

Best[®] Theratronics

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February 27, 2009

U.S. Nuclear Safety Commission
One White Flint North
11555 Rockville Pike
Rockville, MD 20852-2738
United States

Re: QA Program Registration for Best Theratronics Ltd.

To Whom It May Concern,

Please accept the attached documents to replace the previously submitted documents for QA Program Registration for Best Theratronics Ltd.

Please see attached:

- 5.00-QA-00 Quality Assurance Manual
- 5.05-QA-01 Radioactive Material Transport Package Quality Plan

The attached documents have been modified to remove the following wording on the front page footer.

This document contains information proprietary to Best Theratronics Ltd.
Any disclosure or use of this information or any reproduction of this document other than the specified purpose for which it is intended is expressly prohibited except as Best Theratronics Ltd. may otherwise agree in writing.

This statement has been removed at the request of the U.S. Nuclear Regulatory Commission so that the documents may be made public on the ADAMS system.

If there is any other information that you may need, please don't hesitate to reach me at the contact information below.

Best Regards,



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QUALITY MANUAL

Signatures

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Quality Manual

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1. DESCRIPTION OF ORGANIZATION

Best Theratronics Ltd. designs, manufactures, installs and services external beam therapy systems and self-contained irradiators.

2. PURPOSE

The purpose of this manual is to provide our company personnel and customers with a single source of information regarding Best Theratronics Ltd. policies, responsibilities and procedures for assuring and controlling conformity to product requirements. This manual ensures compliance with the standards and regulations listed in Appendix D.

3. SCOPE

The quality management system described by this manual applies to all activities associated with Best Theratronics Ltd. products and contract manufacturing products. Any process that affects product conformity to requirements that is outsourced is controlled under the requirements of this manual.

4. QUALITY MANAGEMENT SYSTEM

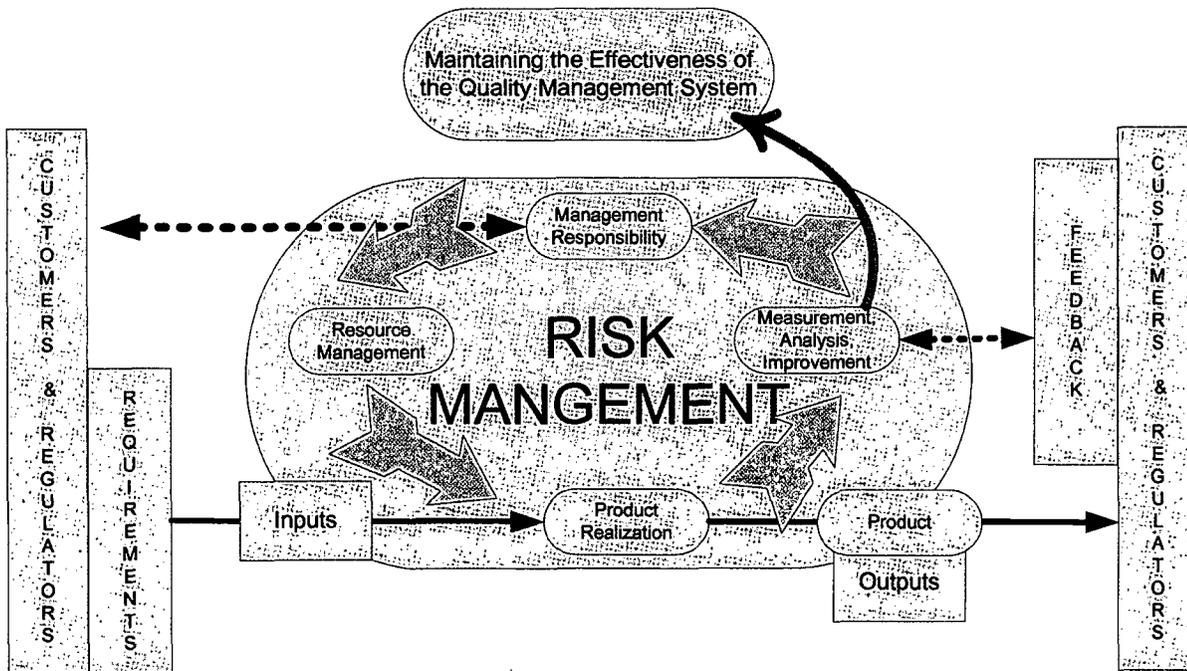
4.1 General Requirements

Best Theratronics Ltd. has established, documented, implemented and maintains a quality management system and continuously improves its effectiveness in accordance with the standards summarized in Appendix D.

Best Theratronics Ltd.:

- Determines the processes needed for the quality management system and their application through the organization;
- Determines the sequence and interaction of these processes;
- Determines the criteria and methods needed to ensure that both the operation and control of these processes are effective;
- Ensures the availability of resources and information necessary to support the operation and monitoring of these processes;
- Monitors, measures where applicable, and analyses these processes;
- Implements actions necessary to achieve planned results and continual improvement of these processes.

The Process Approach



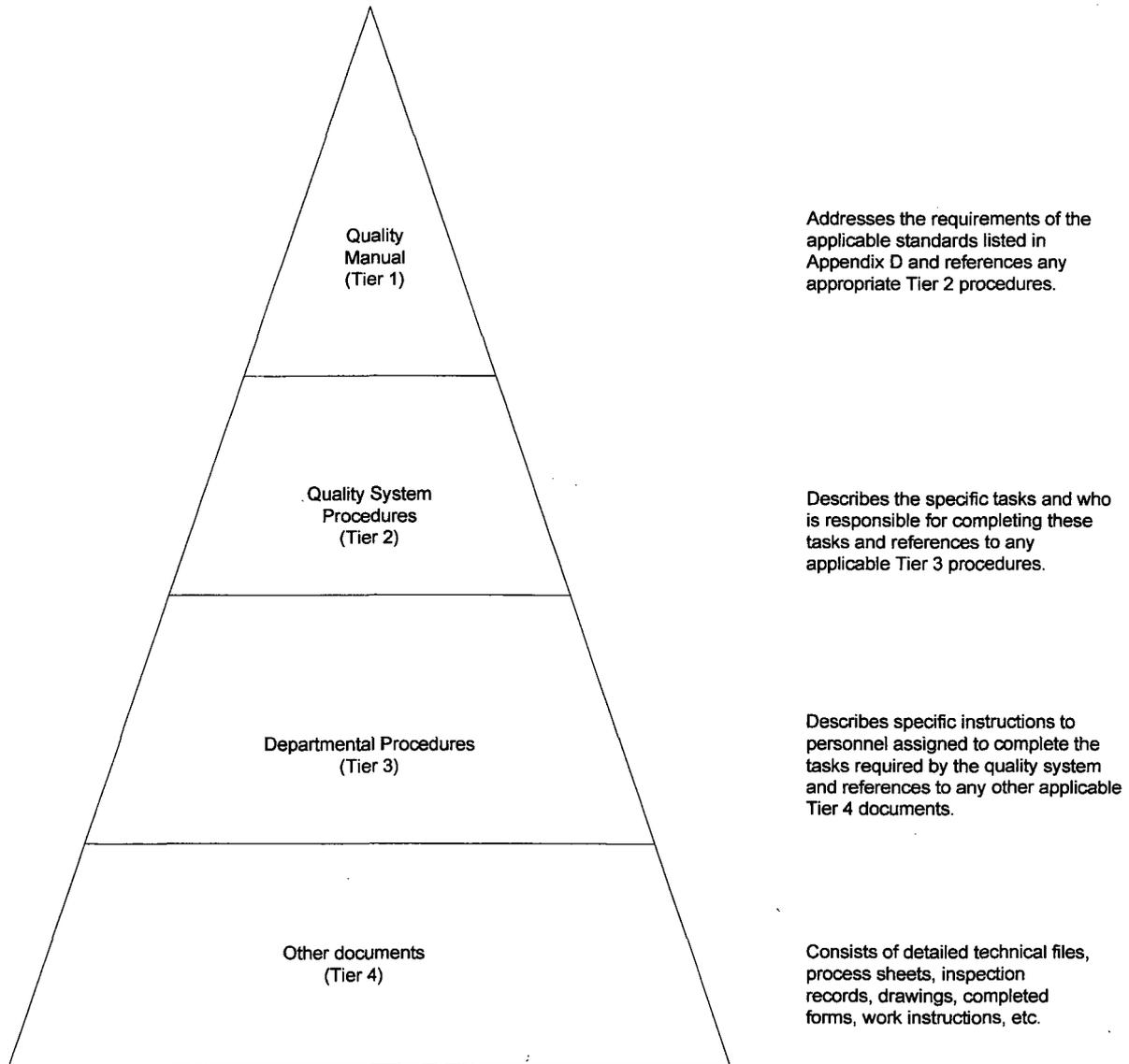
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4.2 Documentation Requirements

