71-0496

Duratek™

10100 Old Columbia Road
Columbia, Maryland 21046
410-312-5100 fax 410-290-9070
www.duratekinc.com

August 29, 2005

Mr. Robert J. Lewis
Transportation and Storage Inspection Section
Spent Fuel Program Office, NMSS
US Nuclear Regulatory Commission
Washington, DC 20555

Re: Quality Assurance Program 71-0496

Dear Mr. Lewis:

This correspondence serves as a request for amendment for the Duratek, Inc. Quality Assurance Program. Revision 8 is submitted for your review and approval prior to Duratek, Inc. implementation. With this request Duratek has attached Revision 8 to Quality Assurance Program 71-0496. Duratek, Inc. will continue to operate to the NRC approved Revision 7 until notified by the Commission of the Revision 8 approval.

Revision 8 reflects changes in the Duratek organizational structure and some minor word changes. Revision 8 does not reduce any of the requirements of controls that are in effect for Part 71, Subpart H activities. Changes are noted for your ease in review.

We respectfully request that you review this revision and provide approval.

If you have any questions regarding this submittal, please contact Norman R. Barker or myself at 410-312-5100.

Sincerely,

W. W. Bixby

Willis Bixby
Sr. Vice President and Group Leader ESHQA
Duratek, Inc.

NMSS01

Quality Assurance Program

Revision 8

Authored By:	R. Campbell, Director, ESHQA, Commercial Services	Date
Reviewed By:	N. Barker, Director, Corporate Quality Assurance	Date
Approved By	W. Bixby, Vice President, ESHQA	Date
Approved By	R. Prince, President and CEO	Date

- ☐ New Procedure
- ☐ Title Change
- ☒ Procedure Revision
- ☐ Procedure Rewrite

Effective Date: October 31, 2005

Table of Contents

PURPOSE

This Quality Assurance Program (hereinafter referred to as the QAP) has been developed to ensure products and services provided by Duratek meet applicable regulatory, industry, and contract requirements. Duratek is committed to the delivery of superior products and service to all our customers.

The QAP meets the requirements of 10 CFR 50 Appendix B; the American Society of Mechanical Engineers (ASME) NQA-1; 10 CFR 71, Subpart H; 10 CFR 72, Subpart G; and 10 CFR 830, Subpart A. A crosswalk matrix is included as Attachment 1 and provides a visible presentation of how these elements have been addressed in the QAP.

SCOPE

The QAP applies to important-to-safety items and activities as defined by the regulatory codes and standards applicable to the scope of work of ~~each~~ Duratek ~~Business Group~~. The QAP is implemented in a graded and customized approach based on a specific evaluation of regulations, risks, complexity, and history of previous implementation. The application of a graded approach philosophy for implementation of the QAP does not relieve Duratek of its responsibility to maintain compliance with associated regulatory codes and standards. The QAP also ensures, by specific application of users, to items and activities important to client safety, radiological protection, and environmental requirements.

1. ORGANIZATION

1.1 Organizational Structure

Primary Duratek organization and facilities are located in Columbia, Maryland; Oak Ridge, Tennessee; Columbia, South Carolina; Barnwell, South Carolina; Lakewood, Colorado; and Richland, Washington. Duratek satellite project and field offices are established as necessary to be responsive to project demands and have reporting relationships to the Duratek organization located at the primary locations. The structure, functional responsibilities, levels of authority, and lines of communication for activities affecting quality are clearly established in writing. The organization depicted in Figure 1 identifies Duratek's Corporate Environmental, Safety and Health, Radiological Protection, and Quality Assurance (ESHQA) organization structure. Figure 2 depicts the typical Business Group ESHQA reporting structure. Detailed charts are maintained at Duratek facilities.

Duratek is organized by functional areas hereafter addressed as Business Groups. An ESHQA group supports these Business Groups. Group descriptions are as follows:

1.1.1 Commercial Services ~~Processing~~

This Business Group provides waste processing services to generators of radioactive waste, ~~and~~ manages Duratek's waste processing fixed facilities,~~. This Business Group also~~ manages large component and special projects, waste transportation services and licensing expertise in support of 10 CFR Part 71 transportation casks. This Group also provides radiological and waste management services at nuclear plant sites, including water processing, fuel pool services, and waste management consulting for nuclear utilities. Waste management services provided also include decontamination and decommissioning, onsite waste services, and brokering of waste shipments at utility, non-utility, and government sites.

1.1.2 Commercial Disposal

Commercial Disposal along with Barnwell operations provides disposal services to generators of low-level radioactive waste in strict accordance with regulatory requirements.

1.1.3 ~~Commercial Services~~Strategic Growth

This Business Group provides strategic growth initiatives in advance technologies, innovation, and international expansion. This group provides strategic evaluation and development of Duratek service offerings~~This Business Group provides radiological and waste management services at nuclear plant sites, including water processing, fuel pool services, and waste management consulting for nuclear utilities. Waste management services provided also include decontamination and decommissioning, onsite waste services, and brokering of waste shipments at utility, non-utility, and government sites.~~

1.1.4 Federal Services

The Federal Services provides comprehensive nuclear and radiological facility operations, site management, engineering, waste management, vitrification, and fabrication services. Federal Services activities are performed on government sites, such as Department of Energy (DOE) sites under customized QA Programs.

1.1.5 Environmental, Safety, Health, Radiological Protection, and Quality Assurance

Corporate ESHQA establishes and communicates the quality policy and quality program requirements. This support Group provides regulatory compliance oversight to assure that Duratek's activities comply with regulatory, permit, license, and contractual requirements. This Group also provides interface with regulatory agencies to ensure safe operations that comply fully with federal, state, and local regulations. Corporate ESHQA includes the following functional areas:

- Quality Assurance
- Industrial Safety and Health
- Environmental Compliance
- Radiological Protection
- Security

1.2 Responsibilities and Authority

The organization chart in Figure 1 reflects the reporting relationship of the Corporate ESHQA organization to the highest level of Duratek Management. This chart is typical and will not be revised in the QAP unless the ESHQA organizational relationship changes.

Figure 2 reflects typical Business Group structures and the reporting relationship with its internal ESHQA function to its highest level of management, as well as the reporting structure to the Corporate ESHQA Group.

1.2.1 President and CEO

The President is the Chief Executive Officer of the company and has the overall responsibility for establishing the quality policy and requirements for the company, including:

- Approval of the Quality Policy and the Quality Assurance Program (QAP).
- Assignment of responsibilities to the Group Leaders and the Vice President, ESHQA for important-to-safety activities of Duratek.
- Evaluation of proper and adequate implementation of the QAP through regular reporting by the Vice President, ESHQA and Group Leaders.

1.2.2 Vice President, ESHQA - Duratek

The Vice President, ESHQA is the management representative designated by the President as responsible for the development of the Quality Program requirements and to assess the Company for the effective implementation of the QAP. The Vice President has direct access to the President to report on matters related to quality and is provided effective lines of communication with Business Group Leaders to obtain appropriate corrective action. The Vice President, ESHQA has authority to stop work when deemed appropriate.

1.2.3 Director, Quality Assurance - Corporate

The Director, Quality Assurance reports directly to the Vice President, ESHQA. The Director, QA is responsible for establishing and maintaining the QAP and corporate procedures controlled by the Vice President, ESHQA, verifying effective implementation, and for providing support to projects and operations. The Director, QA has no unrelated duties and responsibilities that would preclude the attention to these assigned quality responsibilities.

