Best® Theratronics

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PART 71 QA PROGRAM

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Document History

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1. PURPOSE

The purpose of this document is to provide our company personnel and customers with a single source of information regarding Best Theratronics Ltd. (BTL) policies, responsibilities and procedures for assuring and controlling conformity to USNRC 10 CFR 71 Packaging and Transportation of Radioactive Materials.

2. SCOPE

The QA program applies to all activities associated with BTL's USNRC approved Certificates of Compliance (CoC) for Radioactive Material Type A and Type B transport packaging. Any process that affects product conformity to requirements that is outsources is controlled under the requirements of this QA program.

3. QUALITY ASSURANCE REQUIREMENTS

3.1 Approval of QA program

The QA program must be approved by the United States Nuclear Safety Commission (NRC) prior to import or export of radioactive material or transfer within the United States in a transport packaging with a valid CoC.

Any changes to this document must be reviewed and approved by the NRC before being implemented.

Following the NRC technical review and determination that the QA program submitted meets regulatory requirements, the NRC issues a QA Program Approval. The approval expires on the last day of the month stated on the approval document. BTL may request a renewal not less than 30 days prior to expiration.

4. QUALITY ASSURANCE ORGANIZATION

4.1 Structure and Authority

4.1.1 Director, Compliance

Has the overall responsibility for the implementation and compliance of the quality, regulatory, environmental, health and safety programs.

4.1.2 Quality & Regulatory Manager

Has been appointed as the Management Representative having responsibility and authority that includes:

- ensuring the processes of the quality management system are established
- reporting to the Management Team on the performance of the quality management system, including needs for improvement
- promoting awareness of customer requirements throughout the organization
- liaison with external parties on matters relating to the quality program.

4.2 Top Management Endorsement of QA program

BTL is committed to the development and implementation of the QA program and maintaining its effectiveness by:

- consistently communicating throughout the company the importance of meeting customer, statutory and regulatory requirements by such means as training sessions, company intranet and employee meetings
- establishing the quality policy and ensuring it remains relevant and consistent with the overall organization policies
- ensuring the quality objectives continue to be identified for the relevant functions and levels;
- conducting management reviews to ensure the continuing suitability, effectiveness and efficiency of the QA program
- ensuring adequate resources to implement and improve the processes for the QA program

5. QUALITY ASSURANCE PROGRAM

5.1 General Requirements

BTL has established, documented, implemented and maintains a QA program and continuously improves its effectiveness in accordance with applicable standards. BTL's QA program complies with the requirements of 10 CFR Part 71.101 through 71.137.

5.2 Documentation

BTL's QA program documentation includes:

- quality policy and quality objectives
- QA program manual
- documented procedures and records required by the standards
- documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

5.3 Controlled Conditions and Assignment of Responsibilities

To ensure product conformity, BTL determines and manages the work environment needed to ensure conformity to product requirements.

The responsibility, authority and the interrelation of personnel who manage, perform and verify work-affecting quality have been defined, documented and communicated within the organization.

All employees have the responsibility for the QA program and its effective implementation.

6. PACKAGE DESIGN CONTROL

6.1 Design Process

Written plans are prepared for design and verification activities for each new or modified RAM package design at project initiation. The Engineering Director assigns the project to qualified personnel equipped with the resources necessary to prepare a fully compliant design.

6.2 Design Input

The Project Engineer verifies design input requirements for adequate identification and documentation. Design input verification involves, but is not limited to:

- performance and functional criteria, including operational requirements
- applicable performance and safety codes and standards
- IAEA Regulations and 10CFR Part 71
- regulatory requirements, including applicable Package Design Approval or Special Form Radioactive Material Certificates
- environmental conditions
- documentation, training, maintenance and inspection plans
- the need for Special Form Material Certification for the sealed source if initial evaluation of radioactive material transport packaging/device or sealed source/packaging combinations indicate a need
- where applicable, the results of contract review.

