

# ALARON CORPORATION

Plan Title/Approval

## Quality Assurance Program Manual

Control Number: PL-AR-1293-011

Revision: 7



Health Physics/ALARA

July 21, 2009

Date



Industrial Safety

July 27, 2009

Date



Quality Assurance

July 21, 2009

Date



Operations

July 22, 2009

Date



General Manager

July 21, 2009

Date

# ALARON CORPORATION QUALITY ASSURANCE PROGRAM MANUAL

---

## LIST OF EFFECTIVE PAGES (Revision Level 0= Original Document)

Page #	Revision Level	Page #	Revision Level	Page #	Revision Level
1	7	20	6		
2	7	21	6		
3	7	22	6		
4	6	23	6		
5	6	A-1	6		
6	6	A-2	6		
7	7	B-1	6		
8	6	B-2	6		
9	6	C-1	6		
10	6	C-2	7		
11	7				
12	6				
13	6				
14	7				
15	6				
16	6				
17	6				
18	6				
19	6				

# ALARON CORPORATION QUALITY ASSURANCE PROGRAM MANUAL

---

## STATEMENT OF POLICY AND AUTHORITY

The ALARON Corporation is committed to providing Quality Nuclear Services while ensuring the safety of the public and the environment. In order to confirm and document our commitment to quality, this manual establishes the ALARON Corporation Quality Assurance Program and prescribes its implementation.

The ALARON Corporation Quality Assurance Manual states the basic policies, assigns the responsibilities, and establishes and documents the procedural control of activities affecting quality as performed by ALARON personnel. This manual is intended to meet the requirements and intent of 10 CFR 71 Subpart H, 10 CFR 50, Appendix B, and ASME/NQA-1.

This program applies to activities as required by ALARON Corporation's radioactive materials licenses, supporting documents, components, equipment and services, as well as applicable state and federal regulations and contractual agreements.

The management of ALARON Corporation is devoted to the support of the program and all employees are charged with the responsibility of abiding by the established procedural controls for quality related activities.

The **General Manager** of the Corporation retains the overall responsibility for implementation of the program, and ensures, through an annual review of the program, that it is in compliance with current practices and requirements.

The Quality Assurance Manager **has direct access** to the **General Manager** -of the Corporation and is given full responsibility and authority to maintain this manual and to ensure uniform implementation of the program.

**Thomas VanKirk**  
**General Manager**

Date:

**ALARON CORPORATION  
QUALITY ASSURANCE PROGRAM MANUAL**

---

**TABLE OF CONTENTS**

1.0	ORGANIZATION .....	5
2.0	QUALITY ASSURANCE PROGRAM .....	6
3.0	DESIGN CONTROL .....	7
4.0	PROCUREMENT DOCUMENT CONTROL .....	8
5.0	PROCEDURES, INSTRUCTIONS AND DRAWINGS .....	9
6.0	DOCUMENT CONTROL .....	10
7.0	CONTROL OF PURCHASED ITEMS AND SERVICES .....	11
8.0	IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS.....	13
9.0	CONTROL OF SPECIAL PROCESSES.....	14
10.0	INSPECTION.....	15
11.0	TEST CONTROL.....	16
12.0	CONTROL OF MEASURING AND TEST EQUIPMENT .....	17
13.0	HANDLING, STORAGE AND SHIPPING.....	18
14.0	INSPECTION TEST AND OPERATING STATUS.....	19
15.0	CONTROL OF NONCONFORMING ITEMS .....	20
16.0	CORRECTIVE ACTION .....	21
17.0	QUALITY RECORDS .....	22
18.0	AUDITS .....	23
APPENDIX A - Glossary .....		A-1
APPENDIX B - Graded Quality Assurance Program Requirements.....		B-1
APPENDIX C - ALARON QA/QC Organizational Chart .....		C-1

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 1.0 ORGANIZATION

- 1.1 This section identifies the functional organization and assigns the responsibility to assure effective execution of the ALARON Quality Assurance Program (see Appendix C).
- 1.2 The General Manager of ALARON has full authority over company functions and delegates authority and responsibility for selected functions to other personnel or organizations.
- 1.3 The Quality Assurance Manager is vested with the authority and responsibility to ensure that activities affecting quality are performed and documented correctly to the established requirements.
  - 1.3.1 The Quality Assurance Manager is vested with the organizational freedom and responsibility to:
    - Identify quality problems.
    - Initiate, recommend, or provide solutions to quality problems through designated channels.
    - Verify implementation of solutions.
    - Stop unsatisfactory work or further processing, delivery, installation, or use of material until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred.
- 1.4 The Quality Assurance Manager shall have sufficient expertise in the quality discipline to direct the quality functions as appropriate to the established requirements. The Quality Assurance Manager's responsibilities include the development, implementation and administration of the quality program and supporting procedures.
- 1.5 Activities involving radioactive materials are controlled as a joint effort by health physics, health & safety and quality control personnel.
- 1.6 Qualified personnel perform monitoring activities and verification of regulatory, contractual, and/or technical requirements in accordance with controlled documents.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 2.0 QUALITY ASSURANCE PROGRAM

