

# Argonne National Laboratory

## Quality Assurance Requirements and Description

Issue Date: \_\_\_\_\_

Effective Date: \_\_\_\_\_

**Change Notice:** This document supersedes the *Quality Assurance Program Description* and the *Quality Assurance Program Plan*. The *Quality Assurance Procedures Manual* remains in effect.

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
QA/Control Program Manager

Reviewed by: \_\_\_\_\_ Date: \_\_\_\_\_  
Director, ESH/QA Oversight

Approved by: \_\_\_\_\_ Date: \_\_\_\_\_  
Director, Argonne National Laboratory

**NOTICE:** This document is a controlled document residing on the Argonne intranet and may be used to perform work. Copies printed from the intranet are not controlled. Personnel using this document are held responsible for ensuring that the most current revision of this document is used to perform work. If you retain this document, do not start future work without verifying that this document is the most recent version. The most recent revision is on the Argonne intranet. [<http://www.aim.anl.gov/manuals/>]

---

# **Argonne National Laboratory Quality Assurance Requirements and Description**

---

August 1, 2007

## Quality Assurance Requirements and Description

### INTRODUCTION

---

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

---

### INTRODUCTION

The *Quality Assurance Requirements and Description (QARD)* outlines the overarching quality assurance program for Argonne National Laboratory (Argonne, Laboratory). As such, the *QARD* identifies the quality requirements necessary to implement DOE contract requirements and execute the Integrated Safety Management System. The *QARD* directs the user to the manuals, policies, and procedures that detail and execute the quality assurance requirements for Argonne activities including research and development (R&D).

UChicago Argonne, LLC, is the prime management and operating (M&O) contractor for the U.S. Department of Energy (DOE) at Argonne National Laboratory and is committed to implementing plans, processes, and procedures that institutionalize the DOE Quality Management System (QMS).

The DOE quality requirements are imposed through contract clauses. It requires contractors to ensure that the quality requirements are implemented and documented. The DOE QMS also requires that a graded approach to quality be used for implementing and tailoring a quality assurance program for Argonne facilities and activities. It is a fundamental expectation that all work is performed safely and that all work will meet or exceed customer expectations and established requirements.

The owner of the *QARD* is Environment, Safety, Health/Quality Assurance Oversight (EQO) and the point of contact and approval authority is vested in the director of EQO. Minor changes, those that do not add, diminish, or otherwise change requirements, must be approved by the EQO-QA manager. Revisions other than editorial are reviewed by each of the ALD's ESH/QA representatives and comments resolved prior to issue of the changed document.

In accordance with the requirements of DOE O 414.1C, "Quality Assurance," and 10 CFR 830, Subpart A, "Quality Assurance Requirements," the *QARD* must be reviewed annually and submitted to DOE for their review and approval. The submittal must identify the changes, the reason for the changes, and the basis for concluding that the revised quality assurance program continues to satisfy the requirements. If the Laboratory's annual review does not result in any revision, Argonne will notify DOE that the review was conducted and no revision is necessary.

This Argonne National Laboratory *QARD* provides the quality assurance program and the requirements that are necessary to ensure that quality and safety are integrated into the work performed under Prime Contract DE-AC02-06CH11357 (hereafter "the Contract") between UChicago Argonne, LLC, and the Department of Energy.

This *QARD* establishes the program and requirements in accordance with Title 10 of the Code of Federal Regulations (CFR), Part 830, Subpart A, "Quality Assurance Requirements," and

## Quality Assurance Requirements and Description

### INTRODUCTION

---

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

---

DOE Order 414.1C, "Quality Assurance." It is also designed to support the applicable requirements in ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications"; DOE/RW-0333P, "Quality Assurance Requirements and Description," from the Office of Civilian Radioactive Waste Management; and ANSI/ASQ Z1.13, "Quality Guidelines for Research," as they apply to specific organizations within Argonne.

The Argonne Quality Assurance (QA) policy (*Argonne Policy Manual*, Chapter 12) establishes the principles for the program and provides the link between the DOE regulations and the requirements established for Argonne work.

## Quality Assurance Requirements and Description

### Chapter 1 QUALITY MANAGEMENT PLAN

Last revised: August 1, 2007

Last reviewed: August 1, 2007

## 1 QUALITY MANAGEMENT PLAN

### 1.1 PURPOSE AND SCOPE

#### 1.1.1 PURPOSE

- a. The Argonne *QARD* is based on DOE orders and regulations and supplemented, as appropriate, by the guidance given in DOE standards and guides. It establishes the minimum quality requirements for all Argonne organizations.
- b. The *QARD* also delineates the interrelationship with national and international standards, Integrated Safety Management System (ISMS) principles and core functions of DOE P-450.4, and supports the implementation of the DOE requirements for contractor assurance systems (CAS). (DOE O 226.1, "Implementation of DOE Oversight Policy")

#### 1.1.2 SCOPE

The *QARD* establishes the requirements necessary to comply with Title 10 of the Code of Federal Regulations (CFR) 830, Subpart A, "Quality Assurance Requirements," and DOE Order 414.1C, "Quality Assurance." Compliance with the *QARD* is mandatory for Argonne organizations. Additional requirements imposed on those Argonne activities that support a customer with QA requirements must be implemented.