4.2.1 General

The Best Theratronics Ltd. quality management system documentation includes:

- Quality policy and quality objectives;
- A quality manual;
- Documented procedures and records required by the standards summarized in Appendix D;
- Documents, including records, determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.



Quality Manual

4.2.2 Quality Manual

This quality manual has been established and continues to be maintained in order to provide the reader with:

- the scope of the quality management system, including details of and justification for any exclusions;
- a reference to documented procedures as defined in Appendix B;
- a description of the interaction between the processes of the quality management system as demonstrated in Appendix A.

4.2.2.1 Exclusions

- ISO 9001:2000 - there are no exclusions.
- ISO 13485:2003 – 7.5.1.2.1, 7.5.1.3, 7.5.2.2
Products are supplied non sterile and are not subjected to a cleaning process.
- ISO 13485:2003 – 7.5.3.2.2
Best Theratronics Ltd. does not manufacture active implantable or implantable medical devices.

4.2.3 Control of Documents

Documents required for the quality management system such as this manual, quality assurance procedures, instructions, checklists and quality system forms are developed, reviewed, approved, distributed and controlled as defined within the applicable procedure in Appendix B, line 4.

Documents of external origin, determined by Best Theratronics to be necessary for the planning and operation of the quality management system, such as regulations, standards, specifications, customer drawings and other documents are controlled within the applicable procedure.

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

All documents are legible, readily identifiable and retrievable.

Document Management maintains a master listing of all documents and data generated. This master listing is readily available to personnel and identifies the current revision status of each document and its date of effectiveness.

Changes or additions to approved documents and data 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.

Invalid and/or obsolete documents are promptly removed from all points of issue or use. Obsolete documents retained for the purposes of legal and/or knowledge-preservation are identified as "Obsolete" and controlled.

Procedures are established to define the retention period of obsolete controlled documents. The retention period ensures that records are available for at least the lifetime of the device as defined within the applicable procedure in Appendix B, line 15.

4.2.4 Control of Quality Records

Records have been established, maintained and controlled to provide evidence of conformity to requirements and of the effective operation of the quality management system. These records are legible, readily identifiable and retrievable.

The methodology used for the identification, storage, protection, retrieval, retention time and disposition of quality records is defined within the applicable procedure in Appendix B, line 15.

Storage and backup of electronic documents/records, utilizing the company network system, are controlled as per Best Theratronics Ltd. practices.

4.3 Quality Compliance

Compliance with Canadian Medical Device Regulations is required when a product is classified as a medical device. See Appendix G for details of additional requirements.

Compliance with European Directives is required when a product is classified as a medical device intended for the European market. See Appendix H for details of additional requirements.

Compliance with FDA Good Manufacturing Practice is required when a product is classified as a medical device and distributed in the United States. See Appendix I for details of additional requirements.

Compliance with Canadian Standards Association CAN3-Z299 is required when CAN3-Z299 is specified in Technical Specifications, procurement contracts or when required by the governing regulatory authority for products. See Appendix E for details of additional requirements of the CSA Z299 standard.

Compliance with the Canadian Nuclear Safety Commission (CNSC) is required for use of nuclear energy and material to protect health, safety, security and the environment. Best Theratronics Ltd. maintains certificates and licenses as per CNSC regulation.

Compliance with the United States Nuclear Regulatory Commission requirements in CFR Part 71, Subpart H is required when Radioactive Material Type A and Type B transport packaging is used. See Appendix F for details.

5. MANAGEMENT RESPONSIBILITY

5.1 Management Commitment

Best Theratronics Ltd. is committed to the development and implementation of the quality management system 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 organizational 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 quality management system;
- ensuring the availability of resources to implement and improve the processes for the quality management system;

5.2 Customer Focus

Best Theratronics Ltd. management ensures that customer requirements are determined, met and converted into product, service and/or quality system requirements as defined under sections 7.2. and 8.2.1.

5.3 Quality Policy

Best Theratronics is committed to developing, manufacturing, installing and servicing safe, quality products and to continually improving the effectiveness of the quality management system to meet customer and regulatory requirements for health care and research products and services.

The quality policy:

- is appropriate to the purposes of Best Theratronics Ltd.;
- includes a commitment to meeting requirements and maintaining effectiveness of the quality management system;
- provides a framework for establishing and reviewing quality objectives;
- is communicated and understood within the organization through posting of the policy in locations within the facility and through employee training;
- is reviewed for continued suitability during management reviews.

5.4 Planning

5.4.1 Quality Objectives

Quality objectives are established by management and communicated to employees at all levels and functions within the organization. These objectives are set through the management review process and are measurable and consistent with the quality policy.

5.4.2 Quality Management System Planning

Management ensures that:

- the planning of the quality management system is carried out in order to meet requirements given in 4.1 as well as the quality objectives;
- the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

5.5 Responsibility, authority and communication

5.5.1 Responsibility and Authority

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. These are described in Appendix C.

5.5.2 Management Representative

The Director, Compliance has been appointed as the Management Representative having responsibility and authority that includes:

- ensuring that processes of the quality management system are established, implemented and maintained;
- 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 management system.

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5.5.3 Internal Communication

The processes of the quality management system and their effectiveness are adequately communicated and understood within the organization. This is achieved by means such as:

- management review meetings;
- company intranet;
- company meetings;
- team meetings;
- other forms of communication.

5.6 Management Review**5.6.1 General**

Management reviews the quality management system at planned intervals to ensure its continuing suitability, adequacy and effectiveness. The management review team evaluates the need for improvement and/or changes to the organization's quality management system, including the Quality Policy and quality objectives as defined within the applicable procedure in Appendix B, line 23. Records of these reviews are maintained.

5.6.2 Review Input

Inputs to management reviews include the following sources of information as indicators of performance.

- audit results;
- customer feedback;
- process performance and product conformance;
- status of preventive and corrective actions;
- status of action items from previous quality management reviews;
- changes that could affect the quality management system;
- recommendations for improvement;
- new or revised regulatory requirements.

5.6.3 Review Output

Outputs from management reviews include decisions made and actions taken related to:

- improvements needed to maintain the effectiveness of the quality management system and its processes;
- improvement of product related to customer requirements;
- resource needs.

6. RESOURCE MANAGEMENT

6.1 Provision of Resources

Best Theratronics Ltd. determines and provides the resources needed to:

- meet regulatory and customer requirements;
- implement, maintain its effectiveness and continually improve the quality management system;
- enhance customer satisfaction.