6.3 Design Output

Design output is documented and expressed in terms of requirements, calculations, tests, and analysis. The design output shall:

- meet the design input specification
- show design analysis in sufficient detail to allow verification of the adequacy of the design and conformity to appropriate regulatory requirements whether or not these have been stated in the Design Plan,
- include a Safety Analysis Report (SAR) in suitable detail to meet requirements of regulatory guidelines. The extent of the analysis and testing chosen is sufficient to prove the validity of the design
- All new RAM transport package designs must be evaluated to the applicable requirements. For Type B designs, the evaluation is part of a safety analysis report submitted to the competent authority. No Type B packaging design can be used before the evaluation is complete and a Transport Package Design Certificate has been issued. The Project Engineer is responsible for preparing an application for each new or modified Type B RAM transport package design. The SAR must be reviewed by an independent technical reviewer, and must be approved by the Technical Authority (TA).
- include engineering drawings and operating procedures
- include a Technical Specification for Type B packages. The technical specification must be reviewed by the Compliance Representative and approved by the TA.

6.3.1 Safety Analysis Report

The application for certification of a Type B radioactive material transport package includes at least the following:

- package description detailing radioactive contents, containment system, shielding, and operational features
- structural evaluation including but not limited to:

6.3.1.1 Structural design

- design criteria referencing requirements for packages as defined in the design inputs
- mechanical properties of structural materials
- weights and centres of gravity

6.3.1.2 General requirements for packages such as:

- lifting devices
- closure methods
- tie down devices
- external pressure
- chemical and galvanic reactions

6.3.1.3 Conditions of transport

- thermal evaluation
- accident analysis, based on IAEA or national competent authority regulatory requirements
- overview drawing
- preparation for shipment and inspection and maintenance procedures
- Special Form evaluation, as applicable
- test results, and/or engineering justification
- the Design, Manufacture and Operating Specification.

6.3.2 Technical Specification

The Technical Specification is an integral part of the design documentation for a Type B package. It establishes the overall technical requirements for manufacture, assembly, inspection, test and delivery for each model of transport packaging. The Specification defines:

- applicable engineering drawings
- applicable standards
- BTL specifications and procedures
- quality program standards and codes required for manufacture
- where applicable, requirements for welding, fitting and machining, surface finish and cleanliness, lead pouring and bonding, and painting
- nonconformance and corrective action
- inspection requirements
- tests for welds, mechanical operation, lead bonding, radiation shielding, and leakage testing
- requirements for manufacturing history records.

6.4 Design Verification

Designs and associated documents are verified and/or reviewed to ensure that they meet specified design requirements. Design verification is performed by qualified staff by conducting testing or by comparison to similar designs. The TA and the Compliance Representative determine the extent of verification and review required. This decision is based on complexity, novelty, degree of standardization, and safety implications. The Design Plan identifies the verification and review requirements. All verification and review activities are documented. The nature of the verification process must conform to applicable codes and standards. The process involves:

- qualification testing or comparison review according to applicable IAEA standards and competent regulatory authority regulations. Requirements, procedures, data, assumptions, and results are documented and filed. Results are evaluated against specified acceptance criteria. The conclusions of the tests or comparisons are recorded and filed in the transport design history files.
- design review by qualified persons other than those who executed the design. The reviews determine if the design methods are appropriate and correctly applied. The reviewers verify that the assumptions and simplifications used are justifiable, and the design interfaces are properly addressed. Reviews are conducted before design release. They are documented, and include decisions.

6.5 Design Changes

A design change system is used for the control of drawings and supporting documentation. All changes to the design of RAM transport packages are reviewed and approved by an independent TA, the Compliance Representative; and where required, the representatives from Operations. Design changes are reviewed and approved in the same manner as the original design.

The Project Leader documents the change description, the reasons for it, scope, effectivity and validation and verification requirements. The method and extent of the design verification are dependent upon the extent and nature of the changes. The Project Leader identifies the necessary recipients of the revised design documents.