### 1.2 GRADED APPROACH

#### 1.2.1 RESPONSIBILITIES

- a. Associate Laboratory directors (ALDs) and managers must ensure that a graded approach to quality requirements is used, in accordance with this section, for items and services under their control.
- b. Division directors/department heads (DD/DH) must use a graded approach (the assigning of quality levels as defined in Section 1.2.3) when establishing the level of control for accomplishing quality program elements within their functional areas.

**NOTE:** The graded approach should be applied based on prudent management planning, evaluation of risks related to each function, and the consequence of poor quality on the customer, the workers, the community, and the environment.

## Quality Assurance Requirements and Description

### Chapter 1 QUALITY MANAGEMENT PLAN

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### 1.2.2 LIMIT OF THE GRADED APPROACH

The graded approach process must not be used to "grade to zero." Even in the least stringent application of the graded approach, compliance with applicable portions of the stated requirements is mandatory. For further details, see *Quality Assurance Procedures Manual (QAPM)* Section 1.5, "Graded Approach." The graded approach is prohibited in implementing the unreviewed safety question (USQ) process or in implementing technical safety requirements.

#### 1.2.3 QUALITY LEVEL CATEGORY DETERMINATION

- a. 10 CFR 830, Subpart A, "Quality Assurance Requirements," and DOE O 414.1C, "Quality Assurance," require the use of the graded approach in the application of quality assurance. The graded approach levels (quality levels) for Argonne are described below. Specific guidelines and a suggested checklist for determining the appropriate grading for the individual QA criteria are identified in *QAPM* Section 1.5, "Graded Approach."

**Quality Level A** – Very High Risk /Consequence and/or Mission Critical

**Quality Level B** – High Risk/Consequence and/or Mission Major

**Quality Level C** – Medium Risk/Consequence and/or Mission Minor

**Quality Level D** – Low/Negligible Risk/Consequence and Mission Minimum

- b. The purpose of grading is to select the controls and verifications to be applied to various items and activities consistent with their importance to safety, cost, schedule, and success of the program.

**Quality Assurance Requirements and Description****Chapter 2      QUALITY PROGRAM ELEMENTS***Last revised: August 1, 2007**Last reviewed: August 1, 2007***2 QUALITY PROGRAM ELEMENTS****2.1 MANAGEMENT****2.1.1 PROGRAM**

The *Quality Assurance Requirements and Description (QARD)* format is based on the following DOE O 414.1C ten criteria.

**Management:**

- |             |                                       |
|-------------|---------------------------------------|
| Criterion 1 | Program                               |
| Criterion 2 | Personnel Training and Qualifications |
| Criterion 3 | Quality Improvement                   |
| Criterion 4 | Documents and Records                 |

**Performance:**

- |             |                                   |
|-------------|-----------------------------------|
| Criterion 5 | Work Processes                    |
| Criterion 6 | Design                            |
| Criterion 7 | Procurement                       |
| Criterion 8 | Inspection and Acceptance Testing |

**Assessment:**

- |              |                        |
|--------------|------------------------|
| Criterion 9  | Management Assessment  |
| Criterion 10 | Independent Assessment |

Divisions adopt additional quality program requirements as imposed by their customers.

QA guidance documents must be considered in developing and implementing the QARD.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

If divisions must follow requirements in addition to those established in the *Quality Assurance Procedures Manual (QAPM)*, the division must write a supplement(s). The supplement(s) must be developed in accordance with QAPM Section 1.7, "Supplements," and must be reviewed and approved by EQO-QA and by the DD/DH prior to implementation.

#### 2.1.1.1 Integrated Safety Management System (ISMS)

The Worker Safety and Health Program/Integrated Safety Management Description details how work is conducted at Argonne in accordance with the requirements established in 10 CFR 851, "Worker Safety and Health Program," and the Integrated Safety Management System requirements in DOE P 450.4, "Safety Management System Policy." The QARD is consistent with and encompasses the requirements of the *ISM Program Description*.

#### 2.1.1.2 Management Organization

- a. The director of Argonne National Laboratory reports to the CEO of UChicago Argonne, LLC. The Laboratory director has established a succession of authority that stipulates who can act on his behalf.
- b. The Argonne organization is described in the Argonne *Policy Manual*, Chapter 9, "Organization," and is depicted on the Argonne Intranet in "Inside Argonne."
- c. Argonne is divided into scientific research or programmatic directorates and an operations and business management directorate. Each organization is headed by an associate Laboratory director (ALD) who reports to the Laboratory director. Although many of the research projects conducted at Argonne have basic and applied research components, and several involve the operation of facilities, the scientific directorates focus on different specialties in their research.
- d. Each directorate is further divided into divisions, each headed by a division director, and organized largely by their specialty (e.g., research or operational area).