The Director, QA has been granted authority, access to work areas, and organizational freedom to:

- Identify quality problems;
- Initiate, recommend, and provide solutions to quality problems through organizational channels;
- Verify implementation of solutions;
- Assure that further processing, delivery, installation, or use is controlled until proper corrective actions have occurred. The Director, QA has authority to stop work when deemed appropriate; and
- Maintain independence from cost and scheduling considerations.

The Director, QA ensures that persons or organizations not directly responsible for performing the work verify quality achievement. The Director, QA is responsible for assessing the individual Business Groups on the adequacy of implementation of the QAP through periodic assessments and by participating in Business Group level audit and assessment activities. The Director ensures that activities affecting quality are performed at the Business Group level in accordance with written procedures and instructions that provide sufficient detail to meet customer and regulatory requirements.

The position description for the Director, QA includes prerequisite experience and/or required training. Qualifications for the Director, QA include:

- A Bachelor's degree in a technical field or equivalent experience;
- At least ten years experience in quality assurance, engineering, or manufacturing;
- A working knowledge of applicable quality-related codes, standards, and regulatory requirements; and
- The ability to prescribe, apply, and assess compliance with the applicable requirements.

1.2.4 Duratek Group Leaders

The senior management of Duratek Business Groups, specifically the Group Leaders for ~~Commercial Processing,~~ Commercial Disposal, Federal Services, and Commercial Services, have overall responsibility for the development and implementation of quality requirements and

controls for their projects and activities. These activities include, but are not limited to, order entry, organizational structure, personnel responsibilities, and the identification of project criteria and necessary levels of rigor.

The implementation of quality requirements begins with order entry and is performed by receiving, reviewing, and processing customer orders by the responsible project team. The order entry process is limited to orders or procurements that specify items important-to-safety. This project team will be comprised of, at a minimum, representatives from project/facility management, contracts, and ESHQA. These reviews are comprised of verification that customer requirements are adequately defined, documented, and understood and that the company has the capacity to meet the contract requirements. Changes to contracts are reviewed in the same manner as the original order.

Organizational structure is documented for projects defining levels of authority and lines of communication. Personnel responsibilities are defined to provide understanding of project goals and accountability for operations. Quality, safety, technical criteria, and levels of rigor are described in implementing procedures specific to project and fixed-based facility operations.

All levels of Duratek management are responsible for establishing appropriate methods in written procedures and instructions to ensure quality objectives can be achieved as well as meeting customer and regulatory requirements. When more than one organization is involved in the execution of activities, the responsibility and authority of each organization is clearly established and documented. Duratek management is responsible for establishing external and internal interfaces between organizational units, defining responsibilities in writing, and documenting changes when appropriate.

1.2.5 Business Group Director, ESHQA

The Group Directors, ESHQA are responsible to ensure that applicable requirements of the QAP are implemented. These duties include, but are not limited to activities such as training personnel and providing resources before an important-to-safety activity within the scope of the QAP is undertaken by Duratek or by others.

Each Group Director, ESHQA is responsible to assure proper implementation oversight within that Business Group.

The Group Director, ESHQA reports directly to the Group Leader of their respective Business Groups. The Group Director, ESHQA is responsible for implementing the QAP and procedures and for providing support to projects and operations.

The Group Director, ESHQA will be granted authority, access to work areas, and organizational freedom to:

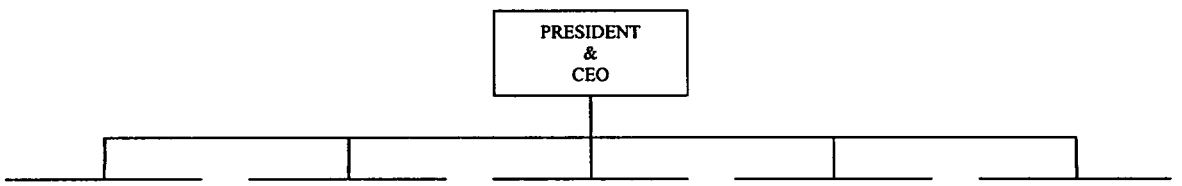
- Identify quality problems;
- Initiate, recommend, and provide solutions to quality problems through organizational channels;
- Verify implementation of solutions;
- Assure that further processing, delivery, installation, or use of items and activities is controlled until proper corrective actions have occurred. The Group Director, ESHQA has authority to stop work when deemed appropriate; and
- Maintain independence from cost and scheduling considerations.

The Group Director, ESHQA ensures that persons or organizations not directly responsible for performing the work verify quality achievement. The Group Director, ESHQA is responsible for assessing their individual Business Groups on the adequacy of implementation of the QAP through periodic audits, assessments, surveillances, and inspections. The Group Director, ESHQA ensures that activities affecting quality are performed at their Business Group levels in accordance with written procedures and instructions that provide sufficient detail to meet customer and regulatory requirements.

1.2.6 Delegation of Work

Senior management of these organizations may delegate, in writing any or all of the work to others. Responsibility, however, cannot be delegated. Senior management retains responsibility for conformance to quality requirements for the delegated activity.

Figure 1: CORPORATE ESHQA ORGANIZATION



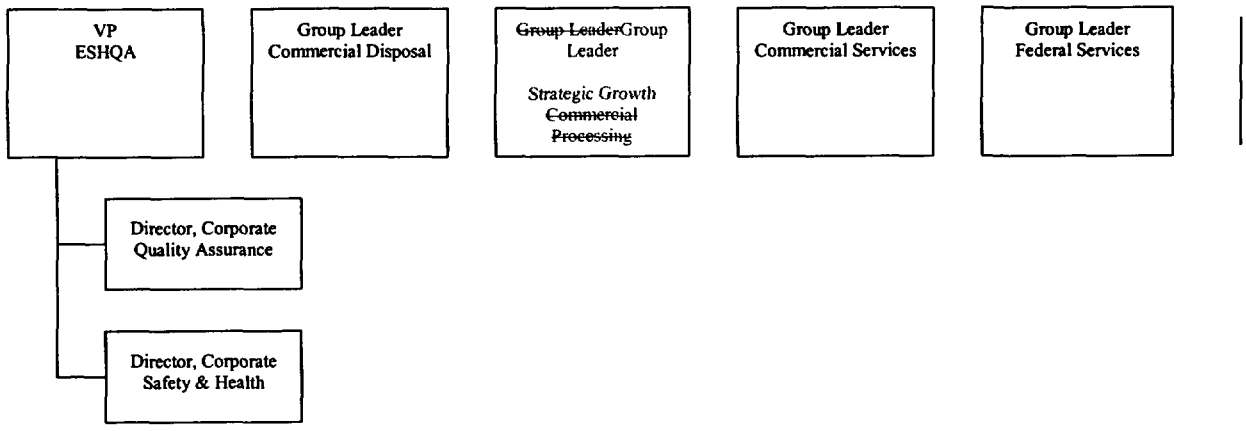
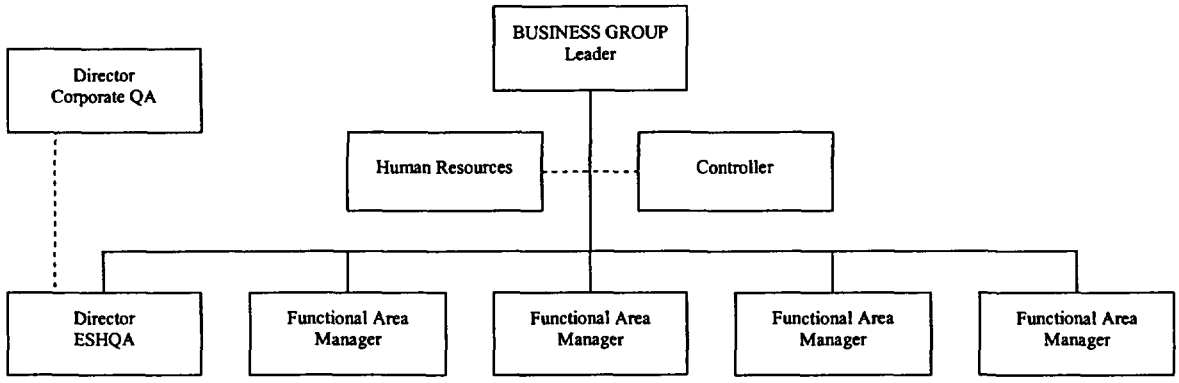


