71-0040

QSA GLOBAL

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US Nuclear Regulatory Commission
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SFPO, NMSS
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Rockville, MD 20555

2 Oct 2007

Re: 71-0040

Dear Mr. Lewis:

We request an amendment to our QA program approval 0040 to incorporate revision 7 of the Quality System Manual. Revisions have been made primarily to reflect some ISO 9001 requirements and minor editorial updates. A list of the changes is given in Appendix D of the Manual.

Please contact me at 781-505-8210, if you have any questions. Thank you for your assistance.

Sincerely,

Cathleen Roughan

Cathleen Roughan
Director, Regulatory Affairs/Quality Assurance

NMSS01

QSA GLOBAL	Document Number QSM-1	Revision: 7
	Effective Date :	

Subject: **Quality System Manual**

Reviews & Approvals			
Name	**Title**	**Signature**	**Date**
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Cathleen Roughan	Regulatory Affairs/Quality Assurance Director	C. Roughan	27 Sep 07
Larry Swift	President QSA Global, Inc.	[illegible]	1 OCT 2007

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1.0 *Management Responsibility*

1.1 Quality Policy & Quality System Objectives

QSA Global commits that all employees working as a team and individually will ensure that all products, processes and services are performed in a controlled, reliable and continuously improving environment and will meet customer, and applicable statutory and regulatory requirements.

- Quality is determined by our customers.
- Quality is measured and evaluated.
- Quality is each individual's responsibility.
- Quality is a team effort.
- Quality is doing it right the first time.
- Quality is a continuously improving process.

With this commitment we will provide our customers, employees, owners, suppliers and society the confidence, integrity and reliability necessary to ensure stability and future growth.

To define and focus QSA activities and effectively implement the Quality Policy quality objectives are established, monitored, and periodically reviewed by management to assess the scope, applicability, implementation, and effectiveness of the quality system. The quality objectives and status are documented and communicated to the QSA staff.

The responsibility for the maintenance of the quality system, and monitoring the implementation of the quality system provisions is delegated to the Director of Regulatory Affairs and Quality Assurance.

Signed: _____ Date: Oct 2007

Larry Swift
President

1.2 Introduction to QSA Global, Inc

QSA Global, Inc manufactures, distributes and redistributes radioactive material in the form of sealed sources, devices and transport packages for use in industrial and medical applications throughout the world. QSA Global performs contract manufacturing of customer designed sources for industrial and medical applications. These sources, devices and transport packages are authorized for use through the following certifications:

- Type B approvals
- Special form approvals
- Sealed Source and Device Registrations
- Type A analyses
- FDA approvals
- Licenses & Approvals Issued by Regulatory Authorities

The design, testing, manufacture and distribution of these products is covered under the following Quality System and/or regulatory requirements:

- 10 CFR Part 21
- 10 CFR Part 32
- 10 CFR Part 50 Appendix B
- 10 CFR Part 71
- 21 CFR 820
- 49 CFR Part 173
- 105 CMR 120
- ISO 9001:2000
- ISO 13485:2003
- Canadian Medical Device Regulations P.C. 1998-783
- European Union Medical Device Directive 93/42/EEC

QSA Global, Inc. is located in Burlington, MA and in Baton Rouge, LA and performs services throughout the world.

Due to the diverse nature of the stakeholders and regulatory entities associated with QSA business activities, the Quality Management System (QMS) has been developed to include measures designed to satisfy the varied requirements identified above. To facilitate identification of specific requirements and where they are addressed by the QMS a cross reference matrix is provided in Appendix A.

1.3 Responsibilities/Organization

The Quality System program is implemented by the various functional areas, including the President, Engineering, Quality Assurance/Quality Control, Operations, Regulatory, Commercial, Finance, Human Resources and Information Technology. The current organizational structure is documented and implements the responsibilities given in this section.

1.3.1 President

The President of QSA Global, Inc is responsible for establishing and implementing a Quality System that complies with the requirements of this Quality System Manual. The president will communicate that all staff and systems must meet statutory, regulatory and customer requirements.

1.3.2 Management Representative

The president appoints the Director of Regulatory Affairs/Quality Assurance (RA/QA) as the Management representative. This position is independent from production schedules and reports directly into the President. The Management Representative should have a BS degree in a scientific discipline, either formal or on the job training in quality systems and experience in QA programs established for compliance to regulatory requirements. This position is responsible for monitoring the implementation of the Quality System. This includes providing guidance and direction for the other functional activities to achieve the effective implementation of the Quality System. This position has the authority and freedom to stop unsatisfactory work. The Management Representative serves as liaison with representatives of external parties on matters relating to the quality system such as the State of Massachusetts, Nuclear Regulatory Commission, Food and Drug Administration, Department of Transportation, and competent authorities of other jurisdictions.

1.3.3 Functional Managers

The functional managers are responsible for the quality program activities described in this manual and ensuring that appropriate systems and procedures are in place. Management is responsible for ensuring that noncompliance and improvement opportunities are addressed in a timely manner and that personnel are indoctrinated and trained in the applicable Quality System requirements.

Functional Managers are responsible for appointing Subject Matter Experts (SMEs). The SMEs are individuals, that by virtue of training and/or experience and an assessment by the manager indicates the individual is an expert for a particular subject. The SMEs are responsible for writing, reviewing and assisting in training in Quality Management Procedures (QMP) and Work Instructions (WI) and associated documentation.

1.3.4 Staff

All staff are trained in the Quality System Manual (QSM) and are responsible for understanding, adhering to and maintaining the stated requirements of the QSM. All staff have the authority to stop unsatisfactory work. All staff have the responsibility to report any defects or noncompliances which could result in a substantial safety hazard or any other condition that could lead to a noncompliant condition.