#### 2.1.1.3 Authority and Responsibilities

- a. **The Laboratory director** has ultimate responsibility and authority for quality at Argonne. The director approves the QA policy and all substantive changes to it and is committed to and is supportive of effective QARD implementation. The Laboratory director appoints the director of ESH/Q Oversight (EQO) and the ALDs.

**Quality Assurance Requirements and Description****Chapter 2      QUALITY PROGRAM ELEMENTS**

---

*Last revised: August 1, 2007**Last reviewed: August 1, 2007*

---

- b. **The director of Environment, Safety, Health/Quality Assurance Oversight (EQO)** is responsible for the maintenance of the ESH and QA programs. The director of EQO approves the *QARD* and all substantive changes to it, advises and assists the Laboratory director in providing continuity, completeness, and appropriate standardization in the overall quality program, and is committed to and supportive of the quality and safety programs. This responsibility includes policymaking, planning, reporting, oversight, and other activities required to achieve an integrated and effective QA program.
- c. **Associate Laboratory directors** are responsible for quality in their respective organizations. As appropriate for their areas of responsibility, the ALDs establish additional or more specific performance quality requirements than those established in the *QARD*. The ALDs are responsible for the performance of assessments, and for sponsoring assessments, to facilitate the achievement of the organizational mission, objectives, and performance requirements. Each ALD must appoint an ESH/QA representative.
- d. **ALD ESH/QA representatives** are responsible for coordinating QA policy implementation in the organizations under the jurisdiction of their ALD by:
- Coordinating reviews of *QARD* and *QAPM* revisions for their ALD organizations,
  - Performing specific QA-related duties as assigned by their ALD,
  - Serving as a participant and point of contact for assessments and incident investigations,
  - Serving as interface with division quality assurance representatives (QARs),
  - Serving as the interface with EQO through the Environment, Safety and Health/Quality Assurance Oversight Coordinating Committee (EQO-OCC).
- e. **Division directors** are responsible for ensuring that their division's activities are conducted in accordance with the principles and requirements of the *QARD*. Each division director must appoint one or more quality assurance representative.
- f. **Quality assurance representatives (QARs)** are responsible for
- Analyzing quality issues,
  - Assisting in supplier evaluations,

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Attending periodic meetings that are held to discuss institutional QA issues and lessons learned and passing that information on to the appropriate people in their organization,
  - Identifying appropriate internal quality assurance actions,
  - Identifying opportunities for quality improvement,
  - Interpreting and applying basic quality assurance program requirements,
  - Maintaining current divisional supplements to tier 2 procedures, and
  - Reviewing procurement processes.
- g. **Argonne personnel** are responsible for the quality of their work and being attentive to opportunities for continuous quality improvement. They are responsible for stopping any activity that poses imminent danger to any individual, the Argonne or divisional mission, or the environment. Employees must inform their immediate supervisors of any conditions that are noncompliant with Argonne policies and requirements.

#### 2.1.2 PERSONNEL TRAINING AND QUALIFICATIONS

##### 2.1.2.1 Introduction

Ensuring competence at Argonne is the goal of the hiring process administered by Human Resources (HR) and described in the *Human Resources Policy and Procedures Manual*, "Training Programs" – Procedure, Section 5100.2. A position description (PD) is prepared, and an individual is hired to satisfy the PD's requirements. The individual must meet established PD requirements in education and/or experience that indicate an individual should have sufficient knowledge and skills to perform the job. Line managers must ensure that personnel possess the experience, knowledge, skills, and abilities that are necessary to fulfill their responsibilities. Administrative controls must be used until personnel complete the training required for their assignments.

- a. The requirements in this section apply to all employees (or persons working as employees) of Argonne, including students, temporary workers, facility users, long-term consultants, and special term appointees.
- b. Visitors and contractors, however, fall into the following classes:

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

1. Those who plan to stay over ten business days at the Argonne site must complete a Job Hazard Questionnaire (JHQ) and all appropriate training.
2. Those who work under contract must follow these specific requirements.
  - i. Those who have service contracts receive the appropriate level of Contractor Safety Orientation and arrive with other necessary, regulation-required training completed.
  - ii. Those working under construction contracts receive Contractor Safety Orientation and arrive with the necessary, regulation-required training completed for contract work. The technical representative, construction field representative, or construction manager for the contract ensures that the proper training has been completed.
3. Those who are escorted during their time at Argonne (including visitors) are the responsibility of the host, who must be trained for entry into hazardous areas or any area visited.
  - c. Administrative restrictions must be placed on new employees prior to their completing certain course work. Such restrictions, administered by the first-line supervisors, ensure that employees do not work in areas or on tasks until they have received the minimum required level of training and can adequately perform the assigned tasks safely without direct supervision.
  - d. The process for developing and providing training is outlined in the *Argonne Training Management Guide*.

#### 2.1.2.2 Responsibilities

- a. **Argonne line managers** must ensure that:
  1. Their personnel are trained and/or qualified to perform their assigned work. They must ensure that position descriptions (PD) appropriately define knowledge, skills, and abilities, and that a JHQ is established.
  2. A JHQ is completed by the supervisor and the employee. Based on the JHQ, a training profile is established and coordinated through the Training Management System (TMS).

