AEA TECHNOLOGY
QSA

AEA Technology QSA Inc.
STANDARD OPERATING PROCEDURES

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TITLE: QUALITY ASSURANCE PROGRAM

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1.0 Purpose

The purpose of this procedure is to describe the general aspects of AEA Technology QSA, Inc. Quality Assurance (QA) program.

2.0 Application

AEA Technology QSA, Inc. QA program applies to the design, purchase, manufacture, inspection and testing of all materials, parts, components, subassemblies and assemblies of radioactive sources, radiographic exposure devices, related handling equipment, radioactive material storage containers, packaging for the transportation of radioactive material and manufactured accessories, that have been classified as important to safety.

3.0 Program Description

3.1 Organization

This section describes the organization of AEA Technology QSA, Inc. Burlington, MA Facility as it relates to QA as described in Section 2.0. The final responsibility for the QA program rests with AEA Technology QSA Inc., Burlington, MA Facility. QA and quality control functions are established by AEA Technology QSA Inc., Burlington, MA Facility. When an outside consultant is used, they will conform to AEA Technology QSA, Inc. QA Program.

The QA program is implemented using the organizational structure described in Attachment 1.

The QA department is responsible for overall administration for the program. Responsibilities for specific portions of this program are delineated in this program description.

QA personnel have the responsibility and authority delineated in writing, to stop unsatisfactory work and control further processing, delivery or installation of nonconforming material.

All employees of AEA Technology QSA, Inc. have the responsibility to report immediately to QA personnel their knowledge of any nonconformance or a condition

which could create a nonconformance.

3.2 **QA Program**

This section describes the general aspects of the QA program.

Management above and outside the QA organization is kept informed of the scope, status, implementation and effectiveness of the QA program to assure that the program is adequate and complies with all appropriate regulatory criteria.

Standard Operating Procedures (SOP's) are established to ensure conformance to regulatory requirements and to assure these requirements are carried out.

Copies of the SOP's are controlled and distributed to all individuals with responsibilities related to the performance of the SOP. Copies are controlled and records of distribution are maintained.

Provisions are established for communication to all responsible organizations and individuals that quality policies and procedures are mandatory requirements which must be implemented and maintained.

The design, purchase, manufacture, inspection, and testing of components, that are classified as important to safety used in or as part of subassemblies and assemblies which comprise radioactive material transportation packages, including radioactive source assemblies, are controlled by the QA Program.

An indoctrination and training program is established such that:

(a) Personnel responsible for performing quality related activities are instructed as to the purpose, scope and implementation of the QA Program, and SOP's.

(b) Personnel performing quality affecting activities are trained and qualified in the principles and techniques for the activity being performed.

(c) The scope, objective and method of implementing the indoctrination and training program are documented.

(d) Proficiency of personnel performing quality affecting activities is maintained by retraining and rectifying.

Quality related activities are performed with specified equipment under suitable environmental conditions, and prerequisites have been satisfied prior to inspection and testing.

Items important to safety are determined and categorized as A, B, or C parts in accordance with established definitions and the list maintained and updated as necessary. The rational for these determinations is documented.

3.3 **Design Control**

This section describes the design control aspects of the QA program.

Measures are established to carry out design activities in a planned, controlled and orderly manner.

Measures are established to translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures and instructions and that maintenance, repair, handling and storing are addressed as needed.

Quality standards are specified in the design documents, and deviations and changes from these quality standards are documented and controlled.

Designs are reviewed to assure that (1) design characteristics can be controlled, inspected and tested and (2) inspection and test criteria are identified.

Proper selection and accomplishment of design verification and checking processes such as by design reviews, alternate calculations, or qualification testing are performed.

Individuals responsible for design verification are other than the original designer.

Design and specification changes are subject to the same design controls and approvals that were applicable to the original design.

The positions responsible for design verification activities and their authority and responsibility are identified and controlled by written procedures.

Appropriate controls are implemented to assure control of drawings and their preparation in accordance with standard engineering practices.