1.4 Quality System

A Quality System is established that will ensure processes are identified and documented and that appropriate procedures are in place. The system ensures that the product conforms to specified requirements.

Quality planning is accomplished through the use of design review and process planning.

The Quality System is integrated into the key processes necessary for the enterprise to achieve its quality objectives. These key processes and process elements are defined as follows:

Management –

- Strategic Planning
- Resource Management
- Performance Management
- Management Review

Product Realization –

- Customer Service & Order Management
- Product Design & Development
- Procurement of Goods & Services
- Manufacturing & Assembly
- Distribution

Support Processes -

- Financial Control
- Facility & Equipment Maintenance
- Information & Data Management
- Quality Verification and Measurement
- Health & Safety

The functional relationship of these key process elements are described and depicted in the process model of Appendix C.

The Quality System is based on a graded approach. Items that are critical to product safety or product quality are identified and appropriate control, traceability and inspection criteria established. The Quality System is implemented using the documents listed below.

1.4.1 The Quality System Manual

The Quality System Manual is the master document (Level 1) that implements and requires that all the applicable quality standards, as described in section 1.2 are met. The manual includes the Quality Policy listed in Section 1.1, which is endorsed by the President of the company.

1.4.2 Quality Management Procedures

The Quality Management Procedures (QMP) serve as the second level (Level 2) of documents and implement the requirements of the Quality System Manual. The QMPs describe the following:

- Minimum requirements for legal and business needs
- How to meet commitments in the quality manual
- Cover the core elements under the relevant QA standard
- Process and responsibilities

The Quality Management Procedures that implement those elements of the quality system defined in 10 CFR 71, subpart H and described in NRC Regulatory Guides 7.10 and 6.9 are tabulated in Appendix B.

1.4.3 Work Instructions

Work Instructions are the Level 3 documents and provide step by step guidance on how to implement requirements in the QMPs. Work instructions provide:

- Instructions to complete task or operation including applicable inspection and acceptance criteria
- References records or equipment as needed for task
- Describes a process and may not be department specific
- Work Instructions may utilize drawings, and/or specification sheets to cover adequate level of detail.

1.4.4 Records

Records are Level 4 documents and provide evidence of implementation of the quality program and associated processes. Quality records are maintained and retained in accordance with applicable laws, regulations, and license requirements.

1.5 Management Review

To assess the effectiveness of the Quality System, a systematic management review of the Quality System is performed at least annually.

The Management Review includes the President of the company, RA/QA Director and appropriate functional management staff. Measurable quality objectives will be established and reviewed during the management review. The Management Review consists of a review of at least the following inputs:

- Results of audits
- Process Performance & Product Conformity
- Status of Corrective and Preventive Actions
- Training and Resource needs
- Customer Feedback
- Medical Device Problem Reports
- Follow-up action from prior Management Reviews
- Regulatory, Process, or Environment changes that could affect the Quality Management System
- Recommendations for Improvement

This data is reviewed and a determination made as to whether the program is suitable and effective and whether the quality objectives are being met. Any decisions or actions relating to improving effectiveness of the program, effectiveness of the product to meet customer requirements or resource needs are documented.

Records are maintained of the Management Review indicating results and actions.

The President is responsible to assure that actions are completed as required.

1.6 Resource Management

Executive management of QSA determines and provides the resource required and necessary to implement the quality system in a manner that meets regulatory, business, and customer requirements.

1.6.1 A system is established to recruit, and train an adequate staff of personnel performing work affecting quality that are competent.

1.6.2 Facilities and equipment including supporting services are provided suitable to the production requirements, and to deliver product that conforms to requirements. A preventive maintenance program is established to ensure critical equipment and facilities are available to support operations.

1.6.3 A system of procedures, reviews, and controls are implemented to establish an appropriate work environment to conduct operations safely and in conformance with regulations. These reviews and controls are applied to any new process or significant changes to existing processes and facilities as applicable. Procedures and controls are established as appropriate to:

- Provide for the safety of personnel
- Establish and maintain the integrity and cleanliness of product

2.0 Contract Review

Procedures are established to ensure that contract and order requirements are adequately defined, coordinated and documented. Customer requirements differing from those provided in a quotation are resolved prior to the acceptance of a contract/order. A review of the contract

also ensures that QSA Global is capable of meeting the contract requirements prior to the acceptance of the contract/order.

Evidence of contract/order review is performed by appropriate personnel as it relates to their department or expertise, prior to the issuance of a quotation and/or acceptance of any contract or order.

The individual performing contract review identifies and addresses any areas of concern and/or non-compliance until resolution. This includes involving any pertinent personnel as needed, i.e.: QA, Engineering, Regulatory, Finance, etc.

Evidence of contract/order review is documented.

Amendments or modifications to a contract or order, by either QSA Global, or the customer, is documented and the customer notified of the changes.

3.0 Design Control

Procedures are established describing the method to control and verify the design of new products or changes to existing products to ensure the specified requirements are met.

3.1 General

Development of concepts for new products or changes to existing products and processes may begin before a full design effort begins. Such concepts must be documented on prototype drawings and/or processes controlled by engineering. For medical products a risk analysis is performed as part of the product and process design.

A design history file is established once a project is initiated. All information regarding the design, testing, verification, and release of the product or process is documented in the design history file. This file is controlled and maintained for the life of the product or process.

3.2 Design Inputs and Reviews

The designer obtains the design inputs, which will include as a minimum any regulatory requirements, contract requirements, customer input, technical and/or performance requirements. Consideration to safety related functions are considered in the design. The Design Engineer ensures the design inputs are addressed by the intended design output. This assessment is reviewed by a qualified individual other than the originator for adequacy. Any incomplete information, ambiguous or conflicting requirements are addressed.