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

3. Personnel training or other actions emphasize correct performance of work, personal accountability and responsibility, and, where appropriate, provide an understanding of QA principles and the relevant management procedures.
4. Appropriate records of education, training, skills, and experience are maintained.
- b. Supervisors must identify other specific qualification/certification requirements when preparing personnel training (see also Section 2.1.2.6).
- c. Line managers and employees must ensure that the employee JHQ, required training, and training records are current.

#### 2.1.2.3 Training Requirements

- a. Employee Training
  1. Employee training is typically subject-based and geared toward job proficiency and safety/quality-related issues. As appropriate, it includes management training and continuing education through courses and seminars.
  2. From the JHQ, a training profile listing training requirements based on job hazards, duties, and responsibilities is provided for the employee's job assignment.
  3. Training is provided, if needed, to achieve initial proficiency, maintain proficiency, and adapt to changes in technology, methods, or job responsibilities. As appropriate, training includes classroom, computer-based, or on-the-job training (OJT). Required training is based on an assessment of the job duties, responsibilities, and specific hazards that the employee may face. Facility-specific training is related to the work location. Job-specific OJT is determined and provided to the employee locally.
- b. Training Documentation
  1. Completed training must be documented and may be tracked in TMS.
  2. All required training identified by the JHQ must be documented in TMS.

#### 2.1.2.4 Qualification/Certification Requirements for Personnel Performing Activities with Specific Qualifications/Certifications

When using the services of qualified personnel, Argonne line management must:

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- a. Identify any special physical requirements needed in the performance of each activity, including the need for initial and subsequent physical examination. The Human Resources "Fitness for Duty Policy" (Section 9100.2 of the *Human Resources Policy and Procedures Manual*) is in place to ensure that a continuous match exists between the capabilities of the employee and the physical requirements and/or mental demands of the current assignment.
- b. Identify those activities that require specific qualification/certification and the minimum requirements for such personnel.
- c. Ensure that only those personnel who meet the qualification requirements are permitted to perform the designated work.

#### 2.1.2.5 Training Records

Records of completed training as well as qualification/certifications are maintained. The status of required training that is entered into TMS is tracked. The supervisor and employee are jointly responsible for ensuring that an individual employee's JHQ, training, and training record are accurate and current.

#### 2.1.2.6 Continuing Training

Personnel must be provided continuing training as appropriate to ensure that job proficiency and compliance are maintained. Continuing training includes lessons learned, equipment changes, procedure changes, and changes in technology. Employee training requirements include safety courses and skill-related certifications that may require retraining.

- a. Supervisors and employees must ensure that appropriate records of education, training, skills, and experience are maintained.
- b. Supervisors must identify other specific qualification/certification requirements when preparing personnel training (see also Section 2.1.2.2).
- c. Employees must ensure that their JHQ is current and that their required training and training records are current.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### 2.1.3 QUALITY IMPROVEMENT

##### 2.1.3.1 Introduction

- a. Continuous quality improvement in efficiency and quality extends beyond the achievement of goals and performance indicators/measures and meeting customer expectations. The continuous improvement process at Argonne is designed to foster a self-critical culture to prevent the occurrence of conditions adverse to quality, such as accidents, incidents, deficiencies, and nonconformances. While the prevention of quality issues and conditions adverse to quality is the central focus of Argonne's quality improvement process, quality issues could still occur regardless of the preventive efforts put forth. Therefore, the quality improvement processes includes provisions to identify, analyze, and resolve quality issues and prevent their recurrence.
- b. Argonne maintains continuous quality improvement through a variety of activities, including assessments, surveillances, walk-throughs, inspections, tests, monitoring, reviews, and analysis. Issues and improvement opportunities are documented and managed utilizing the Argonne issues management system. The lessons learned process is an integral part of continuous quality improvement and the issues management system.

##### 2.1.3.2 Contractor Assurance System

- a. Argonne is committed to implementing processes and systems to fulfill the contractor requirements described in DOE Order 226.1, "Implementation of Department of Energy Oversight Policy." The *Contractor Assurance System Description* document (CASD) describes the implementing processes that Argonne uses to meet DOE Order 226.1 and the DOE expectations for a contractor assurance system.
- b. The six CAS components are:
  - Self-assessment
  - Issues management
  - Incident and event reporting
  - Worker feedback
  - Lessons learned

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Performance indicators/measures
- c. The six components of CAS provide the programs and processes that work together to ensure that issues and improvement opportunities are rigorously and robustly identified, investigated, corrected, and communicated and, when appropriate, dispositioned (e.g., nonconforming hardware, equipment, material), verified, and validated.

#### 2.1.3.3 Issues Management

The DOE Quality Assurance Requirements Rule (Title 10 CFR Part 830, Subpart A), DOE Order 414.1C, and DOE Order 226.1 establish requirements for quality improvement processes. Argonne issues management processes are aimed at meeting the requirements of these rules and orders, as well as other customer and regulatory drivers (NQA-1, etc.), as applicable.