6.2 Human Resources

6.2.1 General

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

Best Theratronics Ltd. has identified resource requirements and provided adequate resources, including the assignment of trained personnel for management, performance of work and verification activities including internal quality audits.

6.2.2 Competency, Training and Awareness

Each manager identifies the competency needs for employees performing activities that affect conformity to product requirements within their department.

Based on these needs, required training or other actions to satisfy these needs is identified and provided to employees through on-the-job instruction, internal or external training.

Employees are aware of the relevance and importance of their activities and how they contribute to the achievement of quality objectives.

The procedure for identifying competency needs, coordinating training, maintaining training records and evaluating its effectiveness is defined within the applicable procedure in Appendix B, line 20.

6.3 Infrastructure

6.3.1 General

Best Theratronics Ltd. facilities are subject to requirements of the Canadian Nuclear Safety Commission (CNSC), Environment Canada, FDA, Health Canada, the Ontario Ministry of Environment and the appropriate building codes, as well as Good Manufacturing Practices. All facilities and processes comply with the requirements set out in applicable legislation and in Best Theratronics Ltd.'s radioisotope licenses.

6.3.1.1 Buildings, Workspace and associated utilities and equipment

Buildings are of suitable design and contain sufficient space to perform necessary operations, prevent mix-ups, and assure orderly handling. To ensure continuous quality output, process equipment as well as office and shop buildings and utilities are routinely maintained.

Documented requirements for maintenance activities, including their frequency, are established, when such activities or lack thereof can affect conformity to product requirements. Maintenance activities are documented.

6.3.1.2 Process Equipment (including hardware and software)

To ensure that only acceptable monitoring and measuring hardware and software are used to verify and validate products and processes, all such devices are controlled and subject to calibration as defined within section 7.6.

6.3.1.3 Supporting Services

All required support services and processes to ensure the achievement of product conformity, continual system improvement and customer satisfaction are provided as identified within this quality manual.

6.4 Work Environment

To ensure product conformity, Best Theratronics Ltd. determines and manages the work environment needed to ensure conformity to product requirements as defined.

6.4.1 Personnel

Documented procedures stating the requirements for health, cleanliness and required apparel have been established where contact between personnel and the product or environment could adversely affect the quality of the product.

6.4.2 Environmental Control

Where environmental conditions or the possibility of contamination could reasonably be expected to have an adverse effect on conformity to product requirements, Best Theratronics Ltd. has established and maintains procedures to adequately control these conditions.

Where manufacturing material could reasonably be expected to have an adverse effect on conformity to product requirements Best Theratronics Ltd. has established and maintains procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material is documented.

Environmental control systems are periodically inspected to verify that the system, including necessary requirements, is adequate and functioning properly. These activities are documented and reviewed.

7. PRODUCT REALIZATION

7.1 Planning of Product Realization

7.1.1 General

Best Theratronics Ltd. 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 quality management system.

In planning product realization, Best Theratronics Ltd. 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 in Appendix B, line 24.

7.2 Customer Related Processes

7.2.1 Determination of requirements related to the product

All customer requirements are documented and include:

- customer specific requirements including delivery and post delivery activities;
- regulatory and statutory requirements applicable to the product;
- requirements necessary for the intended use of the product but not stated by the customer or as determined by Best Theratronics Ltd.

7.2.2 Review of requirements related to the product

Customer orders are reviewed against the original proposal to ensure that all requirements have been defined and documented, and that Best Theratronics Ltd. has the ability to meet the requirements, before committing to supply the product to the customer.

Any discrepancy between the customer order and the proposal will be documented and resolved with the customer before acceptance.

Where product requirements are changed, Best Theratronics Ltd. assures that relevant documents are amended and relevant personnel are made aware of the changed requirements

Records of these activities are documented and maintained.

7.2.3 Customer Communication

The methodology used and the personnel responsible for processing customer inquiries, proposals, orders, contract amendments and customer feedback, is defined within the applicable procedure in Appendix B, line 2.

Best Theratronics Ltd. has established and maintains procedures to specify the responsibilities, requirements and methods for receiving, recording, classifying, investigating, analysing, reporting and resolving all complaints received by Best Theratronics Ltd. as defined in section 8.2.

Where a product quality complaint investigation determines that the activities at a user site contributed to the complaint, relevant information is communicated to the user site.

Documented procedures have been established to ensure notification of regulatory authorities of incidents that meet the reporting criteria as defined within the applicable procedure in Appendix B, line 25.

7.3 Design and Development

The methodology used and the personnel responsible for planning, conducting, reviewing, verifying, validating and controlling design and development activities is defined within the applicable procedure in Appendix B, line 3. Design History Files and Device Master Records are maintained for each medical device.

7.3.1 Design and Development Planning

Design and development planning includes:

- determining each design and development stage involved;
- determining review, verification and validation activities appropriate for each design and development stage;
- defining the responsibilities and authorities for design and development activities.

All technical and organizational interfaces between groups that are to participate in the design and development process are identified and managed to ensure effective communication and clarity of responsibilities.

Design and development planning documents are updated, as appropriate, as the design and development progresses.

The design process includes an evaluation for the need for risk analysis and maintenance of records of any risk analyses performed.

7.3.2 Design and Development Inputs

All design and development requirements and data are identified, documented and reviewed and approved by the appropriate authority for adequacy. These inputs include:

- functional, performance and safety requirements according to intended use;
- applicable statutory and regulatory requirements;
- applicable information derived from previous similar designs;
- output of risk management.
- other requirements determined as essential;

Any requirements that are determined as incomplete, ambiguous or conflicting are resolved between the technical authority and the originating source.

7.3.3 Design and Development Outputs

All design and development outputs are provided in a form suitable for verification against established design and development input requirements.

Design and development outputs:

- meet the design and development input requirements;
- provide appropriate information for purchasing, production and service operations;
- contain or reference the criteria for product acceptance;
- encompass the relevant statutory and regulatory requirements;
- define those design characteristics that are crucial to safety and proper product use.

All design and development output documents are reviewed and approved prior to release and are updated as required, as the design or development progresses.

7.3.4 Design and Development Review

At suitable stages of the design and/or development, systematic reviews are planned, performed and documented to evaluate the ability of the design to meet requirements, identify any problems and propose necessary actions.

Design and development review participants include:

- representatives of the functions concerned with the design and development stage(s) being reviewed;
- an individual with appropriate technical expertise who does not have direct responsibility for the design stage being reviewed;
- other specialist personnel when considered necessary.

Results of these reviews and subsequent necessary actions are recorded within design/development review minutes.

7.3.5 Design and Development Verification

Design and development verification is performed in accordance with planned arrangements based on the complexity of the work involved to ensure that the design and development outputs meet the design and development input requirements.

Results of design and development verification and subsequent necessary actions are recorded and kept on file.

7.3.6 Design and Development Validation

Design and development validation is performed in accordance with planned arrangements to ensure that resulting product or process conform to defined user requirements and will be capable of meeting the intended use.

Whenever practicable, full design and development validation is completed prior to delivery or implementation. When this is impractical, partial validation is performed to the extent applicable.

Results of design and development validation and subsequent necessary actions are recorded and kept on file.

7.3.7 Control of Design and Development Changes

All design and development changes are identified, documented, reviewed, verified, validated as appropriate, controlled and approved prior to implementation.

This review process includes evaluating the effect the change(s) will have on related components and parts as well as products which have already been delivered.

Review of design and development changes and subsequent necessary actions are recorded and kept on file.

7.3.8 Design Transfer

Best Theratronics Ltd. has established and maintains procedures to ensure that the device design is correctly translated into production specifications.

7.3.9 Design History File

Best Theratronics Ltd. has established and maintains design history files for each type of device. The design history file contains or references the records necessary to demonstrate that the design was developed in accordance with the approved design plan and the requirements of this part.