- 2.1 The ALARON Quality Assurance Program complies with the intent of the 10 CFR 830.122, ANSI/ASME NQA-1, and NRC Regulations, 10 CFR 50, Appendix B, 10 CFR 71, Subpart H, as appropriate to the activities performed by ALARON personnel. Corporate policies are defined herein and in those documents written to further delineate the methods of implementation and compliance.
- 2.2 The program provides for the graded application of quality requirements to quality related activities in the operation and maintenance of equipment and services supplied to the nuclear industry (see Appendix B). This is accomplished by ensuring that written procedures and/or instructions are in place before engaging in these activities.
- 2.3 Individuals responsible for quality functions are trained and/or evaluated in accordance with written procedures, regulations, appropriate standards and requirements of the radioactive materials license. These individuals are approved and certified by the Quality Assurance Manager or, designee, as required. The ALARON Quality Assurance Program assures compliance with the quality requirements of engineering specifications, regulatory guidance and specific provisions of contractual agreements. Personnel performing special processes shall be trained/certified in accordance with applicable procedures and/or instructions.
- 2.4 Activities affecting quality shall be accomplished under suitably controlled conditions and according to documented procedures/instructions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions such as cleanliness, and assurance that prerequisites have been satisfied.
- 2.5 Any controversies involving quality that arise from a difference of opinion, shall be elevated to the division managers for resolution, or to the company General Manager if all other efforts are unproductive.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 3.0 DESIGN CONTROL

- 3.1 Design activities shall be properly planned, documented and controlled in accordance with approved procedures.
- 3.2 Procedures/instructions are developed, approved and implemented to assure that the applicable technical requirements such as design bases, regulatory requirements and customer specifications for systems, structures and components are correctly translated into **work permits, supplier purchase orders**, specifications, drawings, or checklists.
- 3.3 Design review shall be conducted in such a manner to assure that the following occur:
- Regulatory and design requirements are correctly translated into specifications, drawings, procedures or checklists.
  - Design documents contain quality/safety requirements as applicable.
  - Deviations from design or quality/safety requirements are controlled.
  - Design verification is performed by personnel independent of the design activity. These verifications may include tolerance studies, alternate calculations or tests.
  - Interface control is established and adequate.
  - Design errors and deficiencies are documented and corrective action is taken to prevent their recurrence.
- 3.4 Revisions and/or changes to design documents or specifications shall be reviewed and approved by the same level, or higher, that performed the original review.
- 3.5 Computer programs designed in-house are subject to outcome verification and analysis.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 4.0 PROCUREMENT DOCUMENT CONTROL

- 4.1 Procurement activities are performed in accordance with approved procedures that implement the applicable requirements defined in this QA Manual section.
- 4.2 Procurement documents shall identify the scope of work, technical requirements, quality/safety program requirements, right of access, inspection and test requirements, special process requirements, documentation requirements, and reporting and disposition of nonconformances, as applicable to the item or service being procured.
- 4.3 Quality related purchase orders and request for quotes shall include requirements, as applicable, such as:
- Identification of the quality requirements for inspection and control, acceptance and rejection criteria, program and/or customer requirements, and invoking standards and codes (i.e. 10 CFR 21, ASME etc.).
  - Material information such as size, type or grade.
  - Basic technical requirements such as specifications, drawings, codes, industrial standards, hold points, inspections or tests.
  - Documentation requirements such as inspection records, test records or certification documents.
  - A statement that allows Q.A. personnel, or designee(s) to have the right of access to supplier facilities for source inspection and/or audit activities as appropriate.
- 4.4 Quality related purchase orders and requests for quotes shall be reviewed prior to release by qualified management, health & safety, and QA personnel, or designee(s), to assure compliance with the applicable section of the QA manual and procedures.
- 4.5 Changes to procurement documents shall be subject to the same review and approval as the original documents.
- 4.6 Procurement documents may require an adequate Quality Assurance Program be in place.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 5.0 PROCEDURES, INSTRUCTIONS AND DRAWINGS