- a. Issues management is utilized to ensure that problems, trends, and issues are identified, documented, trended, analyzed, and prioritized to promote effective resolution in a timely manner. Issues identified are controlled and corrected using a graded approach based on issue risk ranking. The issues management system ensures that assessments, issues, events, and incidents are screened for applicability and reporting under the Price-Anderson Amendments Act (PAAA); 10 CFR 851, "Worker Safety and Health Program"; and Occurrence Reporting and Processing System (ORPS) – DOE O 231.1A, "Environment, Safety and Health Reporting." The lessons learned process is detailed in the CASD and is utilized to assist in preventing events or their recurrence. Evaluations are performed to determine the extent of condition, using a graded approach.
- b. Issues management applies to issues identified through assessments, lessons learned, and worker feedback, as well as injury, incident, and event (mishap) reporting.
- c. Issues management utilizes a centralized database to track, manage, and report the status of identified issues.
- d. Issues management is detailed in the *Issues Management System Description* document.
- e. Causal analysis is an essential element of issues management. Issues, events, and incidents are categorized by significance and importance using a graded approach. This categorization drives the performance of causal analysis, including the depth and breadth of investigation necessary to complete the analysis and identify causes. Significant issues, events, and incidents require formal root cause analysis and

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

documentation, while less significant issues, events, and incidents require less rigorous apparent causal analysis.

#### 2.1.4 CONTROLLING DOCUMENTS AND RECORDS

##### 2.1.4.1 Documents

- a. Argonne documents that specify policies and other requirements, prescribe processes, or establish design specifications must be controlled to ensure that the direction they provide is accurate, current, and approved by authorized individuals.
- b. Argonne's system for managing Laboratory-wide policies and procedures is described in the *Science, Technical, and Business Information Manual*.
- c. Division directors must establish systems to control procedural requirements, design, and other quality management documents used solely within their division.
- d. Where specific quality requirements are imposed by outside customers/sponsors, or are required for nuclear facilities, specific additional document control requirements must be included in a supplement.

##### 2.1.4.2 Records

In accordance with DOE O 414.1C, Criterion 5, records must be identified, prepared, reviewed, approved, and maintained.

Argonne requirements for records creation and management are described in the *Science, Technical, and Business Information Manual*.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

## 2.2 PERFORMANCE

### 2.2.1 WORK PROCESSES

#### 2.2.1.1 Introduction

Work is defined as the design, operation, maintenance, modification, and construction of structures, systems, components, or experiments by Argonne or non-Argonne personnel (contractors, visiting scientists, students, and minors). Argonne work control processes ensure that work is properly controlled, evaluated, reviewed, approved, implemented, inspected, tested, and documented.

#### 2.2.1.2 Develop and Implement Controls, Safety Standards, and Requirements

The work process requirements associated with facilities, structures, systems, components, and experiments are documented in institutionalized Laboratory procedures. These work process requirements include experiment safety reviews and task level safety/hazards analyses to ensure that appropriate hazard controls and safety standards, as well as technical, quality, and scientific requirements are established in work and experiment documents prior to work or experiment execution. Documentation and records associated with work processes are appropriately reviewed, approved, retained, and controlled. The level of rigor for applying quality requirements to Laboratory work is established using the graded approach established in QAPM Section 1.5, "Graded Approach."

The development and implementation of work process controls, safety standards, and technical requirements (including QA) are contained in the following:

- *Environment, Safety and Health Manual* Chapter 21.1, "Hazard Analysis Processes for Nonexperimental Work."
- *Environment, Safety and Health Manual* Chapter 21.2, "Experiment Safety Review."

#### 2.2.1.3 Item Identification and Use Control

- a. Use of items or services procured or otherwise obtained for experimental and nonexperimental work at the Laboratory must be properly controlled including, where applicable, evaluation of suppliers. Items must be inspected/tested/reviewed for acceptance and identified and/or otherwise controlled to ensure appropriate application and use.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

**NOTE:** Items can include, but are not limited to, materials, hardware, assemblies, subassemblies, systems, subsystems, support systems, components, units, equipment, modules, parts, chemicals, gases, software, and structures having technical, quality, and safety requirements.

**NOTE:** Services can include design, analysis, and other consulting, professional and/or support services including construction, demolition, decontamination, painting/coatings, asbestos/lead analysis and abatement, and other services having technical, quality, or safety requirements.

- b. Controls are established for the procurement and acceptance of items and services and are addressed in *QARD* Chapter 2, Section 2.2.4, "Procurement."
- c. Controls are established for the identification and control of items and are addressed in *QAPM* Section 2.6, "Material Control."

#### 2.2.1.4 Item Protection

- a. In order to prevent item damage, loss, or deterioration, controls must be established for proper item storage, in-storage maintenance, and protection commensurate with the item's quality level category, application, and use. These controls are described in *QAPM* Section 2.6, "Material Control."
- b. The *Property Management Manual* also establishes the requirements for controlling and maintaining property, equipment, items, and the site infrastructure. The real property and maintenance management systems provide the processes to prevent damage, loss, or deterioration to the site assets.