7.4 Purchasing

7.4.1 Purchasing Process

To ensure that purchased products conform to all quality and contractual requirements, Best Theratronics Ltd. conducts and controls all of its purchasing processes as defined within the applicable procedure in Appendix B, line 6. These procedures ensure all relevant purchasing data is retained.

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.

The methodology used and the personnel responsible for evaluating and selecting suppliers is based on their ability to meet the contract or order specifications and quality requirements prior to the start of work.

The criteria for supplier selection, evaluation and re-evaluation is based on the criticality and classification of the products to be purchased .

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

7.4.2 Purchasing Information

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.

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

7.4.3 Verification of Purchased Product

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

Where Best Theratronics Ltd. or its customer intends to perform verification at a supplier's premises, Best Theratronics Ltd. 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 section 8.3.

7.5 Production and Service Provision

7.5.1 Control of Production and Service Provision

7.5.1.1 General Requirements

Best Theratronics Ltd. plans and carries out production and service operations under controlled conditions. Controlled conditions include the following, as applicable:

- All information pertaining to product characteristics, including the criteria for acceptance is identified or referenced within the applicable procedures.
- To ensure continuous quality output, only suitable process equipment is used. All process equipment is routinely maintained.
- Only valid, calibrated monitoring and measuring equipment are used to verify production processes and products.
- Work in progress is monitored to ensure good workmanship standards and that specification compliance is being maintained.
- All resulting products are subject to inspection and/or testing;
- Preparation for shipment, product release, delivery and post-delivery activities are performed and monitored.
- Special processes utilized to perform work which directly affect quality is accomplished under controlled conditions as defined within the applicable procedure in Appendix B, line 13;
- Procedures defining the manner of production, installation, maintenance and servicing are established where the absence of such procedures could adversely affect quality;
- Suitable process parameters and product characteristics are monitored and controlled;
- Processes and equipment are approved as appropriate;
- Criteria for workmanship is stipulated in the clearest practicable manner such as written standards, representative samples or illustrations.
- Procedures for changes to a specification, method, process, or procedure are established and maintained. Such changes are verified, or where appropriate validated before implementation and these activities are documented.

7.5.1.2 Installation activities

Documented procedures are in place to provide adequate installation and testing instructions for devices requiring installation as defined within the applicable procedure in Appendix B, line 14.

Installation and testing is performed according to Best Theratronics Ltd. instructions regardless of the installer's affiliation with the company.

7.5.1.3 Servicing activities

Best Theratronics Ltd. has established, and maintains, documented procedures for performing, verifying and reporting that servicing meets the specified requirements as defined within the applicable procedure in Appendix B, line 1.

7.5.2 Validation of Processes for Production and Service Provision

Best Theratronics Ltd. validates all production and service processes where resulting output cannot be verified by subsequent monitoring or measurement including and, as a consequence:

- where product deficiencies will only be apparent after the product is in use or the service has been delivered;
- where validation of product is not possible.

Validation demonstrates the ability of these processes to achieve planned results.

Arrangements for these processes are established by Best Theratronics Ltd. including, as applicable:

- criteria for review and approval of process;
- approval of equipment and qualification of personnel;
- use of specific methods and procedures;
- requirements for records;
- re-validation.

The methodology used and the personnel involved in qualifying processes, equipment and personnel as well as the records to be maintained are in accordance with procedure as defined in section 7.3.

Validation of NC programs prior to production use will include verification of the first article produced to the design/data specification. There are no computer software applications for production or service requiring validation.

7.5.3 Identification and Traceability

A suitable identification system is maintained throughout the product realization cycle. This includes identification of inspection and test status, unique identification of items where traceability is required, and identification of product returned by the customer. These are controlled as defined within the procedures in Appendix B line 8 and line 12.

7.5.4 Customer Property

Unless otherwise defined by contract, upon receipt of customer property, Best Theratronics Ltd. examines items for completeness, proper identification and possible transit damage and identify these items as the property of the relevant customer as defined within the applicable procedure in Appendix B, line 18.

After receipt, Best Theratronics Ltd. exercises care to ensure the protection of customer property against loss or damage until such time as it is incorporated into a product or returned to the customer. Any customer property found to be nonconforming is reported to the customer and records are maintained as defined in section 8.3.

Best Theratronics Ltd. identifies, segregates, handles and protects customer property from time of receipt, subsequent storage, maintenance and during the entire product realization cycle.

Customer supplied products also includes intellectual property and personal data.

7.5.5 Preservation of Product

Best Theratronics Ltd. preserves the conformity of product during internal processing and delivery to the intended destination in order to maintain conformity to requirements.

Best Theratronics Ltd. has established and maintains, documented procedures for the identification, handling, storage, packaging, preservation and delivery of constituent parts of a product and final product as defined within the applicable procedure in Appendix B, line 14.

7.5.6 Handling

Methods for handling product in order to prevent mix-ups, contamination, damage, deterioration or other adverse effects are described as defined within the applicable procedure in Appendix B, line 14.

7.5.7 Storage

Designated storage areas and stock rooms are used to prevent damage or deterioration of product pending use or delivery. Appropriate methods for authorizing receipt to or dispatch from these areas is documented and described as defined within the applicable procedure in Appendix B, line 14. The condition of product in stock is assessed at appropriate intervals to detect deterioration. Procedures have been established for the control of product with a limited shelf-life or requiring special storage conditions.

7.5.8 Packaging

The control of packing, packaging and marking processes (including materials used) is documented as defined within the applicable procedure in Appendix B, line 14 to ensure compliance to specified requirements.

7.5.9 Labelling

Labels and labelling on finished devices, accessories and spare parts are maintained as defined within the applicable procedure in Appendix B, line 22.

7.6 Control of Monitoring and Measuring Equipment

The methodology to be used and the personnel responsible for conducting, documenting and controlling calibration of monitoring and measuring equipment as defined within the applicable procedure in Appendix B, line 5.

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.

Any monitoring or measuring equipment observed during calibration as beyond the acceptance criteria limits established for that equipment type is removed from service and processed.

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.

Monitoring and measuring equipment, including test hardware and software, are safeguarded from adjustments that would invalidate the measurement results.

All monitoring and measuring equipment are removed from use by the date that calibration is due and is protected against damage and deterioration during handling, maintenance and storage.

Calibration records are maintained and updated throughout the life of each monitoring or measuring equipment. These records reflect the dates on which calibrations were performed, the accuracy of results obtained during calibration and any adjustments or re-adjustments made.

Computer software used for monitoring and measuring of specified requirements is validated prior to initial use and reconfirmed as necessary.

Calibration certificates received from outside laboratories and internally generated calibration records, are retained on file in accordance with section 4.2. These records are made available to the customer upon request.

8. MEASUREMENT, ANALYSIS AND IMPROVEMENT

8.1 General

The monitoring, measurement, analysis and improvement process needed are planned and implemented to:

- demonstrate conformity to product requirements throughout the realization cycle
- ensure conformity of the quality management system
- continually improve the effectiveness of the quality management system
- determination of applicable methods, including statistical techniques, and the extent of their use
- to maintain the effectiveness of the quality management system

8.2 Monitoring and Measurement

8.2.1 Customer Satisfaction/Feedback

Best Theratronics Ltd. monitors information relating to customer perception as to whether customer requirements have been met. This information is gathered through the customer complaint systems, as defined within the applicable procedure in Appendix B, line 21.