- 5.1 Activities affecting quality shall be accomplished in accordance with QA approved written procedures, instructions and/or drawings as appropriate to the activity being performed.
- 5.2 Procedures, instructions or drawings shall contain appropriate quantitative and/or qualitative acceptance criteria (including record keeping requirements) for determining that important activities have been satisfactorily accomplished.
- 5.3 The documents when applicable will reference related codes, standards, specifications, customer requirements, and/or procedures.
- 5.4 The approved documents shall be made available to personnel responsible for the specified activity.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 6.0 DOCUMENT CONTROL

- 6.1 The requirements for quality document review, approval, release and change control are delineated in written procedures and provide for review, approval and issuance of documents. Document control responsibilities and requirements are also addressed.
- 6.2 A document is controlled if it is on the ALARON Document control list and is marked as controlled.
- 6.3 Controlled documents shall be reviewed within three years of issue or revision whichever is later.
- 6.4 Changes to documents shall be reviewed and approved by the same level, or higher, that performed the initial review and approval (such review and approval is not required when the changes are inconsequential, such as the correction of minor typographical errors). Changes may be made to documents by a department or individual specifically designated by original reviewers.
- 6.5 A list of controlled documents is maintained delineating the title, number and current revision for drawings, procedures and specifications, which require Quality Assurance approval.
- 6.6 Controlled distribution of documents affecting quality activities shall be accomplished by the use of distribution logs and transmittal forms or by other means of positive receipt acknowledgement.
- 6.7 Documents certifying the degree of compliance to specified requirements, when required, shall be reviewed and signed by the General Manager or the Quality Assurance Manager.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 7.0 CONTROL OF PURCHASED ITEMS AND SERVICES

7.1 Control of purchased items and services shall be performed in accordance with approved procedures.

7.2 Suppliers of Quality related items or services are evaluated by qualified personnel to assure supplier acceptability. These evaluations are based on one or all of the following criteria:

- The supplier's capability to comply with the applicable requirements of this program and/or the material or service specifications.
- A review of previous records and performances of the supplier.
- An evaluation of the supplier's facilities and Q.A. program to determine his capability to supply a product or service which meets the design, manufacturing, and quality requirements.

Results of all supplier evaluations are recorded and are retained in the QA Files.

7.3 Technical and quality assurance **audits** are not required for any of the following conditions.

- The supplier is currently on the approved supplier list for similar items or services.
- The supplier is currently on the customers approved suppliers list or has been specifically selected by the customer and documentation attesting to this approval has been supplied to ALARON by the customer.
- The supplier is a nationally recognized manufacturer of test equipment **or** related calibration services and the calibration services are verified by ALARON prior to use of the equipment.
- The supplier is a regulatory agency or a nationally recognized standards **laboratories**, such as the U.S. National Institute of Standards and Technology, **a nationally recognized calibration laboratory, or approved commercial grade calibration clients of NVLAP or NVLAP signatories. Signatory clients require an initial evaluation and annual verification of the Signatory's continued recognition by NVLAP.**

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

- 7.4 Items and services shall be controlled, monitored (surveilled) and verified upon receipt by qualified personnel to assure conformance with procurement documents in accordance with section 10.0 of the QA Manual.
- 7.5 Surveillance of the supplier's activities shall be performed when determined necessary by the Quality Assurance Manager or designee. The extent or need of surveillance activities by ALARON at the suppliers location, is dependent on the following conditions:
- The complexity or uniqueness of the item and its importance to safety.
  - The need for special controls and surveillance over processes and equipment. Surveillance is performed on those items where verification of procurement requirements cannot be determined upon receipt.
  - The degree to which functional compliance can be demonstrated by receipt inspection and test.
  - The availability of quality history or the degree of standardization of identical items.
- 7.6 For commercial off-the-shelf items, where specific quality assurance controls for nuclear applications cannot be imposed in a practical manner, additional quality verification requirements shall be performed to the extent necessary to verify acceptability of the item to procurement document requirements.
- 7.7 An Approved Suppliers List (ASL) of Category A and B suppliers shall be maintained by Quality Assurance. Purchasing shall be provided or have access to a current copy of the ASL.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 8.0 IDENTIFICATION AND CONTROL OF MATERIALS, PARTS AND COMPONENTS

- 8.1 The identification and control of material, parts and components shall be in accordance with approved procedures, instructions and/or checklists to assure that identification is maintained, either on the item or records traceable to the item to preclude use of incorrect or defective items.
- 8.2 When required by applicable specifications or customer requirements the identification of materials, parts and components shall be traceable to the appropriate documentation, such as drawings, purchase orders, shop travelers, inspection documents, nonconformance reports and physical and chemical test reports.
- 8.3 The procedures shall identify the appropriate criteria and responsibilities in order to assure the correct identification of items is verified and documented in accordance with section 10.0 of this QA Manual.
- 8.4 Identification requirements shall be established when applicable during the generation of drawings and specifications to assure that the location and method of identification is not detrimental to the material and does not affect the form, fit, function or quality of the item.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 9.0 CONTROL OF SPECIAL PROCESSES