#### 2.2.1.5 Measuring and Test Equipment Control

- a. Documented controls must be established to ensure that measuring and test equipment (M&TE) are calibrated, maintained, and controlled commensurate with their intended use. Prior to use, M&TE must be checked to ensure that it is the proper type, range, accuracy, and precision and is uniquely identified and traceable to its calibration records. Procedures must be established for testing, retesting, adjusting, and recalibrating M&TE.

**NOTE:** M&TE includes reference measurement standards used for inspections, tests, measuring, monitoring, and data collection.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- b. Where applicable, M&TE must be recalled and calibrated at specified intervals to standards traceable to the National Institute of Standards and Technology or other national or international standards. Where no recognized standard exists, the basis for calibration is defined and documented. When calibrating and/or checking M&TE for use, consideration must be given to verifying computer programs that are part of the M&TE, where applicable.
- c. M&TE that have passed the calibration due date must be removed from service.
- d. If M&TE is found to be out of calibration, an evaluation must document the validity of previous tests, inspections, measurements, or data collected and determine the acceptability of items previously inspected or tested. The evaluation, including conclusions, must be documented.
- e. Documented controls for measuring and test equipment (M&TE) are found in *QAPM* Section 2.7, "Control of M&TE."

## 2.2.2 SOFTWARE QUALITY ASSURANCE

### 2.2.2.1 Introduction

Software quality assurance (SQA) programs are required contractually by DOE N 203.1, "Software Quality Assurance," and DOE O 414.1C, "Quality Assurance." Requirements are implemented to ensure that software will perform its intended specific function in relation to Argonne structures, systems, components, data, and activities. Software controls are required to be developed and implemented using national and international consensus standards and based on a graded approach to ensure that those controls are applied commensurate with the software application. DOE N 203.1 details the requirements for software quality assurance.

The SQA requirements apply to all DOE software or software customized for DOE use, proposed for use, under development, or being maintained and used, whether that software was developed in-house, licensed from a commercial vendor for customized use, obtained from another organization or otherwise acquired. (DOE N 203.1) The type of software includes, but is not limited to: (a) administrative/business-oriented software, (b) scientific/engineering software (where governed by 10 CFR 830), (c) manufacturing-oriented software, and (d) process control.

Software that is designated "safety software" has additional specific controls imposed as discussed in Section 2.2.2.4. DOE O 414.1C, "Contractor Requirements Document,"

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

Paragraph 5, and DOE G 414.1-4, "Safety Software Guide," detail the requirements for safety software quality assurance (SSQA).

#### 2.2.2.2 Software Control Elements

- a. Line management must ensure adequacy of training programs to meet current and future personnel skill needs in the areas of SQA, software engineering, and software user training.
- b. Argonne senior management must ensure the integration of the SQA program planning process with strategic planning, the Integrated Safety Management System (ISMS), and the budget process, as appropriate, to ensure that SQA program decisions are made, adequately funded, and executed to support DOE organizational and site missions and priorities.
- c. Divisions must develop SQA programs as detailed in Section 2.2.2.3.
- d. Divisions must, in developing their management assessment schedules, ensure inclusion of their SQA programs for periodic review. EQO must conduct systematic reviews to ensure that the requirements of the DOE directives are met.

**NOTE:** Relative to software, these reviews should also ensure that appropriate safety and security controls are in place, are effective, and reflect currently accepted industry practices. (DOE N 203.1)

#### 2.2.2.3 Software Quality Assurance Programs

- a. SQA programs must be developed and documented for software projects and applications. The expectation is that this documentation will be completed at the division or organizational level matching the type and importance of each organizational unit's software applications. The programs must be commensurate with the size, complexity, cost, degree of external impact and customization, functions performed, and other factors important to management, and must include:
  - Identified point of contact
  - Defined authorities
  - Policies, procedures, training requirements

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Adopted standards
  - Conventions tailored to local needs
- b. SQA processes and procedures used must be software product and project life-cycle based; documented to provide a baseline for auditing; and applied in a consistent, repeatable, and predictable manner.
- c. SQA plans must be developed and must address:
- Inspections, audits, and any other requirements specified for an application;
  - Peer reviews;
  - Structured walkthroughs;
  - Testing; and
  - Verification and validation.
- d. Each SQA plan must be commensurate with the level of size, complexity, and scope of the software project. An SQA plan can be adopted and/or adapted for subsequent projects within a program.
- e. Software quality assurance implementation is described in *QAPM* Section 2.4, "Software Quality Assurance."

#### 2.2.2.4 Safety Software

*QAPM* Section 2.3, "Safety Software," is the implementing procedure for the Argonne (SSQA) procedure that must be utilized to meet the DOE specific requirements for safety software applications as well as to meet the requirements as stated in 2.2.2.3 above. It provides the mechanism to address and document applicability and adopted controls required for each of the 10 specified work activities detailed in DOE O 414.1C and DOE G 414.1-4. Work processes involving safety software must be developed and implemented using the applicable national or international consensus standards.