Post-market surveillance

Data is analyzed and used to determine opportunities for improvement, such as:

- correction or prevention of nonconformities;
- continuous improvement.
- Service record review

8.2.2 Internal Audit

The Internal Quality Audit system is implemented and maintained by the Quality Assurance department. Records of the audits and their results are maintained. The audit scope, frequency, methodology used and the personnel responsible for planning, conducting, reporting and following up on internal quality audits is as defined within the applicable procedure in Appendix B, line 7. Audits are conducted by personnel who are independent of those who have direct responsibility for the activity being audited. Audits are scheduled on the basis of the status and importance of the activity being audited.

Results of audits are brought to the attention of the management having responsibility for the area being audited. Follow-up evaluation of corrective action taken is performed to verify the actions taken. Results of verification are documented. A re-audit of deficient matters, is conducted when necessary.

8.2.3 Monitoring and Measurement of Processes

Best Theratronics Ltd. processes are monitored through the internal audit program, as defined in section 8.2.2. The methods of monitoring demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action are taken, as appropriate.

8.2.4 Monitoring and Measurement of Product

8.2.4.1 General

Any product observed as nonconforming is identified and processed as defined within section 8.3.

Best Theratronics Ltd. has identified the need for statistical techniques for establishing, controlling and verifying process capability and product characteristics describing the implementation and control process where required as defined within the applicable procedure in Appendix B, line 19.

These activities are identified and documented within procedures and include the following stages of product realization:

8.2.4.2 Receiving Inspection and Testing

All incoming materials affecting conformity to product requirements are inspected according to approved, documented procedures before release to production, inventory or storage as defined within the applicable procedure in Appendix B, line 9.

Submitted objective evidence of the supplier's verification of conformity to product requirements may also be reviewed and evaluated by Best Theratronics Ltd. to determine if quality and contract requirements have been met.

8.2.4.3 In Process Inspection and Testing

Where required, in-process inspection and testing is conducted as detailed within the applicable procedure in Appendix B, line 10.

Where required, in-process verifications are accomplished at hold points identified within 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.

8.2.4.4 Final Inspection and Testing

All finished products are subject to final verification and/or testing prior to shipping as defined within the applicable procedure in Appendix B, line 11.

Finished devices are adequately controlled until released.

Finished devices are not to be released for distribution until:

- the product meets all specification requirements
- the associated data and documentation is reviewed
- the release is approved by Quality Assurance

Unless otherwise approved by the customer, only items that fully meet contract requirements are shipped to the customer.

8.2.4.5 Inspection and Test Records

All quality records identify the personnel responsible for authorizing product release are filed and maintained as defined within in section 4.2.3.

Inspection and test records indicate the acceptance activity performed, date of activity, results of activity, signature of personnel conducting the acceptance activity and if appropriate the equipment used as defined within the applicable procedure in Appendix B, line 26. These records are part of the Device History Record or batch record and are maintained as per the applicable procedure in Appendix B, line 15.

8.3 Control of Nonconforming Product

8.3.1 General

Nonconforming product is controlled as defined within the applicable procedure in Appendix B, line 16. These procedures ensure that nonconforming product is identified and controlled to prevent unintended use or delivery.

The controls, responsibilities, authorities and methods for managing nonconformities is documented.

Nonconforming material is identified, documented, segregated (where practical), evaluated and dispositioned. This process is documented as described below.

8.3.2 Review and Disposition of Nonconforming Product

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.

Rework/reevaluation activities for devices are documented in the Device History Record.

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.

8.3.3 Reports and Follow-up Actions

In the event that nonconformances are detected after delivery or use has started, Best Theratronics Ltd. notifies the customer, end user, and/or regulatory body as defined in section 7.2.3.

8.4 Analysis of Data

Best Theratronics Ltd. collects and analyzes appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made. Data analysis provides information relating to feedback, conformity of product requirements, characteristics and trends of processes and products including opportunities for preventive action. Analysis of data is carried out and records maintained in accordance with Appendix B, line 27.

8.5 Improvement

8.5.1 Continual Improvement

Best Theratronics Ltd. continually improves the effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, quality management reviews and operations reviews.

8.5.2 Corrective Action

Best Theratronics Ltd. promptly corrects nonconformances and conditions adverse to quality when discovered.

To prevent recurrence, these nonconformances are investigated in order to:

- determine the causes of the nonconformity;
- evaluate the need for actions to prevent recurrence;
- determine and implement required corrective action;
- record results of action taken;
- reviewing the effectiveness of the corrective action taken

8.5.3 Preventive Action

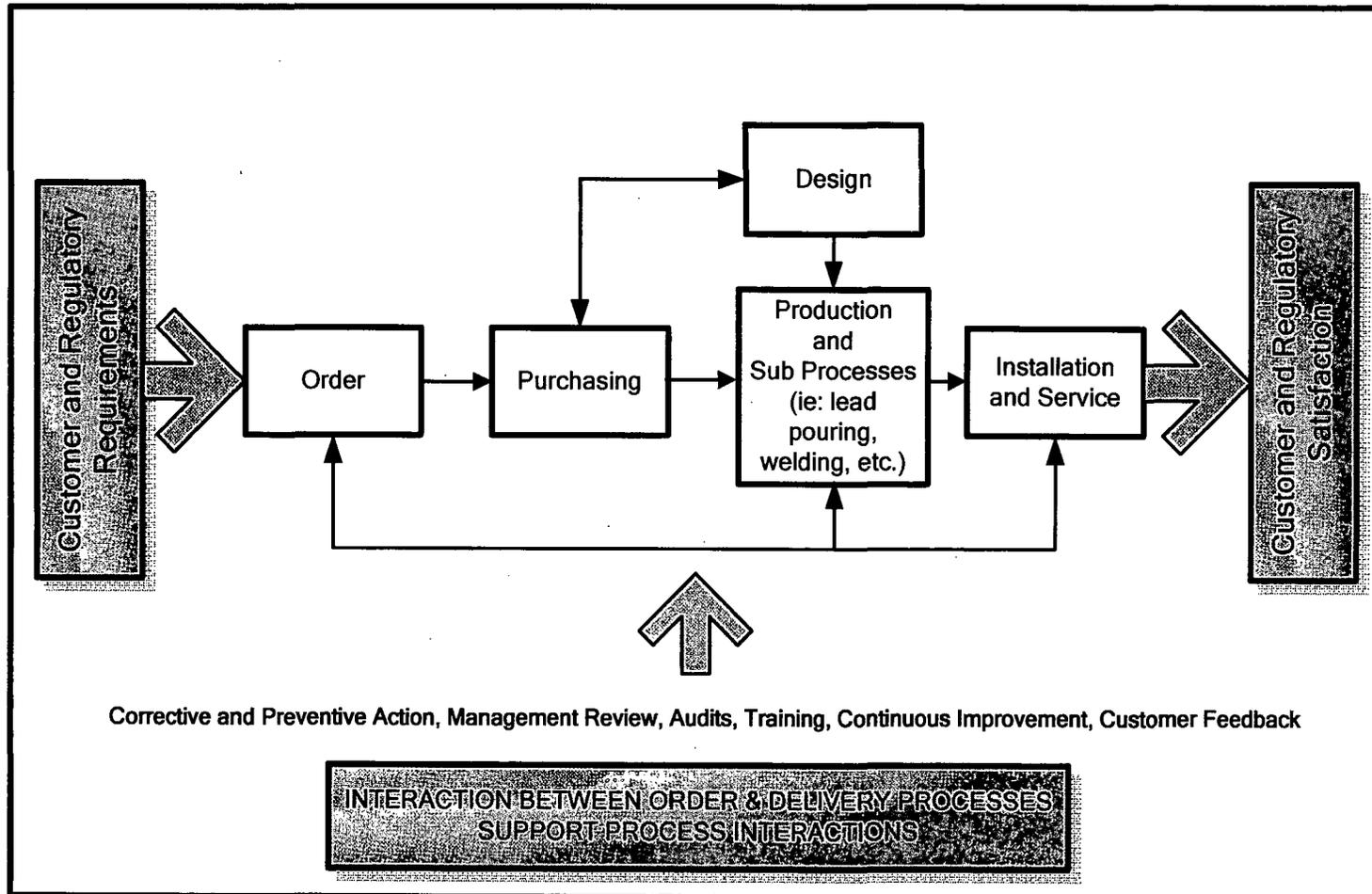
Potential nonconformances are also investigated in order to:

- determine their causes;
- evaluate the need for action to prevent the occurrence of nonconformances;
- determine and ensure the implementation of preventive action needed;
- record the results of action taken;
- reviewing the effectiveness of the preventive action taken.

