Nonconforming items include those items that do not meet specification or drawing requirements. Additionally, nonconforming items include items not fabricated or tested

(1) in accordance with approved written procedures,

(2) by qualified processes, or

(3) by qualified personnel

when use of such procedures, processes or personnel is required by fabrication, test, inspection or other quality assurance requirements.

Nonconforming items are identified and/or segregated to prevent their inadvertent use until properly dispositioned. The identification of nonconforming items is by marking, tagging or other methods that do not adversely affect the end use of the item. The identification is legible and easily recognizable. When identification of each nonconforming item is not practical, the container, package, or segregated storage area is identified appropriately.

Nonconforming conditions are documented on Nonconformance Reports (NCRs) and affected organizations are notified. These reports include a description of the nonconforming condition. Nonconforming items are dispositioned as use-as-is, reject, repair, or rework.

Inspection or surveillance requirements for nonconforming items following rework, repair or modification are detailed in the NCRs and approved following completion of the disposition.

16.0 CORRECTIVE ACTION

Procedures are established to ensure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, defective material and equipment are promptly identified and corrected. In the case of significant conditions adverse to quality, the cause of the condition is determined and corrective actions to prevent recurrence are taken.

Conditions adverse to quality are documented in Corrective Action Reports (CARs) and reported to the appropriate level of management. When necessary, follow up is performed to verify that corrective action requirements have been completed and are effective.

17.0 QUALITY ASSURANCE RECORDS

The control of Quality Assurance records shall be established by Robatel consistent with the schedule for accomplishing work activities. Quality Assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.

Quality assurance records shall be identified, generated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities shall be documented.

18.0 AUDITS

Procedures shall be established to provide for a comprehensive system of planned and documented audits including audits of suppliers. These audit procedures specify the conduct of internal audits of facility and site activities to verify compliance with the applicable aspects of the Robatel QAP, and to determine the effectiveness of the program.

Audits shall be scheduled to provide coverage and coordination with ongoing QAP activities commensurate with the status and priority of the activity. All applicable elements of the Robatel QAP shall be audited at least annually. Audits of suppliers shall be conducted on a triennial basis unless more frequent audits are deemed appropriate.

Audits shall be performed in accordance with pre-established written procedures using checklists and conducted by trained and certified personnel having no direct responsibilities in the areas being audited. Objective evidence shall be examined for compliance with QAP requirements.

ATTACHMENT A

For Information Only

QA Program Implementing Procedures

Implementing Document(s)	Title From 10 CFR 71 Subpart H	Regulatory Position	Description
Quality Assurance Program (QAP), QAP, Section 1 Organization charts	§71.103 Quality Assurance Organization	1	Responsibilities for the establishment and implementation of the quality assurance program are defined. The organization structure, functional responsibilities, levels of authority, and lines of communications for activities affecting quality are documented. The organization chart provides an outline of the organizational structure.
QAP, Section 2 QP 02-01	§71.105 Quality Assurance Program	2	Describes how the quality assurance program is planned, implemented, and maintained. Identifies the activities and items to which it applies. The program provides control over activities affecting quality to an extent consistent with their importance. The program includes monitoring activities in a manner sufficient to provide assurance that the activities affecting quality are performed satisfactorily.
QAP, Section 3 QP 03-01 QP 03-02 QP 03-03	§71.107 Package Design Control	3	Design inputs are specified and translated into design documents. Design interfaces are identified and controlled. Individuals other than those who designed the item or computer program verify design adequacy. Design changes are governed by control measures commensurate with those applied to the original design.
QAP, Section 4 QP 04-01	§71.109 Procurement Document Control	4	Applicable design bases and other requirements necessary to assure adequate quality are included or referenced in documents for procurement of items and services. To the extent necessary, procurement documents require Suppliers to have a quality assurance program consistent with the applicable requirements of the QAP.