Safety software quality requirements ensure that software applications for radiological and/or nuclear facilities perform specific safety functions and provide consistent, repeatable, and correct results. The determination of what constitutes safety software and their appropriate

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

quality level is made by the organization applying the software based on the requirements in DOE O 414.1C, DOE G 414.1-4, and QAPM Section 2.3, "Safety Software."

#### 2.2.3 DESIGN

##### 2.2.3.1 Design Process

- a. The design process must be controlled by the designated design authority (DA). The design process controls are applicable to both in-house or outsourced design services. Agencies and contractors providing design services must be evaluated and selected based on the graded approach and their ability to meet specified requirements.
- b. When applied to existing facilities, components, and equipment that have already been designed, constructed, and are in operation, this process applies to design changes and modifications. A requested design change is defined as one that either alters a component or system function, method of performing the function, or design configuration. Minor modifications (those that are small and simple in nature) may utilize portions of those steps deemed appropriate and applicable, using the graded approach.
- c. When applied to research and development activities, design processes are tailored to meet the controls necessary for successful outcomes. As appropriate, R&D/experimental plans must specify the necessary controls and documentation. ANSI/ASQ Z1.13, "Quality Guidelines for Research," provides a model for research and development activities.
- d. In determining requirements for design activities, consideration must be given to the following items being graded according to their risk and complexity: safety, consequences and probability of failure, uniqueness, applicable codes and standards, performance quality, fabrication capability, software code ability, and cost. The detail of the design process must be determined and documented using the graded approach. The design process must be stipulated by the organizations responsible for design activities. The following requirements must be addressed in design process controls:
  - Design items and processes using sound engineering/scientific principles and appropriate standards.
  - Incorporate applicable requirements and design bases in design work and design changes.
  - Identify and control design interfaces.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Validate the adequacy of design products using individuals or groups other than those who performed the work and validate work before approval and implementation of the design.
  - Verify results of design activities by one of the following or a combination of the following activities: monitoring, testing, checking, and /or assessing.
- e. The design process phases outlined above and detailed below are based on full process application. For research and development, see paragraph c. above.
- f. The design process procedures detailed in the Argonne *Project Management Manual* provide the detail for the application of the design process phases for both new designs and design changes or modifications. Additional requirements specifically related to the design and configuration of vital structures, systems, and components (VSSCs) for its hazard category (HC) 2 and 3 nuclear facilities (Argonne does not have any category 1 nuclear facilities) are detailed in the Argonne *Configuration Management Program* (CMP).

#### 2.2.3.2 Design Authority Responsibilities

The DA responsibilities are applicable whether the process is conducted fully in-house, partially contracted to outside organizations, or fully contracted to outside organizations. DA's are expected to consult with subject matter experts, as needed.

DA is responsible for:

- a. Design control and ultimate technical adequacy of the design process (conventional);
- b. Experiments and associated experimental activities (R&D);
- c. Use of appropriate quality level designations for acquisition of products and services in support of design, construction, and installation activities.

**NOTE:** Examples of design authorities:

- Electrical safety authority having jurisdiction (AHJ)
- Fire and life safety officer (AHJ) for fire protection
- Principal investigator (or equivalent position) for research facilities, equipment and apparatus

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Project engineer or other appointed individuals as designated by the design organization for facilities and infrastructure

#### 2.2.3.3 Design Phases

The following design phases implement the controls for nonexperimental work activities. Program documents describing implementation of these phases are maintained by the design authority.

##### 2.2.3.3.1 Conceptual Design Phase

Design inputs and constraints, including applicable orders, codes, standards, policies, and procedures, etc., will be identified into a design request. Design inputs must be reviewed for accuracy and completeness and to identify any ambiguity or conflict. The safety designation of the structure, system, or component(s) is determined, using the graded approach and based on the documented safety analyses (DSA) or safety plans, technical safety requirements (TSRs), statutory and regulatory requirements, Argonne requirements (pressure safety, hoisting and rigging, etc.), and controlling documents affecting the design, as applicable. Consideration for schedule, cost, and rigor of quality must be accommodated in the conceptual design phase. DSAs and TSRs are required only for hazard category facilities.

Design inputs include such information as the design bases, health and safety considerations, expected life cycle, performance parameters, and codes and standards requirements as they apply to the project.

##### 2.2.3.3.2 Preliminary Design Phase

Design activity is initiated based on the information in the design request. Any conflicts between design input requirements are noted and logic for resolution is defined and documented. Scoping analyses and calculations will be performed as necessary.