Corrective and preventive action taken is appropriate to the magnitude of the problem(s) and risk(s) involved.

The methods used and the personnel responsible for determining the steps required to deal with problems requiring either corrective or preventive action, for initiating these actions and for establishing controls to ensure their effective implementation is as defined within the applicable procedure in Appendix B, line 17.

**APPENDIX A
Processes**



Quality Manual

APPENDIX B
Quality System Tier 2/Tier 3 Procedures

Line #	Description	Procedure
1	General Service Guideline	4.01 family of procedures
2	Contract Review	5.00-QA-03
3	Design Control	5.00-QA-04
4	Control of Documents	5.00-QA-05
5	Process Equipment, including Measuring and Test Equipment	5.00-QA-06
6	Procurement	5.00-QA-07
7	Internal Quality Audits	5.00-QA-08
8	Inspection and Test Status	5.00-QA-09
9	Incoming Inspection	5.00-QA-10
10	In-Process Inspection	5.00-QA-11
11	Final Inspection/Finished Device Inspection	5.00-QA-12
12	Identification and Traceability	5.00-QA-13
13	Process Control	5.00-QA-15
14	Handling, Storage, Packaging, Preservation, Delivery & Installation	5.00-QA-17
15	Quality Records	5.00-QA-18
16	Nonconformance	5.00-QA-19
17	Corrective Action and Preventive Action	5.00-QA-20
18	Customer Supplied Products or Service	5.00-QA-21
19	Statistical Techniques	5.00-QA-22
20	Training	5.00-QA-23
21	Complaint Handling	5.00-QA-24
22	Labelling	5.00-QA-25
23	Management Review Team	5.00-QA-28
24	Device Design Risk Management	5.00-QA-29
25	Field Actions	5.00-QA-30
26	Release for Shipment	5.00-QA-31
27	Analysis of Data	5.00-QA-32

APPENDIX C Management Responsibilities

General Manager: has the primary responsibility to ensure that Best Theratronics Ltd. conforms with the overall quality program and to review the quality policy to ensure consistency and relevance with changing objectives and evolving, long term marketing conditions.

Director, Compliance: has the overall responsibility for the implementation and compliance of the quality, regulatory, environmental and safety programs.

Director, Operations: has the overall responsibility for manufacturing operations of all products and components manufactured by Best Theratronics Ltd.

Manager, Technical Services: has the overall responsibility for performing installation to ensure that all of the Company's products are installed and commissioned such that they meet Company Quality Assurance and product specifications. Technical Services provides parts, cobalt replacement sources, maintenance and servicing support in a professional, helpful and competent manner to all Best Theratronics Ltd. customers and agents throughout the world.

Manager, Engineering: has the overall responsibility for design, development and technical support of products. Engineering is responsible for changes to existing products within the company product lines.

Director, Global Sales & Marketing: has the overall responsibility to provide knowledgeable advice on the full range of Best Theratronics Ltd. products to customers and agents throughout the world and to ensure that customer needs and expectations will be fulfilled in the sales orders that may result. The Director, Global Sales & Marketing is responsible for marketing activities worldwide for all Best Theratronics Ltd. products while improving marketing efforts for all products.

Manager, Human Resources: has the overall responsibility for employee/labour relations, staffing and compensation.

Quality Manual

APPENDIX D Applicable Standards

Document Reference	Standard/Regulation Title
ISO 9001	Quality Management Systems – Requirements
ISO 13485	Medical devices – quality management systems – Requirements for regulatory purposes
N/A	Canadian Medical Devices Regulations
21 CFR 820	Quality Systems Regulation
21 CFR 11	Electronic records; Electronics Signatures
93/42EEC	Europe Medical Device Directive COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device
CAN 3-Z299.2	Canadian Standards Association Quality Standard
N/A	Canadian Nuclear Safety & Control Act and applicable regulations.
10 CFR Part 71	Nuclear Regulatory Regulation, Title 10, Code of Federal Regulations - Packaging and Transportation of Radioactive material, Subpart H -Quality Assurance.
ISO 14971	Medical devices – Application of risk management to medical devices.

APPENDIX E
Canadian Standards Association
CAN3-Z299 ELEMENT

Scope

The quality assurance requirements in this appendix apply when CAN3-Z299 is specified in Technical Specifications, procurement contracts or when required by the governing regulatory authority for products.

Manufacturing, Inspection and Test Plan

Best Theratronics Ltd. has established, and maintains documented procedures indicating the requirements for inspection, test and verification of items and services for all phases of a manufacturing contract.

Quality Assurance and Manufacturing Engineering are responsible for preparing and approving Manufacturing, Inspection and Test Plans in accordance with 5.03-AA-23, "Manufacturing, Inspection and Test Plans".

In-process verifications are accomplished at hold points identified within MITP's and in accordance with documented procedures and relevant instructions.

Quality Program Levels

Best Theratronics Ltd. has established the responsibilities and methods for evaluating the need for and selecting appropriate program levels to be assigned to suppliers for the procurement of items or services.

Quality Assurance in conjunction with Production Planning and Manufacturing Engineering staff are responsible for selecting the program levels in accordance with 5.03-AA-24, "Quality Program Levels".

External Audits

Best Theratronics Ltd. has established the responsibilities for planning and implementing external supplier audits to evaluate and verify the effectiveness of compliance with the quality program standards.

Quality Assurance and Purchasing are responsible for planning and implementing supplier audits in accordance with 3.13-AA-01, "Supplier Qualification Program".

Verification of Quality by Customers

Where specified in the contract, the customer representative may perform a product inspection or Quality System audit and will be provided with the facilities and support required for the proper accomplishment of their work, as defined in the contract.

APPENDIX F
United States Nuclear Regulatory Commission
10 CFR Part 71

Scope

The quality assurance requirements in this appendix apply to USNRC licensed packaging used for transportation of radioactive materials, Material Type A and Type B Transport Packages. eg: F127, F431.

Quality Assurance Program

Best Theratronics Ltd. has established a quality assurance program that complies with the requirements of §§71.101 through 71.137, as described throughout this manual.

Quality Plan

Best Theratronics Ltd. has established a quality plan describing how the quality assurance requirements for the design, fabrication, assembly, testing, maintenance, repair, modification and use of Best Theratronics Ltd. radioactive material (RAM) transport packaging are achieved. The Quality Plan is described in procedure 5.05-QA-01, Radioactive Material Transport Package Quality Plan.

It identifies the activities, responsibilities and actions necessary to ensure that all regulatory, customer and internal QA program requirements that are important to safety are met.

General

Domestic shipments (shipments which originate and terminate within the United States) in packages which a foreign national competent authority certificate has been revalidated by the United States Department of Transportation are not authorized.

Activities conducted regarding transportation packaging are to be executed under applicable criteria of 10 CFR Part 7,1 Subpart H. Authorized activities include: design, procurement, fabrication, assembly, testing, modification, maintenance, repair and use of transportation packaging.

Records and Quality Assurance Records

Records of each shipment of licensed material are maintained for 3 years after that shipment.