- 9.1 Special processes such as nondestructive examination, chemical cleaning, welding, heat-treating, electro polishing, **protective coatings**, waste processing and others as required by applicable codes, standards, specifications and contract requirements shall be delineated in approved procedures that assure control of the processes.
- 9.2 Special process procedures, equipment and personnel shall be qualified for conformance to applicable codes, standards and specifications.
- 9.3 Qualification records of special process procedures, equipment and personnel shall be established and maintained.
- 9.4 When special processes are subcontracted, ALARON procurement documents shall require the supplier to submit special process procedure qualification data to ALARON for review. Selection and control of subcontractors shall be in accordance with section 7.0 of this Q.A. Manual.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 10.0 INSPECTION

- 10.1 Inspection and surveillance personnel shall have been appropriately trained, qualified and certified as required by the discipline manager responsible for the activity being performed. Inspection personnel qualifications are reviewed and approved by the Quality Assurance Manager, or designee, prior to the inspection activity.
- 10.2 Inspection and surveillance activities for receipt, source and in-process shall be performed in accordance with approved documents. The inspection process shall be documented on approved checklists or procedures containing sign off steps, which delineate the acceptance criteria for the items being inspected.
- 10.3 Personnel assigned to perform quality assurance functions are persons other than those who perform the activity being inspected and report directly to the Quality Assurance Manager or the General Manager.
- 10.4 Inspection personnel qualifications are based on their capability to perform the required inspection function in accordance with applicable codes, standards, experience, and ALARON training programs. Qualification reviews are performed periodically to maintain personnel proficiency and to assure current qualification.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 11.0 TEST CONTROL

- 11.1 The control of tests shall be in accordance with approved procedures or instructions that provide for the following:
- The requirements and acceptance limits contained in applicable test specifications, designs, procurement documents, and customer contracts as applicable.
  - Instructions for performing the test.
  - Test prerequisites such as calibrated instrumentation, required test equipment and instrumentation (including their accuracy requirements), suitable and controlled environmental conditions, and provisions for data collection and storage.
  - Mandatory inspection hold points for witness by the customer or ALARON (as required).
  - Acceptance and rejection criteria.
  - Methods of documenting or recording test data and results.
  - Provisions for assuring test prerequisites have been met.
  - The test results shall be documented and evaluated to assure the test requirements and acceptance criteria have been satisfied.
  - Test personnel shall have appropriate training and qualifications for the level of testing being performed.
  - Testing records and records of training shall be maintained as quality records.
- 11.2 Subcontractors performing tests for ALARON shall be evaluated for acceptance by Quality Assurance for capabilities to perform the test. The subcontractors test procedures shall be evaluated to ensure they are adequate for both performance and control.
- 11.3 Computer programs for in-house use will be tested to verify acceptable performance.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 12.0 CONTROL OF MEASURING AND TEST EQUIPMENT

- 12.1 Administration of the calibration of measuring and test equipment and instrumentation is delineated in procedures and approved by Quality Assurance. The calibration system assures that all measuring and test instrumentation, used in the acceptance of material, equipment, and components, is calibrated properly at specified intervals and are traceable to national standards (when required) to maintain accuracy within predetermined limits. Calibration may be performed by ALARON or approved suppliers. Calibrated equipment must be identified and traceable to the calibration test data.
- 12.2 Approved procedures provide detailed requirements for the control of calibration inspection and required documentation for measuring and test equipment.
- 12.3 When measuring and test equipment are found to be out of calibration, an evaluation shall be made and documented of the validity of previous inspection or test results and of the acceptability of items previously inspected or tested.
- 12.4 Special calibration and control measures on rules, tape measures, levels and other such devices are not required where normal commercial practices provide adequate accuracy.
- 12.5 Records of calibration of measuring and test equipment shall be maintained as quality records in accordance with section 17.0 of this QA manual.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 13.0 HANDLING, STORAGE AND SHIPPING

- 13.1 Approved procedures and/or instructions shall be established to describe the controls necessary for handling, packaging, storage, cleaning and shipping of materials, components and systems as required by design and procurement specification requirements to preclude damage, loss or deterioration.
- 13.2 Special handling, preservation, storage, cleaning, packaging and shipping requirements shall be established by qualified individuals in accordance with predetermined work and inspection instructions and/or industry practice.
- 13.3 Special handling tools and equipment shall be inspected and tested in accordance with written, approved procedures, and at specified time intervals, to verify that the tools and equipment are adequately maintained.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 14.0 INSPECTION, TEST AND OPERATING STATUS