Design Reviews are held as needed during the development process. These will involve individuals as needed from other functional areas for applicable input and review. Where necessary, there will be a clear assignment of responsibility between the interfaces of the functional groups.

Once the design is complete it is checked by someone other than the originator of the document. The Design Checker ensures the design outputs matches the design inputs as intended, and this review is documented before release.

3.3 Design Verification and Validation

The design is verified. Design verification may follow one or a combination of the following:

- Testing - All testing is performed in accordance with established procedures that identify the testing requirements, is documented and reviewed as appropriate to the requirements of the design inputs.
- Analysis - Alternate calculations, analysis or assessments may be used to provide evidence that a design output will satisfy the inputs.
- Independent analysis - Submittal to outside agencies for verification. This is either for testing of actual prototypes or calculative analysis.

After verification, it is confirmed that the design outputs meet the design inputs, that inspection and tests are identified and a Final Design Review is conducted to present all testing, design and evaluation results. This design review includes all the necessary functional groups.

The Design Engineer and the Project Manager monitor the initial production run for validation of manufacturing processes to assure the product conforms to the intended user needs and specifications. Any changes required to the design become design inputs and are evaluated appropriately with the same level of control and review as the original.

If required, units from the initial production run may be used to validate the design. Validation is achieved through monitoring of initial units in the field, additional testing, or other methods to ensure that the units conform to users needs and intended uses. Validation is documented in the design history file.

Changes to an approved design are reviewed, verified and validated as appropriate, and approved before implementation. The review of design changes includes an evaluation of the effect of the change on constituent parts and product already delivered. Records of the design change review are maintained in the design history file.

3.4 Design Transfer

The final design is translated into instructions and drawings to ensure production conforms to the design basis. These instructions and drawings include measures for quality verification, and are reviewed prior to issue to verify conformance to the design requirements.

4.0 Document and Data Control

Procedures are established for the control of documents and data pertinent to the Quality System.

The establishment and changes to the Quality Policy, Quality System Manual, Quality Management Procedures, and Work Instructions are procedurally controlled.

Controlled documents, such as, engineering drawings, marketing literature, product manuals and documents of external origin, i.e., standards and customer drawings are processed in accordance with the responsible department's work instructions.

Computer software is validated and controlled as needed.

Documents and data can be in any type form, i.e., hard copy or electronic media.

Documents and data are reviewed and approved for adequacy by authorized personnel prior to issue and have the approval date and the effective date indicated.

4.1 Document Review and Approval

The document originator obtains reviews and approvals from appropriate functional groups.

Document and data changes will be reviewed and approved by the same functions that performed the original review and approval. The functions will have access to pertinent background information to base their review and approval.

Changes will be visibly highlighted in the document. Approved changes will be communicated to appropriate personnel in a timely manner.

4.2 Distribution

All personnel have access to all QMPs and Work Instructions as needed for their activities. A Quality System Document Matrix is updated and maintained. It is a master list of controlled documents and identifies current revision status of documents.

Invalid/obsolete documents will be promptly removed to assure against unintended use.

5.0 Purchasing

Procedures are established for ensuring the quality of procured materials and/or services conform to specified requirements.

5.1 Evaluation of Suppliers, Contractors and Consultants

Purchasing will evaluate and select suppliers based on their ability to meet contract requirements including the quality system and any specific requirements. Quality Assurance will assist in the assessment of suppliers. The extent of the assessment is dependent on the quality class of product provided by the supplier and may include evaluations and/or audits as applicable. One or more of the following methods may be utilized in evaluating the qualifications of a vendor:

- Audits and/or coordinated review by multiple functional groups (e.g. Engineering, Purchasing, and Quality);
- Audits and/or evaluations by other divisions of QSA Global;
- Accreditation by a recognized independent authority (e.g. NVLAP, A2LA, NADCAP, NMAS, ASME)
- Source inspection / surveillance

Considerations to be taken into account when selecting a supplier include technical capability, quality assurance system, ability to meet schedules, price and financial stability of the supplier.

The performance of key suppliers is monitored, and periodically reviewed. The criteria for evaluation and periodic re-evaluation of performance is documented, and records of the reviews are maintained. In cases of contract manufacturing that **does not involve NRC certified devices and packages**, suppliers specified by the customer may be used in lieu of those on QSA Global's approved supplier listing, without evaluation by QSA.

5.2 Procurement Documents

Purchasing documentation contains data clearly describing the products ordered including (with revision levels as appropriate):

- Specifications, drawings, process requirements, inspection instructions and other relevant technical data, including requirements for approval or qualifications of product, material certifications, certificate of conformances, test reports, procedures, process equipment and personnel
- The applicable quality system
- The review and approval of purchasing documents for adequacy of the specified requirements prior to release
- 10 CFR Part 21 applicability is indicated when required
- Any changes to the procurement document will be reviewed and approved to the same level of control as the original document
- As applicable, supplier must notify of any significant changes in process of producing requested product

5.3 Verification of Purchased Product

All materials and/or services contracted must comply with the applicable contractual requirements and identified specifications on the purchase order which may include:

- Inspection at supplier site
- Objective evidence of the quality of the product from suppliers, such as material certification, certificate of conformances or test reports
- Notifications of any changes in the process or component
- Notification of any nonconforming material

6.0 Control of Customer Supplied Product

Procedures are established for assuring that customer supplied product will be handled and stored properly. These are items that will be incorporated into or used with QSA Global products.