Figure 2: TYPICAL BUSINESS GROUP FUNCTIONAL ORGANIZATION



2. QUALITY ASSURANCE PROGRAM (QAP)

The Duratek QAP consists of those planned and systematic actions necessary to assure ~~confidence~~ that activities will be conducted in a satisfactory manner and that equipment and material will perform satisfactorily in service. The system is based on the concept that work performance is a process that can be planned, performed, assessed, and improved. Senior management is responsible for these ongoing activities. Since all work is accomplished using the resources of people, equipment, and procedures as directed by management, management is responsible for fostering an attitude of support and encouraging personnel to complete their work in a quality manner. All employees are responsible for identifying non-compliant work or areas for improvement. Management is responsible for identifying (both internal and external) customer needs and expectations. Meeting these needs and expectations is a measure of quality and success.

2.1 QAP Application

The QAP is the top-level document that describes the policies and practices for a planned and disciplined approach to achieve quality. The QAP is reviewed and

approved by the President and CEO and represents Duratek's overall philosophy regarding quality.

2.1.1 Quality Assurance Project Plans (QAPP) or Quality Assurance Operational Plans (QAOP) are written for the control of special project or operational activities describing criteria unique to the scope of work. QAPP or QAOP's are developed and maintained by the Project or Facility Manager with input and approval from the Director, ESHQA within each Business Group.

2.1.2 Corporate, Group, and project-specific procedures that describe how Duratek implements the requirements of the QAP are developed by each organization within Duratek. These procedures document methods for planning, reviewing, implementing, controlling, and verifying activities affecting quality.

The President and CEO, through the respective Group Leaders, has responsibility to ensure implementation and determine its effectiveness. The Vice President of ESHQA ensures that the QAP is properly established, documented, and approved. Group Leaders and managers are responsible to ensure that applicable requirements of the QAP are implemented.

The applicability of the QAP takes into consideration the regulatory requirements for important-to-safety items and activities, as well as the complexity and impact on safety, the need for special controls, demonstration of compliance through inspection and test, and the degree of standardization of the item. The requirements of the QAP are applied using a graded approach allowing control over items and activities to be commensurate with their importance and level of risk. Measures are established for identifying the components, systems, and structures to be covered by the QAP. During the planning of an activity or design of an item the application of the QAP requirements will be customized though the procedures and instructions. This graded approach will be performed in accordance with approved procedures. Graded applications deploy the appropriate quality requirements based on the level of importance of items and activities and are not reductions in quality requirements.

2.2 Quality Achievement, Management, and Verification

The achievement of quality in all activities is the responsibility of all employees and is led by management. The QAP provides for a systematic approach at various levels for oversight and assessment to assure the adequacy and effectiveness of implementation of QAP, QAPP's, and all implementing procedures. A tiered approach to verification and assessment includes self-checking by the individuals performing the work, supervision and review by leaders, independent inspection, and surveillance and verification to confirm adequacy and effectiveness of results. Managers are required to assess the

effectiveness of their own operations, implementation of their portion of the QAP, and regulatory programs. The group ESHQA personnel perform independent assessments to verify the effectiveness of the QAP. In addition, Corporate ESHQA provides reviews and evaluations, and independent assessments of the effectiveness of QAP implementation.

The management team provides systematic planning to establish the scope of work, analyze hazards, and confirm the appropriateness of controls to be applied. Work performed is then monitored to confirm performance within the established controls and to provide feedback to achieve a continuous improvement as an integral process of assuring effectiveness of the quality and safety systems.

The management team within each business group regularly performs reviews of activities that affect quality, safety, and regulatory requirements. The management team representing engineering, operations, quality assurance, safety, ALARA, and other areas as needed regularly holds formal review meetings, chaired by the group Director, ESHQA.

Oversight evaluations and regular reviews are performed annually evaluating the adequacy and effectiveness of the QAP. Business group management is responsible for assessing the effectiveness of their own operations, implementation of the QAP, and regulatory programs. The Corporate ESHQA Group will advise the President and his senior management team of the effectiveness of the QAP. This is accomplished through the performance and review of audits, assessments, inspections, surveillances, and trend analysis reports.

Resolution of issues concerning quality is resolved by the group Director, ESHQA or as necessary by the Corporate Director, QA.

2.3 Personnel Qualification and Certification

2.3.1 Training and Indoctrination

Managers of activities affecting quality assess their organizations' training needs and conduct or verify training and qualification adequate for the performance of work activities. This includes indoctrination to and familiarization with the QAP and any special skills training required for the performance of job activities. Qualification is completed prior to the commencement of work. The extent of such training is commensurate with the scope, nature, and complexity of the activity, as well as the education, experience, and abilities of the individual. Training scopes, objectives, and methods of implementation are included in approved procedures.

2.3.2 Inspection and Test Personnel

Inspection and test personnel have experience commensurate with the scope of work and the complexity of the activity. Inspection and test personnel are selected and trained in accordance with approved procedures. The job performance of inspection and test personnel is reevaluated at periodic intervals not to exceed three (3) years. Certification or qualifications that are revoked for deficient job performance will result in the evaluation of items inspected or tested by the individual.

Personnel performing nondestructive examinations are qualified in accordance with the American Society of Nondestructive Testing recommended practice.

Certification documentation shall be maintained in accordance with approved procedures.

2.3.3 Lead Auditors and Inspectors

Quality Assurance (QA) Lead Auditors are qualified and certified by Duratek or by Duratek approved suppliers. Lead Auditors are qualified in accordance with established procedures, and records are maintained. Training methods, minimum experience requirements, and certification practices are in accordance with recognized national standards. At least annually, proficiency re-evaluations are performed and documented for individuals performing audit activities and appropriate certification renewal or re-qualification actions are taken.

Personnel performing inspection activities are qualified and certified in accordance with established procedures that comply with ANSI N45.2.6, 1978 or NQA-1, Supplement 2S-3, 1994.

Auditor and Inspector certification documentation shall be maintained in accordance with approved procedures.

3. DESIGN CONTROL

Design Control Programs ensure that the design meets applicable regulatory requirements, and that design activities are carried out in a planned and controlled manner. Programs and procedures describe responsibilities for design interface, control, verification, and change. Approved programs and procedures govern translation of applicable customer and regulatory requirements and design bases into design, procurement, and procedural documents, as well as controlling the design documents and design document distribution.