3.4 **Procurement Document Control**

Procedures are established that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents.

Procurement documents contain or reference the material and component identification requirements, drawings, specifications, codes and industrial standards, test and inspection requirements, and special process instructions as needed.

Changes and revisions to procurement documents are subject to the same review and approval as the original document.

Measures are established for the requirements for reporting and approving disposition of nonconformances.

3.5 **Instructions, Procedures, and Drawings**

Activities affecting quality and safety are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

Provisions are established which clearly delineate the sequence of actions to be accomplished in the preparation, review, and control of procedures, and drawings.

The QA organization reviews and concurs with inspection plans; test, calibration, and special process procedures; drawings and specifications; and changes thereto or acceptable alternatives are described.

Procedures and drawings include quantitative and qualitative acceptance criteria to verify that activities important to safety have been accomplished.

3.6 **Document Control**

The review, approval, and issuance of documents and changes thereto, prior to release, are procedurally controlled to assure they are adequate and the quality requirements are stated.

Changes to documents are reviewed and approved by the same organizations that performed the original review and approval.

Approved changes are included in instructions, procedures, drawings, and other documents prior to implementation of the change.

Current documents are accessible to individuals while performing activities.

Master lists are established to identify the current revision number of instructions and procedures.

3.7 **Control of Purchased Material, Parts and Components**

Qualified personnel evaluate the supplier's capability to provide acceptable quality service and components.

The evaluation of suppliers is based on one or more of the following:

(a) receiving inspection;
(b) a review of previous records and performance of suppliers who have provided similar articles of the type being procured;
(c) periodic special verification and testing against certificates and
(d) a vendor approval program of the supplier's QA program to determine his capability to supply a product which meets the design, manufacturing, and quality requirements.

Results of supplier evaluations are documented and filed.

The supplier furnishes to the purchaser documentation that identifies the purchased material or equipment, the drawing revision if appropriate, the quantity and the P.O. number.

Receiving inspection of the supplier-furnished material, equipment, and services is performed to assure:

(1) The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.

Material, components, equipment's, and acceptance records are inspected and judged acceptable in accordance with predetermined inspection instructions, prior to installation or use.

(3) Inspection records or certificates of conformance attesting to the acceptance of material and components are available prior to installation or use.

(4) Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for further processing.

Measures are established to ensure proper disposition of items that do not meet procurement documents.

3.8 Identification and Control of Materials, Parts, and Components

Procedures are established to identify and control materials, parts, and components including partially fabricated subassemblies.

The identification and control procedures assure that identification is maintained with or on the item or on records traceable to the item to preclude use of nonconforming or defective items.

Identification of materials and parts important to the function of safety-related systems and components can be traced to the appropriate documentation such as drawings, specifications, purchase orders, manufacturing and inspection documents, discrepancy reports, and other applicable test reports.

Correct identification of materials, parts, and components is verified and documented prior to release for fabrication, assembling and installation

3.9 Control of Special Processes

Special processes such as welding, heat treating, nondestructive testing, and cleaning are procedurally controlled.

Procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.

Qualification records of procedures, equipment, and personnel associated with special processed are established, filed, and kept current.

3.10 Inspection

An inspection program which verifies conformance of quality affecting activities with requirements is established, documented, and accomplished in accordance with written and controlled procedures.

Inspection personnel are independent from the individuals performing the activity being inspected.

Inspectors are qualified in accordance with applicable codes, standards, and company training programs; and their qualifications and certifications are kept current.

Modifications, repairs, and replacements are inspected in accordance with original design and inspection requirements or acceptable alternatives.

Final inspections shall be established to ensure traceability of the item to specific records, and to ensure that inspection records (as applicable) are reviewed to assure that all inspection requirements have been met.

Provisions are established that identify mandatory inspection hold points for witness by a second qualified individual.

The inspection plan for the parts is documented and identifies the sampling plan.

3.11 **Test Control**

A test program to demonstrate that the item or component will perform satisfactorily in service is established, documented, and accomplished in accordance with written controlled procedures.