7. PROCUREMENT DOCUMENT CONTROL

7.1 Content of Procurement Documents

Documented procedures are maintained to assure that purchased material, equipment and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents.

Requirements for items and services purchased, including outsourced processes, shall be clearly defined on Purchase Order documents and /or in Supplier Agreements or contracts.

7.2 Replacement Part Procurement

All suppliers shall be approved in accordance with the company's supplier qualification program.

Suppliers may request that a known defect in product or service not yet provided to BTL be considered for acceptance using the appropriate supplier nonconformance form.

7.3 Review and Changes to Procurement Documents

Any amendments to a procurement documents are processed and reviewed in the same manner as the original document.

8. INSTRUCTIONS, PROCEDURES & DRAWINGS

8.1 Quality Assurance Program Procedures

Documents required for the QA program such as instructions, procedures and drawings, including changes, that prescribe all activities affecting quality are controlled, reviewed for adequacy and approved for release by authorized personnel. These documents are distributed and used at the locations where the activity is performed.

These documents must include quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

8.2 QA Review and Concurrence

BTL plans and develops the processes and sub-processes needed for product realization. Planning of product realization is consistent with the requirements of other processes of the QA program. In planning product realization, BTL determines the following as appropriate:

- quality objectives and requirements to be achieved for the product, project or contract involved;
- the need to establish processes and documents and to provide resources specific to the product;
- required verification, validation, monitoring, measurement, inspection and test activity specific to the product and criteria for product acceptance;
- records needed to provide evidence of process and product conformity to requirements; mandatory hold and witness points established by the customer (where applicable) which requires their verification of selected characteristics of an item or process and beyond which work does not progress until verification has been completed.
- documented requirements for risk management are maintained as defined within the applicable procedure.

9. DOCUMENT CONTROL

9.1 Controlled Documents

Documents required for the QA program such as this manual, quality assurance procedures, instructions, checklists and quality system forms are developed, reviewed, approved, distributed and controlled are defined in documented procedures.

9.2 Document Generation and Issuance

Documents are reviewed for adequacy and completeness and approved by the responsible personnel prior to issue.

9.3 Document Changes

Changes or additions to approved documents are reviewed, updated as necessary and re-approved.

Approved documents are transmitted to all functional areas and locations where they apply and are made readily accessible to the personnel concerned.

Documents that are obsolete shall be promptly removed from all points of use or otherwise prevented from unintended use. Documents retained for any purpose shall be suitably identified as obsolete.

9.4 Electronic Documents

Electronic documents/records on the company server are backed up on a daily basis. A third party controls the backup of the Manufacturing Resource Planning system.

10. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, & SERVICES

10.1 Procurement Document Planning

BTL has established and maintains a system for the control of purchased items and services, and defines the responsibilities, control and methods employed to ensure procured items and services conform to specified requirements.

10.2 Selection of Procurement Sources

The type and extent of control applied to the supplier and the purchased product are dependent upon the effect of the purchased product on subsequent product realization or the final product.

Measures are in place, through purchasing and QA procedures for the evaluation, selection and approval of suppliers. These measures include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery.

All quality records containing the results of supplier evaluations and subsequent necessary actions are maintained.

Purchasing documents describe the product to be purchased, including where appropriate:

- Requirements for approval of product, procedures, processes, and equipment
- Requirements for the qualification of personnel
- *Quality management system requirements*

To ensure that all requirements have been adequately specified, procurement documents for raw material, equipment, parts, assemblies or services are reviewed prior to their communication to the supplier.

Documented evidence that material and equipment conform to the procurement specifications before installation or use of the material and equipment. The documented evidence shall be maintained for the life of the package. The documentation is reviewed to assure that the evidence is sufficient to identify the specific requirements met by the purchased material and equipment.

10.3 Bid Evaluation and Award

Compliance is responsible for completing supplier evaluations, re-evaluations and approvals, based on the Suppliers ability to supply product in accordance with requirements.