6.1 Minimum Requirements

The customer is responsible to provide acceptable product and to specify any special requirements. Customer supplied product may be verified as to fitness for use, based on customer needs.

Items will be received, identified and stored in a controlled and traceable manner. Items will be maintained according to original manufacturer's guidance. Items lost or damaged will be documented and reported back to the customer.

7.0 Product Identification and Traceability

Procedures are established for identification, traceability and control of materials, parts, and subassemblies and product.

7.1 Product Identification

Where required, material, parts, subassemblies and product are identified by suitable means from receipt through all stages of production and delivery.

Identification of items is maintained by part number, heat number, or other suitable means.

7.2 Product Traceability

Where and to the extent that traceability is a specified requirement, individual products, lots, or batches will be assigned a unique identification.

Identification will be maintained on the product or on records traceable to the product.

Materials, parts, and components found to be nonconforming will be appropriately marked, removed from use and placed in an isolated hold area.

7.3 Records

According to the level of traceability required by contract, regulatory, or other established requirement, the system will provide that:

- Identification will be maintained throughout the life of the product
- The quality records of a product, including design, production, results of inspections and tests including acceptability can be retrieved
- Appropriate retention periods are specified

8.0 Process Control

Procedures are established to control and document production process control.

8.1 General

Production activities will be adequately documented through controlled procedures, instructions or drawings appropriate to the quality and safety significance. These may include process flow, routings and hold points. Qualification of personnel for the process will be indicated as needed.

Critical features, acceptance criteria and workmanship standards will be clearly described and monitored.

Production activities will be performed in accordance with these documents and applicable regulations, codes, standards or Process Plans.

Evidence of operations and inspections performed will be maintained. The current status of operations and/or inspections of a product will be clearly identified.

Appropriate production equipment that meets specified requirements will be used in suitable work environments. This equipment will be inspected and maintained to ensure process capability. Where applicable any limitations of the equipment will be documented and made available to the operator.

Where applicable, processes and equipment including software will be approved and validated. Medical product manufacturing processes and associated software is validated in cases where the result cannot be verified by subsequent monitoring or measurement. The extent of validation is based on the process risk analysis. Changes or process deviations to these systems will require reassessment and approval.

8.2 Special Processes

Special processes, including welding, heat treating, sterilization, etc on safety critical components will be controlled through the use of qualified people and procedures to meet the relevant standards or industry codes.

9.0 Inspection and Testing

Procedures are established to control the inspection and testing activities for products, materials and services, verifying that they meet the specified requirements.

9.1 General

Parameters, features and characteristics that require inspection or testing are documented. Inspection and testing is performed in accordance with written and approved instructions or plans.

Inspection and test instructions identify the acceptance standards / criteria that items must meet. Test instructions identify the test conditions, including prerequisites, and measuring or test equipment required.

Personnel performing inspection and testing are qualified to the applicable standard. Inspection of items important to safety is performed by qualified personnel other than those who performed the activity being inspected.

9.2 Incoming Inspection and Testing

Incoming items are verified to the specifications used to obtain those items.

The level of inspection is commensurate with the control required for the incoming units with respect to safety, supplier performance and complexity.

The level and results of inspection is documented and trended.

Items not in conformance with the specifications used to obtain them will be identified, segregated and not used without approval by authorized personnel.

9.3 In-process inspection and testing

Where direct inspection is not practical, indirect verification of quality may be used through process monitoring and/or process control.

When necessary, hold points are implemented to check product quality.

Items in process do not progress in the production process until inspected and/or tested as required. Inspection hold points are identified in the processing documents.

Items not in conformance with the specifications used to produce them will be identified, segregated and not used without specific approval by authorized personnel.

9.4 Final Inspection and Testing

Final inspection provides evidence of conformance of the items to the design specifications, verifies that all required operations have been performed, and ensures the overall quality of the

product. Final Inspections provide for:

- Resolution of nonconforming conditions identified during processing,
- The item(s) are identifiable and traceable to specific records, and
- Is adequately protected from damage.

Items are not to be released for sale or use until all inspection documentation has been reviewed and authorized as applicable.

9.5 Inspection & Test Records

Records of inspections and tests clearly show the results and identify the inspecting and authorizing entities.

The evaluation of test results to assure the test requirements have been met is documented.

10.0 Control of Measuring and Test Equipment

Procedures are established for the control of measuring and test equipment, and key process equipment.

10.1 General

Procedures are established for administration and control of calibrated measuring and test equipment, and key process equipment.

All personnel using measuring and test equipment are responsible for ensuring current calibration and performing visual verification for any damage or wear prior to each use and that it is capable of providing the required measurement. Equipment used must be suitable for its intended purpose.

Measuring and Test Equipment and Key Process Equipment will be uniquely identified to facilitate tracking and control.

10.2 Calibration of Measuring & Test Equipment

Measuring and test equipment will be labeled such that its calibration status is readily determined when in use. Labeling will indicate the planned date the next calibration is due.

Measuring and Test equipment will be calibrated at prescribed intervals consistent with the devices use and calibration history, or prior to use.

Calibration procedures will include directions on accuracy and precision as needed.

Records of calibration will be maintained of the device's calibration status and demonstrate traceability to nationally recognized standards. Where no known standard exists, the basis of calibration will be documented.

When applicable, a manufacturer's certificate of accuracy may be used in lieu of calibration by an approved supplier for newly purchased items based on a suitable evaluation and approval.

Calibration services for measuring and test equipment will be performed by approved suppliers.

10.3 Control of Key Process Equipment

Key process equipment will be labeled such that its inspection status is readily determined when in use. Labeling will indicate the planned date the next inspection is due.