Modifications, repairs, and replacements are tested or evaluated in accordance with the original design and testing requirements or acceptable alternatives.

Test results are documented, evaluated, and their acceptability determined by a qualified, responsible individual or group.

3.12 **Control of Measuring and Test Equipment**

Measuring and test instruments are calibrated at specified intervals based on the required accuracy, purpose, degree of usage, stability characteristics, and other conditions affecting the measurement.

Measuring and test equipment is identified and traceable to the calibration test date.

Reference and transfer standards are traceable to nationally recognized standards; or, where national standards do not exist provisions are established to document the basis for calibration.

3.13 **Handling, Storage, and Shipping**

Special handling, storage, cleaning, packaging, and shipping requirements are established and accomplished by qualified individuals in accordance with predetermined work and inspection instructions.

For Type B transport packages, all conditions (e.g., operations, tests, inspections, specifications) of the NRC package approval and the U.S. Department of Transportation shipping requirements are satisfied prior to shipment of a Type B quantity of radioactive material.

Initial distribution will be properly identified by markings and contain the appropriate manuals for its use and maintenance.

3.14 **Inspection, Test and Operating Status**

After inspection is completed, the identification of the inspection, test and operating status of packages and components is indicated by tags, stickers or other status indicators.

The application and removal of inspection and status indicators such as tags, markings, labels, and stamps are procedurally controlled.

The status of nonconforming, inoperative, or malfunctioning packages or components is identified to prevent inadvertent use.

3.15 **Nonconforming Material, Parts, or Components**

The identification, documentation, segregation, review disposition, and notification to affected organizations of nonconforming materials, parts, components, or services are procedurally controlled.

Documentation identifies the nonconforming item; describes the nonconformance, the disposition of the nonconformance, and the inspection requirements; and includes signature approval of the disposition.

Nonconforming items are segregated from acceptable items and identified as discrepant until proper disposition.

Acceptability of rework or repair of materials, parts, components and systems is

verified by reinspecting and retesting the item as originally inspected and tested or by a method which is at least equal to the original inspection and testing method.

Nonconformance reports are reviewed to determine quality trends.

3.16 **Corrective Action**

Measures are established to ensure that causes of adverse quality are promptly identified and an evaluation is conducted to determine the need for corrective action in accordance with established procedures.

Corrective action is initiated following the determination of a condition adverse to quality to preclude recurrence.

Follow-up reviews are conducted to verify proper implementation of corrective actions and to close out the corrective action documentation.

3.17 **QA Records**

Sufficient records are maintained to provide documentary evidence of the quality and safety of items and the activities affecting quality and safety. QA records include operating logs, results of reviews, inspections, tests, audits, and material analyses; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports; nonconformance reports; and corrective action reports.

Records are identifiable and retrievable.

Design related records (e.g., drawings, calculations) are maintained for the life of the shipping package and all other records are maintained for a minimum of two years.

Inspection and test records contain the following where applicable:

(1) A description of the type of observation.
(2) Evidence of completing and verifying a manufacturing, inspection, or test operation.
(3) The date and results of the inspection or test.
(4) Information related to conditions adverse to quality.
(5) Inspector or data recorder identification.
(6) Evidence as to the acceptability of the results.

3.18 **Audits**

Audits are performed in accordance with preestablished written procedures or check lists and conducted by personnel not having direct responsibilities in the areas being audited.

Audit results are documented and then reviewed with management having responsibility in the area audited.

Responsible management takes the necessary action to correct the deficiencies revealed by the audit.

Deficient areas are re-audited on a timely basis to verify implementation of corrective actions which minimize recurrence of deficiencies.

Audits of the QA program are performed at least annually based on safety significance of the activity being audited.