3.1 Design Input

Management and engineering organizations are responsible for identifying and documenting design input. Design inputs include:

- Design basis;
- Performance requirements;
- Regulatory requirements;
- Customer specifications;
- Industry codes and standards; and
- Technical requirements.

The input used in each design is documented, reviewed, and approved in a timely manner by the responsible design organization. Documented design inputs provide the necessary level of detail to ensure the design activity can be carried out correctly and provides a consistent basis for making decisions, accomplishing design verification, and for evaluating changes. Changes from approved design inputs, including the reason for the changes, are documented, approved, and controlled.

3.2 Design Process

Duratek engineering describes and controls the design process through approved procedures. Appropriate design documents are developed to support the design, construction/manufacture, and operation. Quality standards are identified, documented, and approved by cognizant personnel.

In addition, measures are established for selection and review for suitability of application of materials, parts, equipment, and processes.

Design activities result in design output documents that meet the design input requirements. Design documents contain the identification of assemblies and/or components that are part of the item being designed.

These measures include provisions to assure quality standards are specified and included in design documents. Any deviations from these standards are documented, reviewed, and approved.

3.3 Design Analysis

Design analysis is performed and documented in accordance with approved procedures. Design analysis reports provide details of (where applicable):

- The objective of the analysis;
- Design inputs and their sources;
- Literature research and background data;
- Assumptions and designation of those that must be verified as design proceeds;
- Identification of computer calculations, including computer hardware and software; and
- Review and approval as specified in engineering procedures.

3.4 Design Verification

Design verification is performed to ensure that appropriate requirements and customer needs are translated to the design documents. Design verification is performed in accordance with approved procedures that define responsibilities, methods, and documentation requirements. Qualified, independent personnel perform design verification. This could include an engineering supervisor who initiated the design provided he/she did not specify a singular design approach or rule out certain design considerations. No individual is ever the verifier for his/her own work or input.

Design verification methods include, but are not limited to, formal design reviews, alternate calculation, and qualification testing. The level of design verification applied complies with identified requirements. The extent of design verification is based upon the complexity of the item, importance to the safety of Duratek personnel and the public, regulatory requirements, contract requirements, or similarity with previously proven designs.

Design verification is usually performed and discrepancy resolution is complete prior to the release of the design output document for production uses or process implementation. An exception would be cases where insufficient data exists to finalize the design at a point in the project where material procurement or preliminary facility construction must begin. In such cases, unverified portions of the design are identified and controlled. Final design verification is completed prior to reliance on the item or process to perform its function. Engineering Managers shall document completion of design verification.

3.5 Design Review For Important-To-Safety Items

Managers are responsible for ensuring design reviews are performed at appropriate phases of the design process. Design review performance requirements, methods, and responsibilities are included in approved procedures.

The design is evaluated for the adequacy of the incorporated design inputs and the design methods used. Responsibilities for action items are assigned, completed, and action item results are incorporated into the final design.

Individuals or multi-disciplined design review teams perform independent reviews on important-to-safety items. These reviews are performed by competent personnel and address the following:

- Design input selection;
- Design output compared to design input and verification requirements from interfacing organizations;
- Design methods;
- Design inputs correctly incorporated into the design;
- Adequately described, reasonable, and identified assumptions; and
- Assignment of quality levels.

3.6 Alternate Calculation For Important-To-Safety Items

The requirements for verification by alternate calculations are described in procedures that include the review of appropriateness of assumptions, input data, and computer program or other calculation methods used.

3.7 Qualification Tests For Important-To-Safety Items

Qualification testing (synonymous with design validation) provides the assurance that products conform to defined user needs and/or requirements. Qualification tests of important-to-safety items validate and demonstrate the adequacy of performance under conditions that simulate the most severe design conditions in accordance with written test procedures and test specifications. Test specifications are reviewed and approved by the responsible engineering organization. The engineering group responsible for the design approves results of the qualification tests. For tests performed on models or mockups, scaling laws are established and verified. Test results obtained for model or mockup test work are subject to error analysis, where applicable, prior to use in final design work. Information regarding verification that is incomplete, including incomplete qualification tests, is available prior to installation of equipment.

3.8 Design Changes

Changes to final design, field changes, and modifications are justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the

items are still valid. Changes are approved by the same group organization responsible for review and approval of the original design documents.

3.9 Interface Control

Formal design interfaces are established when multiple organizations (internal or external) participate in the design process. Procedures are written that establish and document responsibility and authority for transmittal, review, approval, release, distribution, and revision of design inputs and design output documents.

3.10 Computer Programs

Computer programs (whether generated, transferred, or purchased) used to calculate or develop important-to-safety data shall be subjected to documented verifications or validations. Computer programs may be used for design analysis without individual verification of the program for each application provided:

- The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and
- The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

4. PROCUREMENT DOCUMENT CONTROL

Management has established controls for procured items and services in approved programs and procedures. These programs and procedures require the technical, quality, regulatory, and administrative requirements applicable to the procurement to be specified in procurement documents. To the extent necessary, procurement documents require suppliers to adequately implement a Quality Program consistent with the type and use of the item or service being purchased.

Management of the individual Business Groups is responsible for supplying personnel to perform the procurement process and ensuring that project-specific requirements for procurement documents are documented.

4.1 Content of the Procurement Document

Procurement documents shall include the following as applicable: the scope of work; technical and regulatory requirements; quality criteria for items and services; guidelines for review by quality assurance; quality requirements for suppliers and subtier suppliers; documentation requirements; quality record maintenance and retention; right of access for audit or inspection; requirements for reporting and approving supplier generated nonconformances; and identification of spare and replacement parts required.

4.2 Procurement Document Review

Technical, safety, and quality personnel, as required, who have an understanding of the requirements and intent of the procurement shall review the procurement documents. Procurement documents ~~orders~~ are reviewed, approved, and documented prior to ~~contract~~ award.

4.3 Procurement Document Changes

Changes to procurement documents receive the same levels of review and approval as the original.

5. INSTRUCTIONS, PROCEDURES, AND DRAWINGS

Management is responsible for ensuring that activities affecting quality are described in instructions, procedures, or drawings, which are prepared and approved prior to commencing activities. All Duratek employees are responsible to perform their activities in accordance with the requirements of these documents. These documents include appropriate quantitative, and qualitative acceptance criteria to verify that the activity has been satisfactorily accomplished.

Senior Management is responsible for maintaining these documents current to reflect actual work practice. Instructions, procedures, and drawings are prepared, reviewed, issued, and controlled in accordance with approved procedures. Changes to these documents receive the same levels of review as the original document.

6. DOCUMENT CONTROL

Documents that prescribe or affect quality are controlled to ensure that the proper revisions are used and that superseded or obsolete documents are not inadvertently used. Controlled documents include documentation for activities affecting quality such as procedures and drawings.

The document control system ensures that all documents are properly identified, distributed, and retained as specified in approved procedures. Documents are reviewed for adequacy and approved for release by authorized personnel prior to issuance. Documents are issued to and used at the location where the activity is performed. Document changes other than typographical errors and editorial corrections, or minor changes, are reviewed and approved in the same manner as the original document.