10.4 Supplier Performance Control

The effectiveness of the control of quality by contractors and subcontractors shall be assessed at intervals consistent with the importance, complexity, and quantity of the product or services. Supplier performance is assessed annually by the management review team.

10.5 Verification Activities

All procured products are evaluated to determine the amount of inspection required to ensure that the purchase order requirements have been met.

Where BTL or its customer intends to perform verification at a supplier's premises, BTL states the intended verification arrangements and method of product release in the purchasing information.

All incoming materials affecting conformity to product requirements is subject to verification and testing by authorized personnel, as required.

Any nonconforming product detected while verifying purchased product is processed as defined in applicable procedures.

10.6 Controlling Nonconformances

Nonconforming product is identified and controlled to prevent unintended use or delivery.
The controls, responsibilities, authorities and methods for managing nonconformities is documented.

Records of dispositions are maintained which include the justification for use of nonconforming product and signature of the individual authorizing the use.

10.7 Records

The requirements for procured items is documented in the purchase order and verified upon receipt at BTL. This may be material certificates, batch records, traceability, and applicable codes, standards or specifications applied.

11. IDENTIFICATION AND CONTROL OF MATERIALS, PARTS & COMPONENTS

BTL has established and maintains procedures to ensure the identification and control of materials, parts, and components through the product realization cycle.

Each item or service (bath, lot, component or part) shall be identified to the applicable drawing, technical document, heat or serial number, as applicable, from receipt through production phases to completion.

12. CONTROL OF SPECIAL PROCESSES

Any process, the results of which cannot be fully verified by subsequent inspection and testing of the product and where, for example, processing deficiencies may become apparent only after the product is in use, shall be adequately defined and validated.

Special processes shall be carried out under controlled conditions, and be performed by qualified personnel using approved written procedures and qualified equipment, where required by the applicable codes, standards, specifications and contract requirements.

13. INTERNAL INSPECTION

13.1 General

BTL has established and maintains measures for acceptance activities. Acceptance activities include inspections, tests, or other verification activities.

13.2 Inspection

13.2.1 Receiving Inspections

All incoming materials affecting conformity to product requirements are inspected according to approved, documented procedures before release to production, inventory or storage.

13.2.2 In-Process Inspections

Where required, in–process inspection and testing is conducted as detailed within applicable procedures. Where required, in-process verifications are accomplished at hold points identified with MITP's and in accordance with documented procedures and relevant instructions.

Products are not allowed to progress to the next operation until the required verifications and tests have been completed.

13.2.3 Final Inspections

All finished products are subject to final verification and/or testing prior to shipping as defined within applicable procedures. Finished devices are adequately controlled until released.

Finished devices are not to be released until

- The product meets all specification requirements
- The associated data and documentation is reviewed
- The release is approved by Compliance

13.2.4 Maintenance Inspections

All RAM transport packages are inspected regularly in order to comply with the applicable regulations. Transport packages are subjected to routine inspections after every return and an annual inspection.

13.2.5 Inspectors

BTL employees who perform work affecting conformity to product requirements are competent on the basis of appropriate education, background, training, skills and experience.

Employee training records, qualifications, and certifications are filed and maintained in the employee training file.

Inspections are conducted by personnel who are independent of those who have direct responsibility for the activity being inspected.

13.2.6 Inspection Documentation

Inspection records are maintained as quality records.

14. TEST CONTROL

14.1 Requirements

All testing of transport packaging is performed in accordance with approved written procedures. Any modifications, repairs or rework are completed in the same manner as the original design and testing requirements.

Inspection and test status of items shall be indicated by the application of labels, stamps and tags; completion of manufacturing orders, inspection records or test software; physical location or other suitable means that indicate the conformance or nonconformance of items with regard to the inspection and test performed.

14.2 Procedures

Required inspection and test operations are indicated on each Manufacturing Order including mandatory hold points, recording of equipment calibration dates, and requirements for recording of the test data and criteria for acceptance.