- 14.1 ALARON personnel shall be provided with training in procedural requirements to assure their awareness and understanding of status tag usages. Status tags placed on items by Quality Assurance may only be removed by Quality Assurance personnel.
- 14.2 The status of nonconforming, inoperative or malfunctioning structures, systems and components shall be documented and identified to prevent inadvertent use.
- 14.3 Procedures shall be established to assure that 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 work, operation or installation.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 15.0 CONTROL OF NONCONFORMING ITEMS

- 15.1 Procedures shall be established to describe the identification, documentation, segregation, review, disposition, and notification to affected organizations of nonconforming items, materials, systems, parts and components. Procedures shall be developed to ensure the requirements of 10 CFR 21 are followed when they are applicable.
- 15.2 Nonconforming items shall be dispositioned as "use-as-is", "reject", "repair", "rework", or "return to vendor".
- 15.3 Nonconforming items dispositioned "use-as-is" or "repair" shall include technical justification to indicate and assure continued compliance with design, regulatory and contractual requirements.
- 15.4 Items dispositioned as "rework", "repair", or replacement items shall be inspected and tested in accordance with the original inspection and test requirements or acceptable alternatives which are in compliance with the specified acceptance criteria.
- 15.5 Nonconforming items dispositioned "use-as-is" or "repair" shall be reported to the customer when contractually required by procurement documents or other documents such as specifications.
- 15.6 - Reserved -
- 15.7 All employees are responsible for notifying their supervisor and/or QA of any potential nonconforming conditions.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 16.0 CORRECTIVE ACTION

- 16.1 Procedures shall be established to identify and correct conditions adverse to quality and provide measures to prevent recurrence.
- 16.2 A condition adverse to quality such as a nonconformance, failure, malfunction, deficiency, deviation, defective material or equipment shall be documented and corrected as soon as practical after the condition has been determined.
- 16.3 Significant conditions adverse to quality, including the cause of the condition and the corrective action, shall be documented to preclude repetition and reported to the responsible manager. For the purpose of this section, a significant condition adverse to quality may be defined as, but not limited to, an unsatisfactory quality trend, bypassing of required inspections, tests, or other critical operations, a significant deficiency as defined by 10 CFR 50.55 (e), or a defect or failure as defined by 10 CFR 21.
- 16.4 Timely follow-up action shall be taken to verify proper implementation and closeout of the required corrective action.
- 16.5 A summary report of the status of corrective action reports shall be periodically prepared by the Quality Assurance Manager and submitted to the General Manager of ALARON for review.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 17.0 QUALITY RECORDS

- 17.1 Procedures shall be developed identifying documents which are considered quality records. The quality records system assures that documented evidence pertaining to quality related activities is maintained and available for use by ALARON, its customers, and/or regulatory agencies as applicable.
- 17.2 Quality records are completed documents providing evidence of activity completion as required by controlled documents.
- 17.3 Records are divided into two categories, lifetime and non-permanent. Lifetime records are those records which provide evidence that critical operations or activities are performed and documented in accordance with prescribed procedures, ALARON's Radioactive Materials Licenses, and as required by regulatory agencies. Non-permanent records are retained as appropriate by procedures and/or regulations. The Quality Assurance Manager, or designee, shall have the responsibility for the maintenance of lifetime and non-permanent records.
- 17.4 -Reserved –
- 17.5 Records shall be indexed, filed and maintained in facilities that provide a suitable environment to minimize deterioration or damage, and to prevent loss subsequent to completion of work, during the specified retention time or until transferred to the customer, as required by applicable codes, standards and procurement documents.
- 17.6 Protection for QA records is provided by using one of the following storage methods:
- Two sets of identical records are maintained at separate storage locations, or
  - The official copy of all QA records is maintained in approved fire-proof files or vault, at a single location.
- 17.7 Customer procurement documentation and/or other documents may require a specified retention time for records of a specific work scope or contract. Additionally the contract may require the records to be submitted to the customer.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### 18.0 AUDITS

- 18.1 Procedures shall be established to provide for a comprehensive system of planned and documented audits including audits of suppliers and internal audits of facility and site activities to verify compliance with the applicable aspects of ALARON Corporation's Quality Assurance Program and to determine the effectiveness of the program.
- 18.2 Audits shall be scheduled in a manner to provide coverage and coordination with ongoing Quality Assurance Program activities commensurate with the status and importance of the activity. All elements of the ALARON Corporation Quality Assurance Program shall be audited at least annually. Audits of suppliers shall be on a triennial basis.
- 18.3 Areas found deficient during audits are re-audited on a first priority basis to verify corrective action implementation and effectiveness.
- 18.4 Audits shall be performed in accordance with pre-established written procedures using checklists and conducted by trained and certified personnel having no direct responsibilities in the areas being audited. Objective evidence shall be examined for compliance with quality assurance program requirements.
- 18.5 Audit results shall be documented by auditing personnel and shall be distributed to and reviewed by management having responsibility in the area being audited.
- 18.6 Quality Assurance Management Audits shall be performed to determine the effectiveness of functions for which quality assurance personnel are responsible.