6.1 Document Preparation, Review, Approval, and Issuance

Management is responsible for identifying documents to be controlled and for their distribution. They are responsible for establishing controls that define responsibility, authority, issue, use, and revision of controlled documents.

Managers ensure that documents are reviewed for adequacy, completeness, and correctness prior to issue.

6.2 Document Changes

Major changes are reviewed and approved using the same process as the original document. Minor changes such as inconsequential editorial corrections do not require the same review cycle as the original document. Approved procedures define the types of changes considered minor and the persons who are permitted to make these changes.

7. CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

Duratek procurement controls establish measures to ensure those procured items and services for important-to-safety applications are clearly and adequately specified in procurement documents. Important-to-safety items and services are provided by suppliers and subcontractors who are capable of producing items and furnishing services that conform to procurement document requirements. These procurement methods are controlled by procedures for supplier evaluation, review of procurement requirements, and surveillance of supplier's facilities.

Commercial grade items may be procured and dedicated for important-to-safety applications.

Duratek shall identify the critical characteristics and the method(s) (e.g., special tests and inspections, commercial supplier survey, source verification, and/or acceptable supplier/item performance record) to be used to dedicate commercial grade items. ~~Each Group Director, ESHQA shall concur with the method of dedication.~~ Dedication of commercial grade items shall be accomplished in accordance with approved procedures.

7.1 Supplier Evaluation

Duratek technical, procurement, and QA personnel participate, as appropriate, in evaluation of potential procurement sources. Recommendations of procurement sources are based on these evaluations. Results of supplier evaluations performed prior to contract award are documented and retained. The evaluations cover review of capabilities and facilities for technical, manufacturing, and quality performance, and include any or all of the following, as appropriate:

- Historical performance data, particularly in product quality and delivery.
- Review and comment on supplier's QA Program.
- Source inspections, audits, or surveillances to verify supplier's QA Program implementation, as required.
- Source qualification programs.

Supplier evaluations include elements of the QA Program applicable to the purchased item or services.

Individual Business Group Procurement, Engineering, and the Director, ESHQA will identify and maintain needed supplier purchasing and qualification requirements for supplier qualification documentation.

7.2 Procurement Requirements

Requirements to be met by the supplier are detailed in the procurement documents, which may include procurement specifications. Procurement specifications detail the aspects of supplier QA requirements such as inspection reports, provisions for inspection, equipment calibration prior to use, and provisions for inspection after component repair. The procurement specification may also require the successful bidder to submit the following for Duratek's review:

- Special process procedures for performing welding, heat treatment, and nondestructive examination.
- Recommended inspection point program.
- Appropriate documentation as required by applicable codes, standards, and procurement documents.
- Notices of nonconformance and its disposition.
- Test procedures in accordance with applicable codes and standards.

7.3 Supplier Surveillance

The Business Group's Director, ESHQA is responsible for conducting and documenting supplier surveillance activities. Surveillance activities may include:

- Witnessing tests, inspections, nondestructive examinations, and various special process operations.
- Monitoring heat treatment, welding, cleaning, preserving, and packaging activities.

Verifying supplier conformance with established procedures such as:

- Use of Duratek accepted drawings and procedures.
- Use of accepted product and process quality planning.
- Document change control.
- Material identification and traceability control.

- Control of major welding repairs.
- Control and calibration of measuring and test equipment.

The documentation package for purchased items is reviewed by QA or their qualified designee prior to release of the items for use. This documentation may include material test reports, inspection and test reports, NDE reports, and applicable code data reports.

7.4 Receiving Inspection

Receiving inspection shall be performed for purchased items that are important-to-safety (including spare or replacement parts) to ensure that:

- Items are properly identified and correspond to the receiving documentation.
- Inspection records or certificates of conformance attesting to the acceptance of the items are available.
- Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.
- Physical attributes comply with specified requirements.

7.5 Vendor Evaluation

A documented evaluation is required annually for suppliers maintained on the Approved Vendors Listing (AVL). Vendor audits shall be conducted at least once every thirty-six (36) months in accordance with the audit section of this document.

8. IDENTIFICATION AND CONTROL OF ITEMS

Management will establish controls in written procedures to assure that only correct and accepted items are used or installed. Identification is maintained either on the items or in documents traceable to the item. When such controls are required, the following methods of identification and control will be utilized.

8.1 Identification

Identification such as batch, lot, serial number, or part number is maintained from initial receipt up to and including installation. The identification relates the item to the applicable design or other specification document when appropriate. Duratek utilizes physical identification when possible. Other means, including separation or procedural control, are used when physical identification is not possible.

8.2 Markings

Markings are applied using materials and methods that are clear, legible, and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided. Markings are not obliterated or hidden by surface treatments or coatings unless other identification methods are established.

8.3 Traceability

Duratek procedures specify methods for identification of items when codes, standards, or specifications require identification or traceability of an item. Procedures describe how to maintain traceability to a specification, grade of material, heat, batch, lot, part or serial number, or inspection, test, or other records.

8.4 Shelf/Operating Life

Items having limited calendar or operating life are controlled to preclude use after the shelf life or operating life has expired.

8.5 Maintaining Identification in Storage

Provisions are made in Duratek procedures for maintenance or replacement of markings and identification due to damage from handling or aging, excessive deterioration due to environmental exposure, and for updating records while in storage.

9. CONTROL OF PROCESSES

Management is responsible for verifying that Duratek processes are planned and performed under controlled conditions that ensure conformance to customer requirements, quality system requirements and applicable standards and regulations. Inspection, audit, assessments, surveillance, and nonconformance procedures are used to perform such verifications. Management is responsible for ensuring that only properly trained and qualified personnel are assigned to accomplish work activities and that they are provided adequate facilities, equipment, tools, and information to perform their work in compliance with requirements. Managers monitor the quality of activities through the results of in-process checks described in implementing procedures. These checks may be performed by co-workers or supervisory personnel and provide a method of tracking and trending events that affect the quality, safety, or regulatory status of operations, products, and services.

9.1 General Processes

Instructions, procedures, drawings, checklists, process control documents, or other appropriate methods control processes affecting the quality of items and services. When required, process parameters and environmental conditions are specified and maintained.

9.2 Special Processes

Special processes are those that control or verify quality such as processes used in welding, heat treating, and nondestructive examination. Special processes are controlled through written procedures and records are then established and maintained. Personnel, equipment, and procedures used to perform special processes are qualified in accordance with established procedures. Conditions necessary for accomplishment of the process such as proper equipment, controlled parameter of processes, and calibration requirements are included in procedures. Documentation of personnel, equipment, and process qualifications is maintained.

10. INSPECTION

The Business Group ESHQA, engineering, and technical support representatives are responsible for ensuring that inspections required to verify conformance of an item or activity to specified requirements are planned, executed, and documented by qualified personnel according to approved procedures.

Equipment modifications, repairs, and replacement are inspected in accordance with the original design and inspection requirements unless an approved alternate exists.

10.1 Personnel

Inspection personnel do not report to supervisors who are directly responsible for performing the work being inspected. Personnel who verify conformance of work for acceptance are qualified to perform the inspection in accordance with established procedures. Personnel in training for qualification as an inspector by on-the-job training are directly supervised by a qualified person who verifies the inspection results until qualification is achieved.