14.3 Acceptance Tests

All transport packages are inspected in accordance with a Factory Acceptance Test prior to first use.

14.4 Maintenance Tests

All RAM transport packages are subjected to routine inspections after every return and an annual Inspection. This typically includes a check for: damage, rust, cracks, dents, perforation, contamination, condition of gaskets and lifting rings, etc. Any noted items are recorded on a non-conformance report and the package is quarantined until such time that it is dispositioned and released for use.

14.5 Results

Applicable results are maintained as quality records within the QC department.

15. CONTROL OF MEASURING & TEST EQUIPMENT

15.1 Calibration Control

Each monitoring and measuring equipment employed for the purpose of verifying conformity to product requirements or monitoring processes are assigned a unique identification control number. The calibration status of each monitoring or measuring equipment is indicated by an appropriate label affixed to the item calibrated.

At defined intervals, as necessary, based on stability, purpose and degree of usage, measuring and monitoring devices are subject to calibration. The specific measurements to be made, the accuracy required and the comparator to be used is identified within documented calibration instructions.

Calibration is performed using reference standards and/or equipment whose calibration is traceable to nationally or internationally recognized standards. Where no recognized standard exists, the basis used for calibration is recorded.

15.2 Out-of-Calibration Equipment

When any measuring and test equipment is found not to conform to requirements, the validity of the previous measuring results is assessed. The results of the calibration and verification are recorded and maintained. Appropriate corrective action is initiated on the measuring and test equipment and any affected product.

16. HANDLING, STORAGE & SHIPPING CONTROL

16.1 Preservation

Methods for handling product in order to prevent mix-ups, contamination, damage, deterioration or other adverse effects have been established Designated storage areas are used to prevent damage or deterioration of product pending use or delivery. Each production and inspection department is responsible for ensuring that safety precautions, good housekeeping and good shop practices are maintained to prevent damage or deterioration of product.

Only qualified and authorized personnel are permitted to handle cranes, forklift trucks and other handling equipment.

16.2 Preparation, Release and Delivery to Purchaser

All RAM transport packages are prepared for shipment in accordance with Preparation for Shipment procedures. These procedures provide instructions to ensure the units are prepared for shipment in accordance with the requirements of the package Safety Analysis Report and include requirements for contamination testing, radiation surveys and labeling.

After final inspection, testing and packaging, the product shall be held until release for shipment has been authorized by Compliance.

17. INSPECTION, TEST & OPERATING STATUS

Inspection and test status of items within BTL shall be indicated by the application of labels, stamps and tags; completion of manufacturing orders, inspection records or test software; physical location or other suitable means that indicate the conformance or nonconformance of items with regard to the inspection and test performed.

Inspection Plans are written for inspections performed during the life cycle of RAM transport packaging. These plans outline the type of inspection or testing to be undertaken. For each returnable RAM transport packaging type, an inspection and maintenance plan is prepared.
The plans include, as applicable:

- new packaging first-off inspection and acceptance requirements
- periodic inspections after shipment, and before reuse
- annual inspection and maintenance
- inspection and maintenance checklists
- instructions for special tests such as: leak testing, pressure tests, shielding tests, etc.
- quality records to be kept

18. NON-CONFORMING MATERIALS, PARTS OR COMPONENTS

Nonconforming product is identified and controlled to prevent unintended use or delivery. BTL has documented the control, responsibilities, authorities and methods for managing nonconformities. Nonconforming material is identified, documented, segregated (where practical), evaluated and dispositioned.

The evaluation of nonconforming product includes a determination of the need for an investigation and notification of the responsible party for the nonconformance. All evaluations and investigations are documented.

Records of dispositions are maintained which include the justification for use of nonconforming product and signature of the individual authorizing the use.

Repaired product is documented in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval, a determination of any adverse effect of the rework upon the device is made and documented by the Technical Authority.