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QA Program Implementing Procedures (continued)

Implementing Document(s)	Title From 10 CFR 71 Subpart H	Regulatory Position	Description
QAP, Section 5 QP 05-01 QP 05-02	§71.111 Instructions, Procedures, And Drawings	5	Activities affecting quality and services are prescribed by, and performed in accordance with, documented instructions, procedures, or drawings that include or reference appropriate quantitative or qualitative acceptance criteria for determining that prescribed activities have been satisfactorily accomplished. The activity is described to a level of detail commensurate with the complexity of the activity and the need to assure consistent and acceptable results.
QAP, Section 6 QP 06-01	§71.113 Document Control	6	The preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality such as instructions, procedures, and drawings are controlled to ensure that correct documents are being employed. Such documents, including changes thereto, are reviewed for adequacy and approved for release by authorized personnel.
QAP, Section 7 QP 07-01 QP 07-02	§71.115 Control of Purchased Material, Equipment, and Services	7	The procurement of items and services are controlled to ensure conformance with specified requirements. Such control shall provide for the following as appropriate: source evaluation and selection, evaluation of objective evidence of quality furnished by the Supplier, source inspection, audit, and examination of items or services upon delivery or completion.
QAP, Section 8 QP 08-01	§71.117 Identification and Control of Materials, Parts, and Components	8	Controls are established to assure that only correct and accepted items are used or installed. Identification is maintained on the items or in documents traceable to the items, or in a manner that assures that identification is established and maintained.
QAP, Section 9 QP 09-01	§71.119 Control of Special Processes	9	Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, are performed by qualified personnel using qualified procedures in accordance with specified requirements.

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For Information Only

QA Program Implementing Procedures (continued)

Implementing Document(s)	Title From 10 CFR 71 Subpart H	Regulatory Position	Description
QAP, Section 10 QP 10-01	§71.121 Internal Inspection	10	Inspections required to verify conformance of an item or activity to specified requirements or continued acceptability of items in service are planned and executed. Characteristics subject to inspection and inspection methods are specified. Inspection results are documented. Qualified persons other than those who performed or directly supervised the work being inspected perform inspections for acceptance.
QAP, Section 11 QP 11-01	§71.123 Test Control	11	Tests required to collect data such as design input, to verify conformance of an item or computer program to specified requirements, or to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with test requirements and acceptance criteria are evaluated.
QAP, Section 12 QP 12-01	§71.125 Control of Measuring And Test Equipment	12	Tools, gages, instruments, and other measuring and test equipment used for activities affecting quality are controlled, calibrated at specific periods, adjusted, and maintained to required accuracy limits.
QAP, Section 13 QP 13-01	§71.127 Handling, Storage, and Shipping Control	13	Handling, storage, cleaning, packaging, shipping, and preservation of items are controlled to prevent damage or loss and to minimize deterioration. These activities are conducted in accordance with procedures or instructions specified for use in conducting the activity.

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QA Program Implementing Procedures (continued)

Implementing Document(s)	Title From 10 CFR 71 Subpart H	Regulatory Position	Description
QAP, Section 14 QP 14-01	§71.129 Inspection, Test, and Operating Status	14	The status of inspection and test activities are identified either on the items or in documents traceable to the items where it is necessary to ensure that required inspections and tests are performed and to ensure that items that have not passed the required inspections and tests are not inadvertently installed, used, or operated. Status is maintained through indicators, such as physical location and tags, markings, shop travelers, stamps, inspection records, or other suitable means.
QAP, Section 15 QP 15-01 QP 15-02	§71.131 Non-Conforming Materials, Parts, or Components	15	Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use. Controls shall provide for identification, documentation, evaluation, segregation when practical, and disposition of nonconforming items, and for notification to affected organizations.
QAP, Section 16 QP 16-01	§71.133 Corrective Action	16	Conditions adverse to quality are identified promptly and corrected as soon as practicable. In the case of a significant condition adverse to quality, the cause of the condition is determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality are documented and reported to appropriate levels of management. Completion of corrective actions is verified.
QAP, Section 17 QP 17-01	§71.135 Quality Assurance Records	17	The control of quality assurance records is established consistently with the schedule for accomplishing work activities. Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements. Quality assurance records are identified, generated, and maintained, and their final disposition specified. Record control requirements and responsibilities for these activities are documented.

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For Information Only

QA Program Implementing Procedures (continued)

Implementing Document(s)	Title From 10 CFR 71 Subpart H	Regulatory Position	Description
QAP, Section 18 QP 18-01 QP 18-02 QP 18-03	§71.137 Audits	18	Audits are performed to verify compliance to quality assurance program requirements, to verify that performance criteria are met, and to determine the effectiveness of the program. Personnel who do not have direct responsibility for performing the activities being audited perform these audits in accordance with written procedures or checklists. Audit results are documented and reported to, and reviewed by, responsible management. Follow-up action is taken where indicated.