Critical characteristics of key process equipment will be verified by inspection or approved acceptance tests at periodic intervals based on the equipment's use and wear history.

Inspections of key process equipment will be performed using calibrated measuring devices, and will be documented on records traceable to the device.

10.4 Damaged or Out of Calibration Equipment Control

Measuring and test equipment and key process equipment found to be damaged or out of calibration will be identified, removed from service, and segregated if practical to prevent further use.

A review of the use of the device since the last verifiable acceptable calibration or inspection will be performed, and the impact of the device's deviation evaluated and documented.

Potentially impacted product will be identified and evaluated as nonconforming product and appropriate corrective actions taken.

11.0 Inspection Test and Operating Status

Procedures are established to assure the inspection, test, and operating status of materials, parts, and products is identified and maintained.

11.1 General

Work instructions are in place to insure that the identification and status of materials are maintained throughout manufacturing, installation, and service processing. This includes the rework/repair of all non-conformances.

Where necessary to ensure compliance to engineering/regulatory specifications quality control hold points are planned and implemented in processing documents to require determination of quality status prior to continued processing.

Processing, inspection and acceptance status may be accomplished through the use of a combination of stamps, labels, route cards, forms and service check sheets.

Acceptance status of goods is indicated by suitable non-damaging identification or otherwise by means of a signature on the documentation identifiable to the item.

12.0 Control of Nonconforming Material

Procedures are established that documents the methods to control materials, parts, and components that do not conform to specified requirements in order to prevent use.

12.1 General

An item that is, or is suspected to be, unacceptable, will be identified and documented as to its status and type of nonconformance.

Nonconforming items will be quarantined or placed in controlled hold areas, when practical, until proper disposition is completed.

The review and disposition of nonconforming items will be conducted and approved by a Material Review Board or other approved personnel.

Acceptance of reworked or repaired nonconforming items will be verified by re-inspecting or re-testing the item to the original requirements, or approved alternative instructions.

Final disposition of non-conformances will be identified and documented including justification.

Any affected functions will be notified of the nonconformance and agreed corrective/preventive action.

Nonconformance reports will be analyzed to determine quality trends for appropriate management review and assessment

13.0 Corrective and Preventive Action

Systems are established for documenting, investigating and implementing Corrective and Preventive Actions.

13.1 General

A Condition Report (CR) or equivalent is used to document the need for a corrective action to fix and prevent recurrence of a nonconformance, and internal or external customer dissatisfaction or a finding resulting from program audits. A CR can also be issued as a preventive action or improvement item when a program weakness or an enhancement opportunity is found.

A CR can be generated as a result of any of the following activities:

- Internal or external audit
- Customer Feedback/Customer Complaint
- Product Non-conformance
- Supplier audit
- Observations during routine or non routine events

13.2 Process

The CR is evaluated by management to determine the need for an investigation to determine cause and corrective action based on the condition's potential or actual significance in terms of impact or consequences. This evaluation includes considerations of impact on safety, quality, and public confidence. CRs are classified as major or minor based on the evaluation.

Condition Reports evaluated as significant are assigned to a qualified person for investigation and the determination of appropriate corrective or preventive action. A root cause determination is performed for CRs classified as major. The results of the investigation are disseminated to affected functions.

QA conducts follow-up of major CRs to assess implementation and effectiveness of corrective action. A log is kept of CRs which is periodically reviewed for trends. Trends are evaluated during the periodic management review meeting.

Any required 10 CFR Part 21 or Medical Device Reporting to the regulators will be documented and notifications made in accordance with regulatory requirements.

14.0 Handling, Storage, Preservation and Delivery

Procedures are established for assuring that product throughout the business process will be handled and stored in ways that preserve the product quality.

14.1 Handling

Personnel handling product will work to prevent damage or degrading of the quality of the product during processing. This includes:

- Maintaining identity and traceability as required
- Cleaning
- Prevention, detection and removal of foreign objects or contamination
- Special handling as appropriate for the product

14.2 Storage and Preservation

Designated stock areas will be maintained for the storage of product. Control will be maintained of:

- Inspection prior to stocking
- Receipts to stock
- Identity and traceability as required
- Prevention of damage or degrading of quality
- Suitable environment for storage
- Release from stock

Product that may degrade from age will be rotated and assessed as appropriate.

14.3 Labeling

As applicable, labeling activities will be controlled and inspected for accuracy prior to release. Labeling for medical products is subjected to an inter-disciplinary review to verify technical accuracy and suitability for use.

14.4 Packaging

Items are placed in suitable packaging for the product. The packaging will protect the item from damage or alteration during normal transport. All packaging will conform to appropriate regulatory requirements for the product.

14.5 Delivery

Products will be delivered to the end user with all appropriate documentation, eg. manuals. Delivery will be accomplished using appropriate transportation to ensure integrity of the product and to ensure compliance with established regulatory requirements. Records are maintained of the distribution.

15.0 Control of Quality Records

Procedures are established for identification, specifying retention periods, collection, indexing, access, filing, storage, maintenance and disposition of quality records.

15.1 General

Quality records are maintained to demonstrate conformance to requirements and effective operation of the quality system. Records may be any type, such as, hard copy or electronic media.

Records include pertinent quality records from suppliers.
Quality records will be retained such that records are readily retrievable and readily accessible to authorized personnel and auditors. Where contractually required, records are available for customer evaluation for an agreed period.

Retention times of records are established and recorded. Records will be retained in a suitable environment to prevent damage, deterioration and loss.

15.2 Medical Device Records

A quality system record, device master record and device history file will be established and maintained as applicable.

16.0 Internal Audits

Procedures are established for planning and implementing internal quality audits.