Records providing evidence of packaging quality are maintained for 3 years after the life of the packaging.

Records describing activities affecting packaging quality are maintained for 3 years after the quality assurance program approval is terminated.

Internal Inspections

Inspections are performed by individuals other than those who performed the activity being inspected.

APPENDIX G
Canadian Medical Device Regulations
Health Canada

Scope

Additional medical device requirements to comply with the Canadian Medical Device Regulations are as follows:

Responsibilities

Quality Assurance:

- Ensures classification of medical devices as required in accordance with CMDR.
- Informs Health Canada in writing of any changes to the process, service or quality management system which may affect product certification or compliance. Any substantial proposed modification to the product, changes to license applications, amendments or renewals are in accordance with procedure 5.03-AA-36, "Conformity Assessment of Medical and Non-Medical Devices".
- Renews the Health Canada Medical Device Licence, annually. Health Canada will forward Best Theratronics Ltd. the forms to be completed prior to November 1st of each year. This includes signing to confirm the information on file for the device is still correct or describing any changes.
- Submits a copy of a new or modified quality system certificate (SCC ISO 13485) to Health Canada within thirty days of issue.
- Informs Health Canada within thirty days after the discontinuance of the sale of a licenced medical device in Canada.
- Maintains in the Device History Record any Export Certificates prepared for devices that have not received Health Canada approval.

APPENDIX H

European Directives

Scope

Additional medical device requirements to comply with the European Medical Device Directives are as follows:

Responsibilities

Quality Assurance:

- Informs the notified body in writing of any substantial proposed modification to the product, process, service or quality management system which may affect product certification or compliance with the documents listed in Appendix D. Any change to the designated person who maintains contact with the notified body is also confirmed in writing to the notified body.
- For devices imported into the European community, the instructions for use contain the name and address of the authorized representative of Best Theratronics Ltd. established within the Community or of the importer established within the Community, as appropriate.
- Ensures classification as required by the applicable regulations is in accordance with the European Medical Device Directive 93/42/EEC (MDD) and the Health Canada Medical Device Regulations.
- Ensures preparation of technical file summaries, declaration of conformities and essential requirements in accordance with European Medical Device Directive.

APPENDIX I
Food & Drug Administration
21 CFR Part 820

Scope

Additional medical device requirements to comply with FDA 21CFR Part 820 are as follows:

Responsibilities

Quality Assurance:

- Ensures the annual Establishment Registration is renewed.
- Prepares annual reports (September 1) in accordance with 21 CFR Part 1002 on the Raycell product line. Reports cover the 12-month period ending on June 30 preceding the due date of the report.
- Prepares Premarket Notification 510(k) in accordance with 21 CFR Part 807.
- Prepares medical device reports in accordance with 21 CFR Part 803 and Best Theratronics Ltd. procedure 5.00-QA-24, "Complaint Handling".
- Prepares Corrections & Removals in accordance with 21 CFR 806 and Best Theratronics Ltd. procedure 5.00-QA-24, "Complaint Handling".

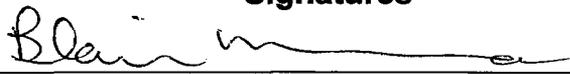
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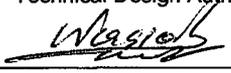
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RADIOACTIVE MATERIAL TRANSPORT PACKAGE QUALITY PLAN

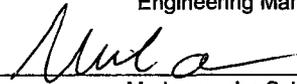
Signatures

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Document History

Effective	Version	Comments	Prepared By	Reviewed By	Approved By
08-10-14	1	Original Issue	B. Menna	T. Wasiak	M. de van der Schueren

Radioactive Material Transport Package Quality Plan

1. PURPOSE

This Quality Plan describes how the quality assurance requirements for the design, fabrication, assembly, testing, maintenance, repair, modification and use of Best Theratronics radioactive material (RAM) transport packages are achieved. It identifies the activities, responsibilities and actions necessary to ensure that all regulatory, customer and internal QA program requirements that are important to safety are met.

2. SCOPE

This plan is applicable to all Best Theratronics Radioactive Material Type A and Type B Transport Packages.

3. APPLICABLE DOCUMENTS

- 3.1 Best Theratronics Procedure 5.00-QA-00, Quality Manual
- 3.2 IAEA Safety Standard Series, Regulations for the Safe Transport of Radioactive Material, Regulation No. TS-R-1, 2005 Edition.
- 3.3 IAEA Safety Guides, Safety Guide TS-G-1.1(ST-2) Advisory Material for the IAEA Regulations for the Safe Transport of Radioactive Material (2002)
- 3.4 USNRC Regulation 10 CFR 71 Packaging and Transportation of Radioactive Material
- 3.5 USNRC Regulation 10 CFR 21, Reporting of Defects and Noncompliance
- 3.6 Packaging and Transport of Nuclear Substances Regulations, Nuclear Safety and Control Act
- 3.7 International Standard ISO 9001-2000 Quality Systems Management - Requirements
- 3.8 Best Theratronics Procedure 5.00-QA-04, Design Control
- 3.9 Best Theratronics Procedure 3.24-AA-01, Design Change

4. PROCEDURE**4.1 Management Responsibility****4.1.1 Quality Policy**

The Best Theratronics Quality Policy is included in the Quality Manual. It is the responsibility of all applicable staff, at all levels, to be aware of and understand the Quality Policy and supporting procedures.

4.1.2 Organization**Responsibility and Authority**

Senior management responsibilities are described in the Quality Manual. Responsibility assignments for other specific functions involved in quality related activities for transport packages are described below.

Director, Compliance

The authority for the administration of the Quality Assurance Program is assigned to the Director, Compliance, who reports to the General Manager

Radioactive Material Transport Package Quality Plan

Technical Design Authority - Transport Packaging (TDA-P)

The Technical Design Authority - Transport Packaging is responsible for the design, specification and testing of radioactive material packages. The TDA-P is responsible for verifying that all regulatory submissions for RAM transport package certification are accurate and complete.

Project Engineer

The Project Engineer reports to the Engineering Manager, and is responsible for design projects from inception to completion. This includes the preparation or review of design documentation, design qualification testing, the preparation of specifications for manufacturing, and the review of Manufacturing, Inspection and Test Plans (MITP).

Engineering Manager

The Engineering Manager is responsible for resourcing project engineers to complete design, specification and testing of radioactive material transport packaging. The TDA-P reports to the Engineering Manager.

4.1.3 Management Review

Procedures for management review of the quality system are described in the Quality Manual.

4.2 Contract Review

Selection of transport packaging for shipments is performed by Customer Service. Non-standard uses of transport packaging are referred to the TDA-P, for review. Each nonstandard application is reviewed for its capability to meet the standard, code, and regulatory requirements. For Type B packages, regulatory approval is obtained before use of any new packaging configurations.

4.3 Design Control**4.3.1 Design Planning and Activity Assignment**

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

4.3.2 Design Input

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

- a) performance and functional criteria, including operational requirements
- b) applicable codes and standards

The standard for the design of a radioactive transport package are the IAEA Regulations. However, other national codes, such as 10CFR Part 71 shall be considered, as applicable.

- c) regulatory requirements, including applicable Package Design Approval or Special Form Radioactive Material Certificates
- d) environmental conditions
- e) documentation, training, maintenance and inspection plans

Radioactive Material Transport Package Quality Plan

- f) 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
- g) where applicable, the results of contract review.

Incomplete, ambiguous, or conflicting requirements are resolved by the Project Engineer.

4.3.3 Design Output

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

- a) meet the design input specification
- b) 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,
- c) 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 reviewer, normally the Director, Compliance, and must be approved by the TDA-P.