**ALARON CORPORATION  
QUALITY ASSURANCE PROGRAM MANUAL**

---

APPENDIX A

GLOSSARY

(2 Pages)

# ALARON CORPORATION QUALITY ASSURANCE PROGRAM MANUAL

---

## GLOSSARY OF TERMS

**APPROVAL** - Act of endorsing or authorizing, requires a signature and date.

**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. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

**CERTIFICATION** - The act of determining, verifying, and attesting qualifications are in accordance with specified requirements.

**CRITERIA** - Technical requirements describing objectives, conditions, and limitations.

**EXAMINATION** - inspection to determine conformance to specified requirements.

**INSPECTION** - Examination or measurement to verify conformance to requirements.

**ITEM** - A material, product or service.

**NONCONFORMANCE** - A deficiency in the characteristics, documentation or procedure, which renders the quality of an item or activity unacceptable or indeterminate.

**PROCUREMENT DOCUMENTS** - Documents used to define purchase requirements.

**QUALITY ASSURANCE** - The planned and systematic actions necessary to provide adequate confidence that a material, component, system or service meets the established requirements. Quality assurance includes quality administration and quality control.

**QUALITY CONTROL** - Those quality assurance actions performed to measure and control the characteristics of and/or process to established requirements.

**REPAIR** - The process of restoring a non-conforming 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 requirement.

**REVIEW** - A technical assessment that a document/activity complies with the appropriate requirements. As used in this manual, review requires a signature and date.

**REWORK** - The process by which an item is made to conform to original requirements by completion or correction.

**SURVEILLANCE** - The act of monitoring or observing to verify whether an item or activity conforms to specified requirements.

**SPECIFICATION** - A concise statement of the requirements that a product, material or process must satisfy in order to be acceptable.

**ALARON CORPORATION  
QUALITY ASSURANCE PROGRAM MANUAL**

---

APPENDIX B

Graded Quality Assurance Program Requirements

(2 pages)

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

### Graded Quality Assurance Program Requirements

In order to facilitate the identification of quality requirements, a graded approach will be used. The purpose of a graded program is to provide the flexibility needed to ensure that the level of quality verification and controls applied is compatible with safety, cost, schedule, and program success. The guidance in this appendix is intended to be just that, guidance for determining proper quality levels. It is not intended to be all-inclusive and deliberate planning is still required to ensure success.

Quality categories would then be established based on the relative quality significance of each Q item and, where appropriate, their subcomponent parts. Categories shall be identified as A for items that are critical to quality operation, B for items with a major impact on quality, and C for items with a minor or no impact on quality.

Category A items shall be items whose failure or malfunction could result directly in a significant condition adversely affecting public or employee health and safety or the environment. This would include such conditions compromising the integrity of NRC licensed containers or requiring reporting per 10 CFR 21. Suppliers of Category A items shall have had an on-site evaluation of their facility, personnel, and implementation of their quality assurance program, which verifies their technical and quality capability.

Category B items shall be items whose failure or malfunction could indirectly result in a condition adversely affecting public or employee health and safety or the environment. An unsafe condition could result only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence. The selection of suppliers is based on an evaluation of the supplier's capability to provide the required items or services. This evaluation may be based upon responding favorably to a Supplier Quality Survey, current quality records supported by documented qualitative and quantitative information, identical or similar product in the past and a history of satisfactory product performance, facility audit, verifiable proof of a recognized third party evaluation, or their use has been directed by Alaron's customer.

Category C items shall be those items whose failure or malfunction would be unlikely to create a condition adversely affecting public or employee health and safety or the environment. Supplier evaluation is informal. Acceptance is based on verification of the item's quality through documentation and receipt inspection.