Audits are carried out to verify whether activities and related results comply with planned arrangements and to determine the effectiveness of the quality system.

Quality Assurance is responsible for:

- Planning and scheduling internal audits
- Assignment of lead auditors
- Review and approval of audit plans, checklists and reports
- Determination of follow-up actions
- Reporting internal audit results for management review

16.1 Process

Audits will be scheduled on the basis of status and importance. Personnel, independent of those having direct responsibility for the activity being audited will carry out the audits.

The results of the audit will be recorded and reviewed with personnel having responsibility in the area audited.

The responsible manager will determine and initiate corrective actions in a timely fashion.

Follow-up audit activities will be conducted as required to verify and record the implementation and effectiveness of the corrective actions.

Internal audit results will be presented and reviewed at management review.

17.0 Training

Procedures are established to identify training needs, control training requirements, qualifications and verification of training. Training activities are developed and implemented to ensure individuals have the requisite knowledge and skills to perform their assigned tasks competently.

17.1 General

Training of staff is operations (task) based. An operation may encompass a number of procedures and may span disciplines.

Training required for the operation is determined and documented by an SME (subject matter experts) and functional managers, and usually is of two types:

- **Awareness**. Familiarization with procedures that do not have a direct affect on the operation, but provide information and guidance. Testing is usually not required to satisfy the training.

- **Verification.** Training that has a direct effect on performing the operation. Testing or other methods of evaluation is required to verify satisfactory completion of the training.

When applicable as required by license, standards, or regulations qualification for a specific task is provided in accordance with the governing standard to ensure competency. (e.g. welding, non-destructive examination, etc.)

Functional managers are responsible to ensure that individuals they are responsible for, are trained for the operations assigned.

Training will be documented and become part of the employee's training record.

SME's may provide training. When used, manner and method of testing is under the control of the SME and functional managers.

All individuals involved in operations will be trained before performing that operation (task) independently. Individuals will be made aware of the relevance and importance of the activity in meeting the quality objectives. Individuals will be made aware of potential defects that could result from improper performance of process.

18.0 Servicing and Installation

Procedures are established for servicing and installing equipment manufactured or distributed by QSA Global, Inc.

18.1 Servicing

Service activities will be adequately documented through controlled procedures, instructions or drawings appropriate to the quality and safety significance of the product.

Required service inspections will be identified with their frequency.

Inspection results will be documented.

Findings which are not due to normal wear or clear accident conditions should be reported to Engineering for evaluation and trending.

18.2 Installation

Where required, installation of product will be controlled by instructions or specifications. Any required testing is performed and documented to demonstrate proper installation.

19.0 Statistical Techniques

Procedures are established as needed for controlling statistical techniques.

This procedure controls use and documentation of statistical techniques used in production design and service.

The use and extent of statistics will be determined by the process and/or item under study. This determination will be made by qualified personnel. Determination of specific methods and their application will be documented. All documentation will be checked by a competent individual other than the author.

Analysis derived from application of said statistics will be used to determine actions taken as determined by the SME (subject matter expert).

20.0 Process Monitoring, Measurement & Continual Improvement

Procedures are established for managing Continuous Improvement of the quality of QSA Global products, and/or the efficiency and effectiveness of our processes.

20.1 Customer Satisfaction

Measures are established to collect and analyze information relative to meeting customer expectations. These measures are documented, and records of analysis maintained.

20.2 Analysis of Data

Key quality indicators will be identified and measured. Input may be obtained from, but not limited to:

- Non-Conformance Reports
- Customer Feedback, internal or external
- Quality Records
- Internal and external audit reports
- Corrective and Preventive action reports.
- Design Reviews & Design Change Requests
- Management Reviews
- Any other sources of information relating to the quality of products, or process efficiency and effectiveness.

Trends of agreed upon indicators or objectives will be analyzed and documented. Results of trend analyses will be reported to management for review. The selection of indicators is designed to provide information relative to:

- Conformance of product to requirements
- Supplier performance
- Process trends including opportunities for preventive action
- Assessment of customer satisfaction
- Progress towards meeting quality system objectives

Management reviews will utilize this analysis to identify and recommend actions to be taken to improve quality system performance.

21.0 Project Management

Procedures are established to describe the methods for Project Management.

A determination will be made as to whether a new process will be managed as a project or whether it can be managed in accordance with standard business processes and procedures (e.g. Process Plans).

Once it has been determined that the process will be managed as a project, a Project Manager will be assigned. The Project Manager will establish a project team with specific functions assigned to the team members. Key activities, tasks, and deliverables will be established. The project schedule and costing will be compiled.

Periodic project review meetings will be held with key members of the project team. Minutes of these meetings will be published to record key actions, status, and decisions. The Project Manager is responsible for the project schedule and costs.

22.0 Safety Programs

Programs are implemented to develop, maintain, review and improve safety programs at QSA Global. The Safety Programs include Radiation Protection and Occupational Safety.

22.1 General

Operational risks and requirements with respect to health and safety are identified and documented and will provide the basis for program design. Safety programs are designed to control the hazards identified, and incorporate policies, procedures, and standards to assure compliance.

Roles and responsibilities of functional groups and individuals, with respect to safety programs, are identified in the programs. Workers are trained in the content of safety programs, including policies, procedures and standards, with specific training commensurate with individuals' tasks.

Audits are periodically conducted to evaluate whether safety policies and procedures are being followed. Safety reviews are applied to the design of new or modified facilities or equipment to include all necessary safety features.

Information systems are established to provide documentation and demonstrate compliance, and allow for tracking and trending to measure performance. Appropriate references are periodically reviewed to identify proposed changes to regulations or new regulations; existing safety programs are updated in a timely manner to reflect such changes.