- d) include engineering drawings and operating procedures
- e) include a Technical Specification for Type B packages. The technical specification must be reviewed by Quality Assurance and approved by the TDA-P.
- f) include a Design, Manufacturing and Operating Specification for Type B packages. The Design, Manufacturing and Operating Specification must be approved by Quality Assurance and the TDA-P.

Safety Analysis Report

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

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

Radioactive Material Transport Package Quality Plan

2. General requirements for packages such as:
 - lifting devices
 - closure methods
 - tiedown devices
 - external pressure
 - chemical and galvanic reactions
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.

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:

- a) applicable engineering drawings
- b) applicable standards
- c) Best Theratronics specifications and procedures
- d) quality program standards and codes required for manufacture. The manufacturer's quality program is normally subject to International Standard ISO 9001 or CSA CAN3-Z299.2. The code requirement for welding and welder qualification is normally ASME BPV Code Section IX or CSA W59.
- e) where applicable, requirements for welding, fitting and machining, surface finish and cleanliness, lead pouring and bonding, and painting
- f) nonconformance and corrective action
- g) inspection requirements
- h) tests for welds, mechanical operation, lead bonding, radiation shielding, and leakage testing
- i) requirements for manufacturing history records.

Design, Manufacture and Operating Specification

Each new project involving a Type B package shall include the issue of a Design, Manufacture and Operating Specification. The purpose of this document is to provide the design envelope to the applicable regulatory authority. The design envelope summarizes regulatory commitments and includes, at least:

- a) the authorized contents, isotope, activity and form
- b) the possible range of external dimensions

Radioactive Material Transport Package Quality Plan

- c) safety critical materials used and their thickness
- e) reference to an information drawing which identifies the key features of the package
- f) marking and labeling
- g) requirements for quality assurance in manufacture
- h) requirements for use, including preparation for shipment and inspection and maintenance.

When design changes result in changes to the Design, Manufacture and Operating Specification, regulatory approval is required for type B packages prior to implementation.

4.3.4 Design Verification and Review

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 TDA-P and Quality Assurance 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:

- a) 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.
- b) 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.

4.3.5 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 the TDA-P, Quality Assurance; and where required, the representatives from Operations. 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.

4.4 Document and Data Control

Documents and data that relate to the needs of the Quality Plan are controlled according to established procedures.

Radioactive Material Transport Package Quality Plan

4.5 Purchasing

Documented policies and procedures are maintained to ensure that the purchased RAM transport packaging, components, materials, and services conform to specified requirements.

Suppliers are selected based on their ability to meet the quality requirements. Measures are in place, through purchasing and QA policies and procedures, for the evaluation, selection and approval of suppliers. It is the responsibility of the TDA-P to ensure that the purchasing documents clearly describe the material required. The key document for the information necessary is the purchase requisition, which references technical requirements such as the technical specification, drawings etc.

Each order for a transport packaging requires certain control activities and records, specifically:

- a) only approved suppliers are used
- b) suppliers' Inspection and Test Plans are reviewed and approved by Engineering
- c) Incoming inspection is performed according to the Inspection and Test Plan
- d) requests for disposition of nonconformances must be submitted to the purchasing department in writing. Disposition is decided by the TDA-P, or designate, and Quality Assurance.
- e) For suppliers located in the USA, purchase orders for transport packagings (or components) are required to indicate that the provisions of 10 CFR Part 21 apply.

4.6 Control of Customer Supplied Product

Transport packaging supplied by customers is used in accordance with design and licensing documentation. As a minimum requirement, the customer is required to provide:

- a) copies of relevant transport certificates, including certification of Special Form Radioactive Material Approval Certificates, if applicable
- b) Operating Procedures.

4.7 Product Identification and Traceability

Each Type B package is identified with a model number and a unique serial number.

4.8 Process Control

During the manufacture of packaging, requirements for process control are defined in the Technical Specification.

4.9 Inspection and Testing

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:

- a) new packaging first-off inspection and acceptance requirements
- b) periodic inspections after shipment, and before reuse
- c) annual inspection and maintenance
- d) inspection and maintenance checklists
- e) instructions for special tests such as: leak testing, pressure tests, shielding tests, etc.

Radioactive Material Transport Package Quality Plan

f) quality records to be kept.

Some or all of these procedures may exist only electronically, and the records may exist only in a database.

Procedures for ongoing inspection and maintenance are normally prepared by the project engineer.

4.9.1 Package Qualification

Type B RAM packaging and components are inspected in accordance with the Technical Specification. Inspection and testing during manufacture are carried out using the Inspection and Test Plan approved by the Project Engineer. Manufacturing, Inspection and Test Plans are retained.

Confirmation testing and/or review of supplier generated records to specific requirements is carried out at Best Theratronics prior to final acceptance of the RAM package. As a minimum requirement, a radiation survey must be performed prior to release for shipment. Documentation of the results is maintained.

4.9.2 Inspection and Maintenance

In use packaging is periodically inspected to the appropriate Inspection and Maintenance Procedure.

4.10 Control of Inspection, Measuring and Test Equipment

Procedures for the control of Inspection, Measuring and Test Equipment are described in the Quality Manual.

4.11 Inspection and Test Status

During manufacture, the inspection and test status of packaging is maintained in accordance with procedures. Systems are in place to ensure that the inspection and test status of all packagings is maintained.

4.12 Control of Nonconforming Product

Following the procedures in the Quality Manual, disposition of nonconforming material is reviewed and the activity recorded. The system requires that the disposition of nonconformances be requested in writing.

4.13 Corrective and Preventive Action

Documented procedures are in place for implementing corrective and preventive action.

4.14 Handling, Storage, Packaging, Preservation and Delivery

The Project Engineer identifies, in the Technical Specification for Type B packages, the requirements for handling and storage.

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.

Documented procedures are in place to receive transport packages.

Radioactive Material Transport Package Quality Plan

4.15 Control of Quality Records**Design Files**

Project design files are normally filed with the design control documentation.

Manufacturing History Records

Records are maintained to show that the specified quality requirements were met. Records are maintained in secured areas with limited access. The retention period for these records is the life of the packaging + 10 years. The following records are prepared:

- a) Copies of Purchase Orders and all amendments, if applicable
- b) Inspection and Test Plans
- c) Completed inspection records
- d) List of drawings and specifications with current revisions in effect at the time of manufacturing and the serial numbers of the units supplied,
- e) Copies of Nonconformance records, including disposition by Best Theratronics
- f) Certified Material Test Reports, Certificates of Compliance or similar
- g) Certified Non-destructive Examination (NDE) reports,
- h) Welders' qualification certificates
- i) Radiation survey data.

Service History

Service history is maintained for each transport package design. This includes electronic inspection and maintenance records.

4.16 Quality Audits

Internal quality system audits are planned and performed in accordance with the Quality Manual.

Radioactive Material Transport Package Quality Plan

4.17 Training

Training requirements are defined for all key roles affecting safety of RAM transport. Actual training is tracked against requirements including technical knowledge, control of process, specific skills and general theory in quality issues, safety, and company policies.

Detailed instruction for the carrying out of training is provided in each department's administrative procedures. The training requirements are summarized below:

- a) all personnel involved in the transport of radioactive material receive training in radiation safety and transport regulations
- b) specific qualification, training, and certification requirements are determined on an individual basis by line management. This determination is based on: the type of work, potential effect on quality, and the applicability of codes, standards or regulations
- c) the line managers are responsible, with Human Resources, for maintaining records of staff selection, qualification, certification, and training. They also provide for the necessary training, and evaluate needs during staff performance reviews.

4.18 Servicing

Routine inspection and maintenance to transport packages discussed in section 4.9.

4.19 Statistical Techniques

Documented procedures are in place for acceptance sampling of components.