10.2 Inspection Hold Points

Responsibilities for identifying and specifying hold points are established in procedures reviewed and approved by the Business Groups Director, ESHQA. Engineering and technical support representatives are responsible for identifying inspection hold points in appropriate documents to ensure that no further work is performed until a certain inspection has been completed. Work does not proceed beyond hold points without consent from the organization that established them. This consent is recorded prior to continuation of work.

10.3 Inspection Planning

Inspection planning is accomplished to ensure that inspection procedures, instructions, or checklists identify the characteristics and activities to be inspected: acceptance and rejection criteria; responsible organization for performing inspection; and recording of objective evidence of inspection results. Planning also includes identification of hold or witness points; approval of data by supervisors to ensure that all inspection prerequisites and requirements have been satisfied, including operator and equipment qualifications; and establishment of sampling methods, if applicable, in accordance with approved procedures or project plans.

10.4 In-Process Inspection

Inspections are performed as necessary to verify conformance to requirements. Indirect control by monitoring may be utilized when direct inspection is impractical. Both inspection and monitoring are performed when control is inadequate without both. A combination of inspection and process monitoring is performed in a systematic manner to assure quality is achieved throughout the duration of the process.

10.5 Final Inspection

Final inspection includes a record review of the results of inspection and resolution of nonconformances identified in previous inspections. Items are inspected for completeness, markings, calibration, adjustments, and protection from damage. The acceptance of the item will be documented and approved by authorized personnel. Modification, repair, or replacement requires re-inspection or retest as appropriate to verify acceptability.

10.6 In-Service Inspection

In-service inspection methods are established to verify that the characteristics of an item continue to stay within the specified limits. Inspection methods include routine evaluation of emergency and safety systems, and verification of calibration or integrity of instruments or systems and their maintenance, as appropriate.

10.7 Inspection Records

Inspection records contain, at a minimum, the item inspected, date of inspection, inspector, type of observation, acceptance and rejection criteria, results or acceptability, and reference to nonconformances.

11. TEST CONTROL

Business Group ESHQA, engineering, and technical support representatives are responsible for ensuring that testing of processes, equipment, and products to verify conformance to specified requirements and to demonstrate satisfactory service performance is performed by qualified personnel in accordance with approved procedures.

11.1 Test Requirements

Engineering and technical support representatives are responsible to ensure that test requirements and acceptance criteria are developed and incorporated into appropriate test plans, procedures, or checklists. The test methods and acceptance criteria are based on specified requirements contained in design or other technical documents. As appropriate, test plans are established, procedures developed, and results documented on checklists or other suitable records.

11.2 Test Procedures

Test procedures include or reference test objectives and prerequisites. Prerequisites such as calibrated instrumentation, equipment and its condition, personnel qualification, environmental conditions, and collection and recording of data are taken into consideration during development of test procedures. Test procedures are reviewed and approved by cognizant technical, quality, and management personnel.

11.3 Test Results

Test results are documented and evaluated by a responsible authority to assure the test requirements were satisfied. Records include as a minimum the item tested, date of test, tester, observations, acceptance and rejection criteria, results and acceptability, action taken for deviations noted, and person evaluating results.

11.4 Testing after Modifications

Modification, repairs, or replacements shall be in accordance with the original design and test requirements or acceptable alternatives approved in the same manner as the original.

11.5 Computer Program Testing

Testing of computer programs is performed in accordance with written procedures that address test requirements, verification methods, in-use tests, test results, and records requirements.

12. CONTROL OF MEASURING AND TEST EQUIPMENT

Management is responsible for ensuring that Measuring and Test Equipment (M&TE) used for activities affecting quality is controlled in accordance with established procedures to ensure accuracy. These procedures identify the responsible organizations, the devices to be controlled, the controlling and calibration methods, and calibration intervals to maintain accuracy within the necessary limits.

Management is responsible for selecting the appropriate type, range, accuracy, and tolerance of M&TE to verify conformance to specified requirements.

M&TE are calibrated, adjusted, and maintained at scheduled intervals against certified equipment or standards having known valid relationships to nationally recognized standards. If no national standard exits, the basis of calibration is documented. The method and interval of calibration for each item is based on the type of device, stability characteristics, required accuracy, purpose, frequency of usage, and environment where it will be used.

Calibration methods are documented and performed by competent personnel in an environment that does not adversely affect the calibration. Special controls for usage, handling, and storage are documented and applied when they are required for environmental conditions such as temperature, humidity, cleanliness, or radiation to maintain accuracy or operating characteristics of the device.

When an M&TE device is found out of calibration, previous test results are validated. Out-of-calibration devices are tagged or segregated until repaired and recalibrated or replaced.

Record of calibration history is maintained and equipment is marked to indicate calibration status.

13. HANDLING, STORAGE, AND SHIPPING

Management is responsible for ensuring that materials considered critical, sensitive, perishable, or of high value are handled, cleaned, stored, packaged, and shipped in accordance with codes, standards, regulations, engineering specifications, or customer requirements.

13.1 Instruction

Handling, storage, and shipping processes are conducted in accordance with written procedures, inspection instructions, drawings, specifications, shipment instructions, or other documents, as appropriate.

13.2 **Requirements**

A special protective environment is provided when specified in instructions or procedures. The use of special handling equipment or techniques is addressed in procedures. Special tools and equipment are inspected and tested in accordance with approved procedures that describe the inspection and test methods, time intervals, maintenance methods, and personnel qualifications and training requirements.

13.3 **Marking**

Suitable marking or labeling to identify, maintain, and preserve the item is provided during packaging, shipment, handling, and storage.

13.4 **US NRC-Licensed Packages**

Duratek shall obtain and maintain US NRC approval of the QAP and exercise these commitments to meet the requirements of 10 CFR 71, Subpart H.

Transportation cask handling and operation shall conform to the handling and operating procedure for each licensed cask.

Prior to the shipment of a transport cask, conditions of the NRC's Certificate of Compliance (specifications, tests, and inspections) shall be satisfied. Required shipping papers shall be prepared and shall accompany the shipment.

Established safety restrictions concerning handling, storage, and shipping shall be included in the handling and operating procedures for transport casks.

14. INSPECTION, TEST, AND OPERATING STATUS

Management is responsible for ensuring that the status of items can be determined at any point throughout an operational process to prevent inadvertent use, installation, or operation of nonconforming or defective items. Status indicators are required to the extent possible to prevent operation of items removed from service for test, calibration, maintenance, or repair, and to ensure that required inspections and tests have been performed.

Operating procedures shall include reporting requirements that establish the equipment status at key events.

Status is identified by the use of tags, markings, stamps, or travelers. The authority for application and removal of status indicators is identified in approved procedures. Quality Assurance personnel routinely monitor Duratek activities to assure status indicators are used and removed, as appropriate, in accordance to procedures. Operating status of

systems and components are controlled through use of lock out tags secured to appropriate valves and switches.

15. NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

A nonconformance is defined as a deficiency in characteristic, documentation, procedure, or system that renders the quality of an item or activity unacceptable or indeterminate. At Duratek, nonconforming items are controlled to prevent inadvertent installation or use. The Vice President, ESHQA is responsible for ensuring that a program and procedures are established for reporting, identifying, documenting, evaluating, segregating (when feasible), dispositioning nonconforming items, and notifying affected organizations.

Individual Business Group Management is responsible for establishing an environment for identifying potential conditions adverse to quality. Business Group Management shall conduct analysis, as appropriate, to systematically determine significance on these conditions and actions appropriate to the conditions.