		General	Type B Transport Packages		Sources					
					General	Reactor	Medical Devices			
QMS Element Description	**QMS Section**	**ISO 9001-2000(E)**	**10 CFR 71, Subpart H**	**R.G. 7.10**	**R.G. 6.9 (10CFR32)**	**10 CFR 50, Appendix B**	**21 CFR 820**	**ISO 13485: 2003(E)**	**CMDCAS (Section)**	**EU Directive Article/Annex**
Management Responsibility	1.0	5.1	71.105	1.1	2.0	II	820.20	5.1	10-20	AII 3.2(b)
Quality Policy	1.1	5.2, 5.3, & 5.4	--	1.2	--	--	--	5.2, 5.3, & 5.4	--	AII 3.2(a)
Responsibilities / Organization	1.3	5.5	71.103	1.1	1.0	I	820.20	5.5	--	AII 3.2(b)
Quality System	1.4	4.1 & 4.2	71.105	2	7.0	II & V	820.20	4.1 & 4.2	32	AII & V
Instructions, Procedures & Drawings	4.0	4.2.1	71.111	5	7	V	820.20	4.2.1	32	AII 3.2
Management Review	1.5	5.6	71.105	--	--	II	820.20	5.6	32	AII 3.2(b)
Contract Review	2.0	7.2.2	--	--	--	--	--	7.2.2	26	--
Design Control	3.0	7.3	71.107	3	4.0	III	820.30	7.2.2	9-20 & 34	Article 9 AII 3.2(c) & 4
Document & Data Control	4.0	4.2.3	71.113	6	4.0	V & VI	820.40	4.2.3	32	--
Purchasing	5.0	7.4	71.109 & 71.115	4 & 7	5.0	IV &VII	820.50	7.4	9	AII 3.2(d)
Control of Customer Supplied Product	6.0	7.5.4	--	--	--	--	--	7.5.4	--	--
Product Identification & Traceability	7.0	7.5.3	71.117	8	6.0	VIII	820.60, 65, & 120	7.5.3	52-56	AII 3.2(d)
Process Control	8.0	7.5.2	71.119	9	7.0	IX	820.25 & 70	7.5.1 & 7.5.2	17	AII 3.2(d)

		General	Type B Transport Packages		Sources					
					General	Reactor	Medical Devices			
QMS Element Description	**QMS Section**	**ISO 9001-2000(E)**	**10 CFR 71, Subpart H**	**R.G. 7.10**	**R.G. 6.9 (10CFR32)**	**10 CFR 50, Appendix B**	**21 CFR 820**	**ISO 13485: 2003(E)**	**CMDCAS (Section)**	**EU Directive Article/Annex**
Inspection & Testing	9.0	8.2.4	71.121 & 71.123	10 & 11	8.0	X & XI	820.80	8.2.4	32	AII 3.2(e)
Control of Measuring & Test Equipment	10.0	7.6	71.125	12	3.0	XII	820.72	7.6	32	AII 3.2(b)
Inspection and Test Status	11.0	7.5.3	71.129	14	6.0	XIV	820.86	7.5.3.3	32	AII 3.2(b)
Control of Nonconforming Material	12.0	8.3	71.131	15	9.0	XV	820.90	8.3	32	AII 3.2(b)
Corrective & Preventive Action	13.0	8.5	71.133	16	11.0	XVI	820.100	8.5	57, 59, 63-65	Article 10 & 19 AII 3.1
Handling, Preservation, Storage, and Delivery	14.0	7.5.5	71.127	13	10.0	XIII	820.130 to 820.160	7.5.5	14, 52-56	--
Control of Quality Records	15.0	4.2.4	71.135	17	13.0	XVII	820.180	4.2.4	55	AII 3.2 & 6.1
Internal Audits	16.0	8.2.2	71.137	18	12.0	XVIII	820.22	8.2.2	32	--
Training	17.0	6.2.2	71.105	2	2.0	II	820.25	6.2.2	32	--
Servicing & Installation	18.0	7.5.1	--	--	--	--	820.200	7.5.1	32	--
Statistical Techniques	19.0	8.2.3	--	--	--	--	820.250	8.2.3	--	--
Process Monitoring & Continuous Improvement	20.0	8.4	--	--	11.0	--	820.250	8.4	32	AII 3.1
Project Management	21.0	5.4.2 & 7.2	--	--	--	--	--	5.4.2 & 7.2	10, 32	--
Safety Programs	22.0	--	--	--	--	--	--	--	--	--