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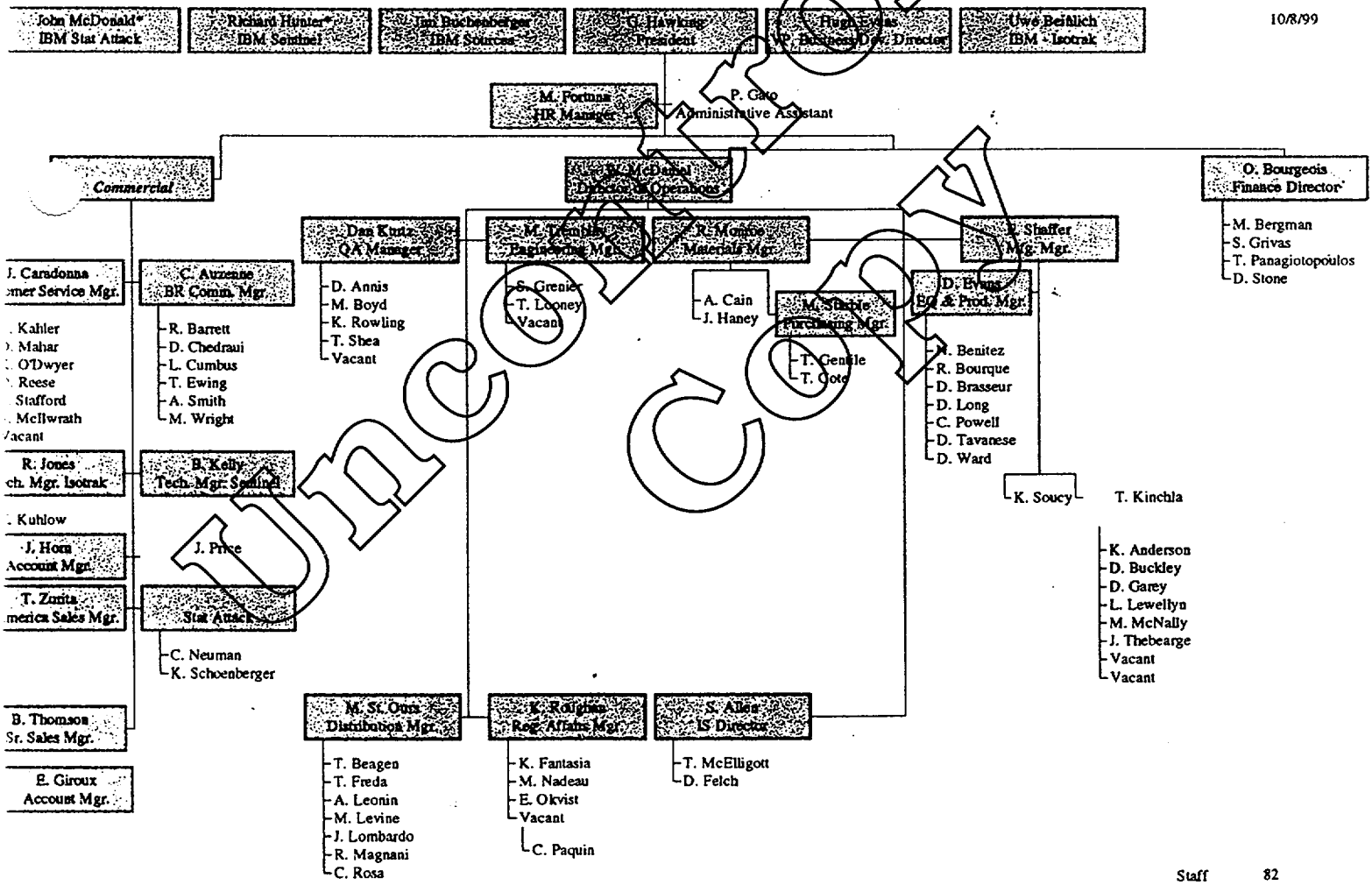
ATTACHMENT I

SAMPLE ORGANIZATIONAL CHART

AEA TECHNOLOGY QSA, INC.



Staff	82
Vacancies	7
**Total Posts	89

* Not included in staff count
** Includes 2 p/t staff