All Duratek employees are responsible for reporting nonconforming conditions. Duratek management, at all levels, fosters a "no fault" attitude toward the identification of conditions that are adverse to quality, such as failures, malfunctions, nonconformances, and out-of-control processes including the failure to follow procedures. Nonconforming items are identified by using marking, tagging, or other means that do not adversely affect their end use.

To avoid inadvertent use, nonconforming items are segregated in holding areas when feasible, or in the case of large items, marking, or roping designates special storage areas.

Responsibility and authority for the evaluation and disposition of the nonconformance, including 10 CFR 21 or the Price Anderson Amendment Act (PAAA) reportability, are defined in approved procedures.

Disposition of nonconformances shall be addressed in a timely manner by management. The disposition of nonconformances is evaluated and approved by the Business Group Director, ESHQA. Disposition of a nonconformance, involving repair or use-as-is, is based on documented technical justification and may include provisions for retest or reinspection to the original acceptance criteria. Any changes to design require the same design controls as those applied to the original design. Accept-as-is dispositions of materials and items require engineering approval. Accepted deviations are reflected in as built records.

Nonconformances are closed and documented by Business Group Directors, ESHQA and records are maintained in accordance with Duratek procedures.

Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance. Significant conditions adverse to quality and significant trends are reported to the Vice President, ESHQA.

16. CORRECTIVE ACTION

Conditions adverse to quality (e.g., nonconformances, failures, malfunctions, deficiencies, defective material, etc.) shall be evaluated to determine the need for corrective action in accordance with established procedures.

Corrective action shall be promptly initiated when it is determined that a condition adverse to quality exits. In cases where it is not possible to accomplish a corrective action immediately, the appropriate Business Group management provides a written response describing the cause of the deficiency and the proposed corrective action to be completed within a specified time.

Business Group management are responsible for providing information to their respective Director, ESHQA concerning problems and solutions of corrective actions. For significant conditions adverse to quality, procedures provide for the identification of conditions; assignment of responsibility for corrective action; documentation of the cause and corrective action taken; implementation, evaluation, and verification of corrective action to prevent recurrence; and reporting to the appropriate levels of management.

The Business Group Director, ESHQA has the authority to stop work or ensure adequate controls are in place until effective corrective action has been taken and any applicable changes have been incorporated in procedures and communicated to appropriate personnel.

The Business Group Director, ESHQA ensure follows-up on corrective actions to verify ~~ensure~~ that they are effectively implemented and trends adverse conditions to determine quality tendency for management review. The Director is responsible for verifying the effectiveness and closure of corrective actions. The Director has the responsibility to report significant conditions adverse to quality to the Vice President, ESHQA.

Corrective actions under the purview of 10 CFR 21 or Price Anderson Amendments Act (PAAA) are reported, dispositioned, tracked, and closed in accordance with approved procedures.

Documentation of corrective actions may include root cause analysis, logs, formal reports, objective evidence of satisfactory implementation, and the cost of nonconformance. This documentation is maintained in accordance with approved procedures.

17. QUALITY ASSURANCE RECORDS

17.1 Maintenance and Access to Records

The record system maintained by Duratek includes, at a minimum, the retention of those design, procurement, fabrication, and inspection and surveillance records

essential to demonstrate product quality for important-to-safety items and activities. It provides for the identification of materials and their corresponding manufacturing, installation, test, and inspection records and certificates. Operating records maintained will include inspection, test, and audit results. Records are maintained according to established procedures, are identifiable, and are readily retrievable.

Management is responsible for developing and implementing approved procedures that describe the requirements for records classification, legibility, identification, collection, filing, indexing, storage, transmittal, distribution, retention, retrieval, completeness, and disposition.

17.1.1 Records Administration

Records include but are not limited to: contract documents, specifications, procedures, and documents that implement customer, federal, and state requirements. Applicable design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records to be generated, maintained, or supplied.

Documents are considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated.

Duratek records indexing system includes record retention times, the location of the record within the record system, and provides sufficient information to permit identification between the record and the item or activity to which it applies. Correction of quality records is in accordance with established procedures. Records are made accessible to customers in accordance with applicable contractual and regulatory requirements.

Records are classified as Nonpermanent and Lifetime. Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item. Lifetime quality records are those maintained for the life of the item or the operating life of Duratek (no less than 40 years). For Duratek activities associated with US NRC-licensed packages, required records are retained for three years beyond the date when Duratek last engages in those activities.

Lifetime file records shall include, as a minimum: design specifications, stress reports or stress calculations, "as-built" and interface control drawings, copies of material test reports, tabulation of materials for "as built" configuration, nondestructive examination reports, including examination results, and nonconformance reports.

Lifetime record retention is based on the life of the program, life of the item, life of the facility, or life of the license, as applicable.

17.1.2 QA Records for Packaging and Transportation of Radioactive Materials

QA Records for packaging and transportation of radioactive materials include instructions, procedures, drawings, and closely related specifications such as required qualifications, procedures, and equipment. These records will be maintained for three years beyond the date Duratek last engages in the packaging and transportation of radioactive materials under the rules of 10 CFR 71. Superseded procedures or instructions are retained for a minimum of three years after the procedure or instruction is superseded.

17.2 Storage, Preservation, and Safekeeping

Management is responsible for controlling and safekeeping records. A receipt control system is delineated in approved procedures. Records are protected against deterioration, damage, and/or loss in accordance with established procedures, and important-to-safety records requiring long-term storage are maintained either at an approved record storage facility or by storage of duplicate copy at separate geographical locations.

18. AUDITS, SURVEILLANCE, AND ASSESSMENTS

Planned audits shall be performed to provide comprehensive, independent verification, and evaluation of the Duratek or vendor activity being audited. The term audit, as used in this section, also includes independent assessments. The audit scope shall encompass evaluation of quality system practices and/or procedures and the effectiveness of their implementation, monitoring of operations and activities, and a review of pertinent documents and their control and maintenance. Audits of the elements of the program will be audited at least annually.

The Business Group Director, ESHQA is responsible for ensuring implementation of a comprehensive system of planned and periodic audits to verify contract or specification compliance, effective procedure implementation, and the effectiveness of the QAP. The audit program consists of internal program audits including project specific reviews and external audits of Duratek suppliers. The audit program is implemented in accordance with approved procedures.

Business Group ESHQA and Corporate ESHQA provide organizational independence of audit personnel as well as providing for adequate funding and resources to implement the audit function.

18.1 Scheduling, Preparation, and Performance

The audit program includes an audit schedule, which is based on key elements that cover all aspects of the QAP. Internal and external audits are scheduled based on the status and importance of an activity, and schedules are updated as necessary to ensure that adequate coverage is maintained.

Each audit has a documented plan, which includes the scope, requirements, personnel, activities to be evaluated, organizations to be notified, applicable documents, schedule, and written checklists. An audit team, composed of one or more individuals, is identified for each audit using personnel who have no direct responsibility for the activity being covered. A lead auditor, as a member of the team, is designated as a team leader.

The team uses an audit checklist, which contains the elements of the activity being covered and the requirements to evaluate them. The audit team uses objective evidence to make its evaluations.