**ALARON CORPORATION  
QUALITY ASSURANCE PROGRAM MANUAL**

---

APPENDIX C

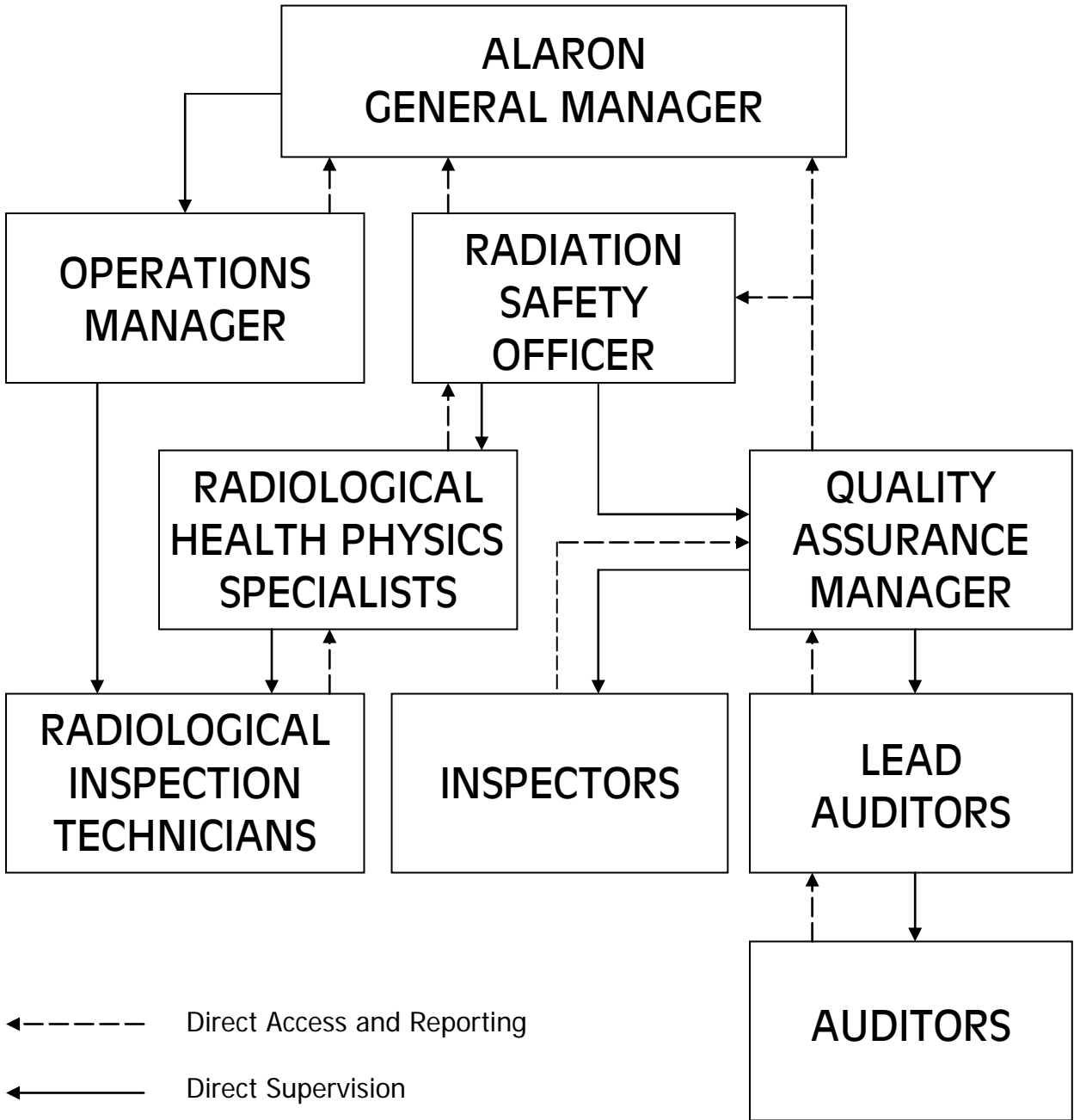
ALARON QA/QC ORGANIZATIONAL CHART

(2 pages)

**ALARON CORPORATION  
QUALITY ASSURANCE PROGRAM MANUAL**

---

**ALARON QUALITY ASSURANCE / CONTROL ORGANIZATION CHART**



# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

Notes to Alaron's Quality Assurance Program Manual,  
PL-AR-1293-011, Revision 3

Alaron's review of its Quality program found that Alaron had unnecessarily burdened itself with requirements that were not applicable and that could therefore not be followed. The QA Manual has remained in its original text since 1993 with the exception of the insertion of Joe Harverson as the Alaron General Manager in 1999. This revision is summarized as follows:

<u>Section</u>	<u>Revision</u>
3.0	Added a statement that Alaron does not currently perform design activities.
4.0	The word "Applicable" added to requirements in this section.
4.6	Removed old unnecessary requirement with a requirement from the two 10 CFR regulations.
6.2	Removed requirements of this section because it specified documents to be controlled that may not necessarily require control. Section now gives a simple definition of control.
6.3	Removed requirements of this section because it was confusing and contained an overly burdensome requirement that is accomplished by periodic review of controlled documents. Section now specifies a frequency for reviewing documents.
6.4	Statement added to allow for changes to be made to documents by a department or individual specifically designated by original reviewers.
9.4	Unnecessary reference to supplier selection in this manual was removed.
14.2	Unnecessary reference to control of nonconforming items removed.
15.6	Removed, requirement was not practiced and is not incorporated in Alaron procedures. Section is now reserved.
16.2	References to other sections removed as unnecessary.
16.5	The 'as required' summary of corrective actions was changed to periodic since there does not seem to be a requirement in standards.
17.2	Quality record is redefined.
17.4	Removed as repetitive. Section is now reserved.
18.2	The audit of all 18 elements of Alaron's Quality Assurance Program was changed from at least annually to biannually to reflect resources available.

# ALARON CORPORATION QUALITY ASSURANCE PROGRAM MANUAL

---

Notes to Alaron's Quality Assurance Program Manual,  
PL-AR-1293-011, Revision 4

Justification for changing the frequency of auditing the quality system from every year to every two years was not feasible. Alaron desires to maintain its 10 CFR 50, Appendix B Quality Assurance Program approval and by regulatory guide 7.10 could not find adequate justification for the change. ASME/NQA-1 also requires quality be maintained for computer programs. This revision also addresses this issue. This revision is summarized as follows:

<u>Section</u>	<u>Addition</u>
3.5	Computer programs designed in-house are subject to outcome verification.
11.3	Computer programs for in-house use will be tested to verify acceptable performance.

<u>Section</u>	<u>Revision</u>
18.2	Quality Assurance Program audit frequency changed to annually.
A-2	Definition of Controlled Document changed

# ALARON CORPORATION QUALITY ASSURANCE PROGRAM MANUAL

---

Notes to Alaron's Quality Assurance Program Manual,  
PL-AR-1293-011, Revision 5

The removal of the last sentence of section 9.4 gave a measure of ambiguity to the intention of the section. The sentence has been replaced in this page change to the Quality Assurance Program Manual.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

Notes to Alaron's Quality Assurance Program Manual,  
PL-AR-1293-011, revision 6

This revision to the Quality Assurance Program Manual is facilitated by a change in the management structure of Alaron Corporation, an increase in quality related enterprise, and a need to revamp Alaron's graded approach to quality. The management structure was changed by the elimination of the position, Manager of Environment, Health and Safety and Quality Assurance. The previous graded approach was geared toward production and design. Alaron enterprises now focus on service. The graded approach is now simplified. Changes made in this revision are noted below.

<u>Section</u>	<u>Page#</u>	<u>Comment</u>
Policy	3	Responsibility for the Quality Assurance Program delegated to the Quality Assurance Manager. Manager EHS&QA eliminated here and throughout the manual. Alaron has eliminated the position.
1.6	5	Specific types of procedures change to controlled documents.
2.1	6	10 CFR 830.122 added to list of regulations the Quality Assurance Program Manual meets the intent.
3.5	7	"for" changed to "are" (typo repair).
6.7	10	Certification responsibilities defined.
7.7	12	Categories A and B suppliers specified as being on the ASL. These categories require formal evaluations prior to acceptance of quality items. Access to current ASL included allowing an intranet copy.
10.2	15	"procedures" changed to "documents" to reflect current use of work instructions as guidance documents.
10.3	15	Manager EHS&QA eliminated.
17.2	22	"approved procedures" changed to "controlled documents" to reflect current use of work instructions as guidance documents.
Appendix A		Glossary size reduced.
Appendix B		Grade QA Program requirements simplified
Appendix C		Organizational chart updated.

# ALARON CORPORATION

## QUALITY ASSURANCE PROGRAM MANUAL

---

Notes to Alaron's Quality Assurance Program Manual,  
PL-AR-1293-011, Revision 7

<u>Section</u>	<u>Page</u>	<u>Revision</u>
Authority	3	Alaron's president left the corporation. The parent company, Veolia Environmental Services Technical Solutions opted to replace the position with a General Manager.
3.2	7	Customer audit sought Alaron to include "order entry" elements into the Quality Assurance Program Manual. This section is now revised to include "work permits" and "supplier purchase orders" to the list of documents to which customer specifications may be translated.
7.3	11	NVLAP and its signatories added to the list of conditions not requiring an on-site supplier audit.
9.1	14	Protective Coatings added to list of special process example of processes requiring approved procedures.
Appendix C	C-2	Organizational Chart restructured to reflect current hierarchy.