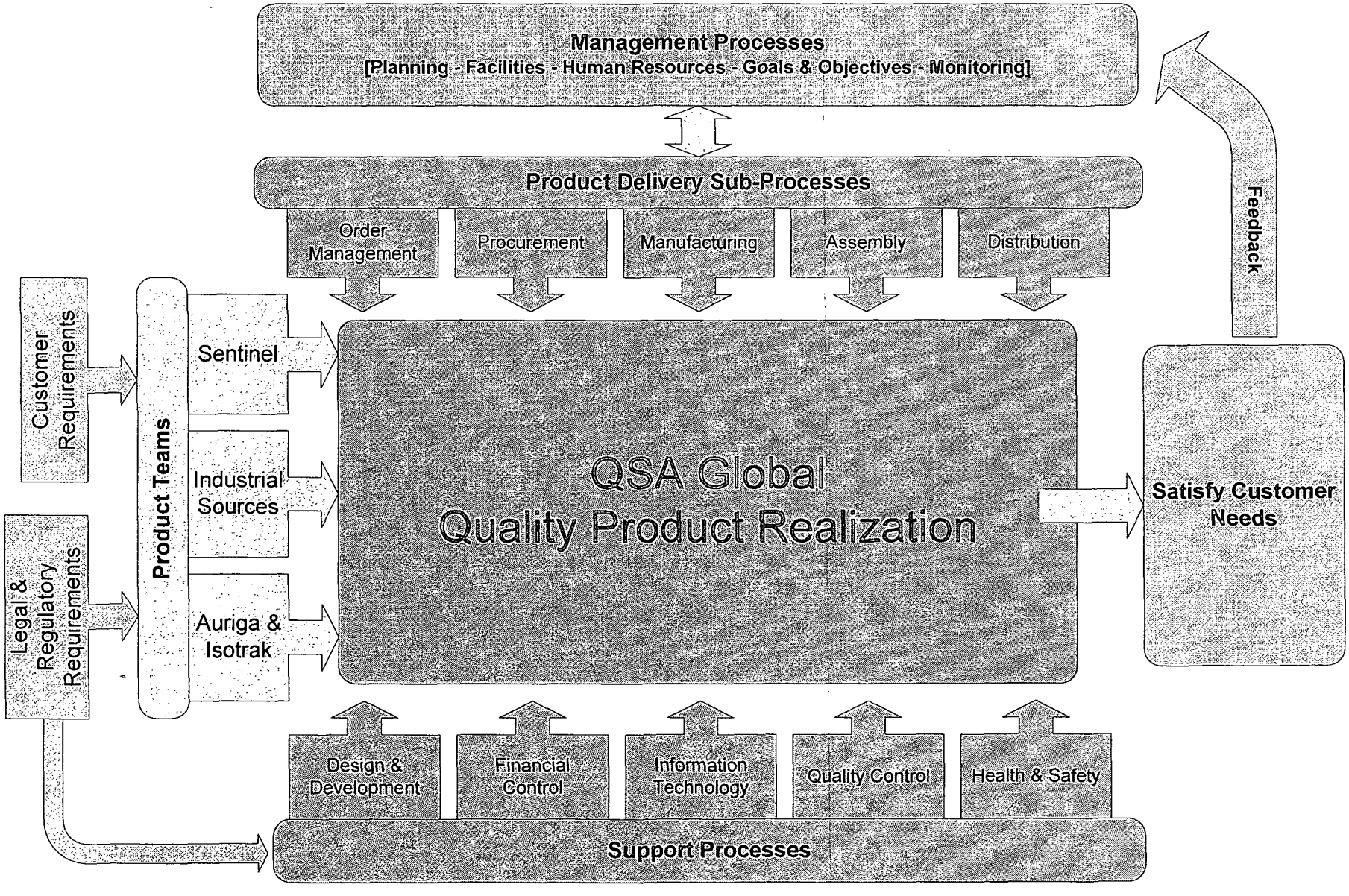
Appendix B – Quality Management System Implementing Procedures

NRC Position		Procedure	Title	Description
RG 7.10	RG 6.9			
1	C.1	QSM-1	Quality System Manual	Overall description of business, functional organization, and quality assurance program.
2	C.1			
3	C.4	QMP-1200	Design Control	This procedure establishes and maintains the method to control and verify the design of new products to ensure the specified requirements are met.
4	C.5	QMP-1400	Purchasing	This procedure describes the requirements for ensuring the quality of procured materials and/or services conform to specified requirements.
5	C.4	QMP-1300	Document & Data Control	This procedure describes the requirements for the control of documents and data pertinent to the quality management system.
6	C.4			
7	C.5	QMP-1400	Purchasing	This procedure describes the requirements for ensuring the quality of procured materials and/or services conform to specified requirements.
8	C.6	QMP-1600	Product Identification and Traceability	This procedure describes the requirements for identification and control of materials, parts, and components.
9	C.7	QMP-1700	Process Control	This procedure describes the methods for production process control.
10	C.8	QMP-1800	Inspection & Testing	This procedure controls the inspection and testing activities for products, materials and services (units) verifying that they meet the specified requirements.
11	C.8			
12	C.3	QMP-1900	Control of Measuring & Test Equipment	This procedure describes the method for control of measuring and test equipment, and key process equipment used at AEA Technology QSA Inc.
13	C.10	QMP-2300	Handling, Storage, Packaging, & Delivery	This procedure describes the requirements for assuring that product throughout the business process will be handled and stored in ways that preserve the product quality.

Appendix B – Quality Management System Implementing Procedures

NRC Position		Procedure	Title	Description
RG 7.10	RG 6.9			
14	C.8	QMP-2000	Inspection & Test Status	This procedure describes the methods used to assure the Inspection, Test, and Operating Status of materials, parts, and products is identified and maintained.
15	C.9	QMP-2100	Control of Nonconforming Material	This procedure describes the methods to control materials, parts, and components that do not conform to specified requirements in order to prevent use.
16	C.11	QMP-2200	Corrective and Preventive Actions	This procedure describes the requirements of a system for documenting, investigating and implementing Corrective and Preventive Actions.
17	C.13	QMP-2400	Control of Quality Records	This procedure describes the requirements for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.
18	C.12	QMP-2500	Internal Quality Audits	This procedure describes the requirements for planning and implementing internal quality audits.

Appendix C – Key Process Model



Appendix D – Summary of Changes to Prior Revision

Section / Paragraph	Description of Change
Table of Contents	Revised to reflect page number changes.
1.2 Introduction	Added contract manufacturing to scope
1.6.3 Resource Management	Added procedures and controls are established to protect personnel and product
3.4 Design Transfer	Added language describing how design is translated into instructions for implementation by production.