The key elements for effectively implementing the audit program include:

- Scheduling and notifying management of scope and nature of audit
- Team selection, orientation and planning
- Entrance conference
- Exit conference
- Reporting and response
- Follow-up action

18.2 Reporting, Response, Follow-up-Action, and Records

Reports documenting results are prepared upon completion of the audit and distributed to appropriate management for review. Audit reports require managers of the audited organizations to provide a response within a specified time period to identify planned corrective actions, including cause and action to prevent recurrence, and a schedule for completion, thereof, when applicable. The adequacy of responses is evaluated by the auditing organization. It is the responsibility of the Business Group Director, ESHQA to verify that effective corrective actions are in place before closing the audit.

Audit records include checklists, reports, written replies, and documentation of completed corrective actions. Audit files are retained as quality records.

18.3 Surveillance

Where surveillance is more practical for assessment of ongoing activity, the surveillance may be used in support of audits to cover the necessary scope of the

entire QAP. Adequate demonstration of the areas covered by surveillance is a requirement to be considered as part of an effective part of the audit program. Surveillance must be documented in sufficient detail to identify the activity covered, identify individuals doing surveillance, and to document results and any corrective measures necessary.

19. ATTACHMENTS

19.1 Attachment 1, Matrix of Quality Assurance Requirements

19.2 Attachment 2, Glossary of Terms

ATTACHMENT 1

MATRIX OF QUALITY ASSURANCE REQUIREMENTS

DURATEK QUALITY ASSURANCE PROGRAM CRITERIA	10 CFR 50 APPENDIX B & 10 CFR 72 SUBPART G	10 CFR 71 SUBPART H	ANSI/ASME NQA-1	10 CFR 830 SUBPART A
Organization	I	71.103	R-1	1
Quality Assurance Program	II	71.105	R-2	1, 2, 9
Design Control	III	71.107	R-3	6
Procurement Document Control	IV	71.109	R-4	7
Instructions, Procedures, & Drawings	V	71.111	R-5	5
Document Control	VI	71.113	R-6	4
Control of Purchased Material, Equipment, & Services	VII	71.115	R-7	7
Identification & Control of Materials, Parts, & Components	VIII	71.117	R-8	5
Control of Special Processes	IX	71.119	R-9	5
Inspection	X	71.121	R-10	8
Test Control	XI	71.123	R-11	8
Control of Measuring & Test Equipment	XII	71.125	R-12	5, 8
Handling, Storage, & Shipping	XIII	71.127	R-13	5
Inspection, Test, & Operating Status	XIV	71.129	R-14	8
Non-Conforming Materials, Parts, or Components	XV	71.131	R-15	3

DURATEK QUALITY ASSURANCE PROGRAM CRITERIA	10 CFR 50 APPENDIX B & 10 CFR 72 SUBPART G	10 CFR 71 SUBPART H	ANSI/ASME NQA-1	10 CFR 830 SUBPART A
Corrective Action	XVI	71.133	R-16	3, 9
Quality Assurance Records	XVII	71.135	R-17	4
Audits	XVIII	71.137	R-18	3, 10

ATTACHMENT 2

GLOSSARY OF TERMS

Acceptance Criteria —Specified limits placed on characteristics of an item, process, or service defined in codes, standards, or other requirement documents.

Audit —A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

Certificate of Compliance —A written statement, signed by a qualified party, attesting that the items or services are in accordance with specified requirements and accompanied by additional information to substantiate the statement.

Certificate of Conformance —A written statement, signed by a qualified party, certifying that items or services comply with specific requirements.

Certification —The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements.

Characteristic —Any property or attribute of an item, process, or service that is distinct, describable, and measurable.

Commercial Grade Item —An item satisfying (a), (b), and (c) below:

(a) Not subject to design or specification requirements that are unique to nuclear facilities;

(b) Used in applications other than nuclear facilities;

(c) Is to be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (for example, catalog).

Computer Program —A sequence of instructions suitable for processing by computer. Processing may include the use of an assembler, compiler, interpreter, or translator to prepare the program for execution as well as to execute it.

Conditions Adverse to Quality —An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A significant condition adverse to quality is one, which, if uncorrected, could have a serious effect on safety or operability.

Corrective Action —Measures taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.

Design Change —Any revision or alteration of the technical requirements defined by approved and issued design output documents and approved and issued changes thereto.

Design Input —Those criteria, parameters, bases, or other design requirements that are the basis for final design.

Design Process —Technical and management processes that commence with identification of design input and that lead to and include issuance of design output documents.

Deviation —A departure from specified requirements.

Documentation —Any written or pictorial information describing, defining, specifying, reporting, or certifying activities, requirements, procedures, or results. A document is not considered a Quality Assurance Record until it satisfies the definition of a Quality Assurance Record.

External Audit —An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.

Final Design —Approved design output documents and approved changes thereto.

Guideline —A suggested practice that is not mandatory in programs intended to comply with a standard.

Important-to-safety —Refers to the classification of an item, service, or associated activity resulting from an assessment of risk and consequences that might reasonably result in public health and safety and the environment from an inadequacy, malfunction, or failure.

Inspector —A person who performs inspection activities to verify conformance to specified requirements.

Inspection —~~Measurement~~ Measurement to verify whether an item or activity conforms to specified requirements.

Internal Audit —Audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.

Item —All-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

May —An option.

Measuring and Test Equipment —Devices or systems used to calibrate, measure, gage, test, or inspect in order to control or acquire data to verify conformance to specified requirements.

Nonconformance —Deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.

Objective Evidence —Documented statement of fact or other information or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified.

Procedure —Document that specifies or describes how an activity is to be performed.

Procurement Document —Requisitions, purchase orders, drawings, contracts, specifications, or instructions used to define requirements for purchases.

Purchaser —Organization responsible for establishment of procurement requirements and for issuance, administration, or both, of procurement documents.

Qualifications (Personnel)—The characteristics or abilities gained through education, training or experience, as measured against established requirements, such as standards or tests that qualify an individual to perform a required function.

Qualified Procedures —Procedures that have been demonstrated to meet the specified requirements for their intended purpose.

Quality Assurance (QA) —Planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Quality Assurance Record —Completed document that furnishes evidence of the quality of items and/or activities affecting quality.

Receiving —Delivery of an item.

Repair —Process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirements.

Rework —Process by which an item is made to conform to original requirements by completion or correction.

Right of Access —Right of a Purchaser or designated representative to enter the premises of a Supplier for the purpose of inspection, surveillance, or quality assurance audit.

Safety Related —Related to or affecting those structures, systems, or components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public and/or the environment.

Service —Performance of activities such as design, fabrication, inspection, nondestructive examination, repair, remediation, or installation.

Shall —A requirement.

Should —A guideline or recommendation.

Special Process —Process whose results are highly dependent on the control of the process or skill of the operators, or both, and for which the specified quality cannot be readily determined by inspection or test of the product.

Supplier —Individual or organization or individual who furnishes items or services in accordance with procurement documents. An all-inclusive term used in place of vendor, seller, contractor, subcontractor, fabricator, consultant, or their ~~subtier~~sub tier levels.

Surveillance —Act of monitoring, observing, or otherwise verifying that an item or activity conforms to specified requirements.

Testing —Element of verification for the determination of the capability of an item to meet specified requirements by subjecting them to a set of physical, chemical environmental, or operating conditions.

Traceability —Ability to trace the history, application, or location of an item and like items or activities by means of recorded identification.

Use-As-Is —Disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use.

Verification —Act of reviewing inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements.

Waiver —Authorization to depart from specified requirements.