Where required, acceptance by the customer or relevant external authority will be obtained.

In the event that nonconformances are detected after delivery or use has started, BTL notifies the customer, end user, and/or regulatory body as required.

19. CORRECTIVE ACTION

19.1 Reporting

BTL promptly identifies and corrects conditions adverse to quality. Best Theratronics has documented and implemented procedures defining the responsibilities and actions for identifying and correcting conditions adverse to quality. Any nonconformances are investigated in order to:

- Determine the cause of the nonconformity
- Evaluate the need for actions to prevent recurrence
- Identify and report to appropriate management levels
- Determine and implement required corrective action, and/or obtain corrective actions from supplier

Corrective/preventive action statistics are reported to the Management Review Team by the Compliance department.

19.2 Closeout, Retrieval, and Disposition of Records

Compliance is responsible to:

- Record results of action taken
- Close the corrective/preventive action
- Review, verify and document effectives of the corrective/preventive actions taken
- Records are maintained with the Compliance department.

20. QUALITY ASSURANCE RECORDS

20.1 General

Quality records have been established, maintained and controlled to provide evidence of conformity to requirements and of the effective operation of the quality program.

20.2 Generating Records

20.2.1 Indexing and Classification Records

A listing of applicable quality records, the department responsible for them and their respective retention times is detailed in documented procedures.

20.2.2 Receipt, Retrieval, and Disposition of Records

Quality Records are legible, readily identifiable and retrievable.

Records shall be made available to Compliance, the customer or regulatory agency representative for the purpose of audit, analysis or review, in a timely manner when requested.

Quality records will be retained for not less than 5 years after the last device/transport package model has been removed from service unless otherwise specified by a contract or quality system procedure.

Records still in retention after 25 years will be assessed by the department responsible for them and Compliance will be advised of any record that is due for destruction.

20.2.3 Storage, Preservation, and Safekeeping

Electronic documents/records on the company server are backed up on a daily basis. A third party controls the backup of the Manufacturing Resource Planning system.

21. AUDITS

21.1 Elements of an Audit Program

BTL has established and documented procedures for planning and implementing internal quality audits to verify compliance with applicable standards, regulatory and internal requirements. The audit scope, frequency, methodology used and the personnel responsible for planning, conducting, reporting and following up on internal quality audits are defined. The audit program is implemented and maintained by the Compliance department.

21.2 Scheduling of Audits

Internal audits are scheduled on the basis of the status and importance of the area and/or process to be audited and in sufficient depth to verify that the quality program is being implemented effectively.

The QA program shall be audited a minimum of once per calendar year. An audit schedule shall be prepared and maintained by Compliance and revised as necessary to ensure that all required audits are performed.

21.3 Team Selection

Individuals who are sufficiently trained or experienced in auditing Good Manufacturing Practices are eligible to be considered auditors capable of conducting internal audits. Auditors must be independent of the specific activities in the areas that they audit.

Auditors must have at least one of the following:

- Attended an auditing course at a recognized institution
- Possess a Certified Quality Auditor (CQA) Certification from ASQ
- Conducted two internal audits with the guidance of a qualified auditor.

21.4 Pre-Audit Conference

Prior to conducting the audit the auditor shall review prior audits, determine the scope of the audit, perform a desk study, develop an audit checklist and contact the responsible manager of the area being audited and establish mutually acceptable dates.

21.5 Post-Audit conference

A closing meeting for the management of the area being audited should be held to discuss the audit results.

21.6 Reporting and Response

The audit report shall be prepared within a target of ten days from completion of the audit. Management of the area audited shall ensure any observations raised shall be corrected and *corrective action taken as appropriate to eliminate the nonconformance and their causes.*

21.7 Follow-up Action

Follow-up evaluation of corrective action taken is performed to verify the effectiveness of actions taken. Results of verification are documented. A re-audit of deficient matters is conducted when necessary.

22. REFERENCED DOCUMENTATION

10 CFR Part 71, Subpart H