After the preliminary design is prepared, the output of the design effort (e.g., plans, specifications, analyses and calculations, etc.) is packaged along with the design request into a preliminary design review package. A preliminary design review should be held. Other additional intermediate reviews should be considered. The adequacy of design products must be verified/validated using individuals or groups other than those who performed the work. The results of the review are documented, including the resolution of comments and recommendations.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### 2.2.3.3.3 Final Design Phase

- a. The DA must finalize the design, being sure to take into account any earlier design review recommendations. The output of the final design effort (i.e., design review documentation, plans, specifications, analyses, calculations, etc.) is packaged into a final design review package, a final design review is performed, and an action plan is developed and documented to address concerns/recommendations regarding the final design. The results of post final design review activities, including action plan implementation and resolution of concerns and recommendation, are documented.

**NOTE:** The final design review is significant in that it ensures that the final design provides the documentation and requirements necessary for procurement/fabrication and acceptance as well as safe and proper use during service (e.g., drawings, specifications, component lists, set-points, inspection and testing requirements, functional requirements, acceptance and performance criteria, system design descriptions, etc.).

- b. Design changes must receive the same level of review as the original design.

#### 2.2.3.3.4 Design Implementation Phase

After completion, review, and acceptance of the final design, an engineering order (EO) is prepared by the DA that, along with the completed final design documents, is issued and distributed to project personnel to provide the technical and quality requirements to support procurement, fabrication, and/or construction of the structure, system, or component (SSC), including acceptance of proof testing or inspection, and documentation requirements.

#### 2.2.3.3.5 Procurement/Fabrication Phase

- a. The structures, systems and components (SSC) will either be procured from a vendor/contractor or fabricated by an Argonne organization(s). The procurement process must be controlled to ensure that purchased SSC conform to the technical and quality requirements specified in the engineering order. Vendors and contractors are evaluated and selected based on their ability.
- b. The procurement or fabrication and associated documentation, including material certifications and test reports, final revisions of fabrication drawings, marked-up as-built drawings, and inspection/test results must be inspected, reviewed, and accepted.
- c. When using other than procured items, such as salvage, or customer-provided materials, the design authority must ensure the quality of the product.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- d. All divisions must safeguard the conformity of their work during internal processing and delivery to the intended destination. The safeguarding must address such things as identification, handling, packaging, storage, and protection.
- e. Where special handling equipment is made by modification of commercial equipment, the manufacturer's engineering or an equivalent engineering approval of the modification is obtained and documented.

#### **2.2.3.3.6 Installation and Commissioning Phase**

- a. The installation of the SSC will be performed by either a vendor/contractor or by an Argonne organization(s). The procurement process is controlled to ensure that installation conforms to the technical and quality requirements specified in the engineering order. Installation vendors and contractors are evaluated and selected based on their ability.
- b. The installer for the newly designed structure, system, or component will receive copies of all design documents required to perform installation activities. During installation activities, any deviations encountered and the reasons for them must be documented and resolved or dispositioned. The affected design documents must be marked with any approved deviations by the vendor or Argonne organization installing the design and associated authorizations for those deviations made available for review. Design deficiencies or inadequacies in released design disclosure documents must be documented as nonconformances.
- c. The installation and associated documentation, including material certifications and test reports, marked-up as-built drawings, and inspection/test results must be inspected, reviewed, and accepted.

#### **2.2.3.3.7 Close Out**

Upon completion of installation acceptance, the final design must be commissioned (i.e., proof-tested, operational readiness review/readiness assessment performed, etc.) in accordance with a qualification plan prior to placing the structure, system, or component into service. Upon completion of commissioning, a documentation package including qualification test results, final revisions of fabrication drawings, marked as-built drawings, proof-tests, operational readiness review/readiness assessments, etc., must be assembled and retained as the final design closeout package.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### 2.2.3.3.8 As-Built Status and Configuration Management

- a. Changes, additions, and modifications to the above processes must be controlled in accordance with design procedures documented by the design organization. This is necessary to maintain adequate as-built configuration for facilities, structures, systems, or components plans, specifications, analyses, calculations, etc., to provide an accessible history of document modifications and changes.
- b. It is the policy of Argonne National Laboratory to identify vital structures, systems, and components (VSSCs) for its hazard category (HC) 2 and 3 nuclear facilities (Argonne does not have any category 1 nuclear facilities), and to effectively manage the configuration of these VSSCs throughout the lifetimes of the nuclear facilities with a disciplined and uniform methodology to ensure that Argonne achieves its safety goals for these facilities. The function used to achieve these policy goals is detailed in the *Argonne Configuration Management Program (CMP)*. It is part of Argonne's Integrated Safety Management System (ISMS) for its HC nuclear facilities. The CMP implements the requirements for configuration management (CM) from DOE Order 420.1B, "Facility Safety," with appropriate consideration of the requirements and recommendations from DOE-STD-1073-2003, "Configuration Management."
- c. The design organization must address configuration management in its organizational procedures for radiological facilities and nonnuclear facilities.

#### 2.2.3.4 Design Reviews

Design reviews are a vital component of the entire design process that is normally explicitly included in the schedule for the design effort.

- a. Design reviews must be conducted in accordance with complexity and risk and must involve a formalized, structured, and documented approach to ensure that the reviews are comprehensive, objective, professional, and documented. The authorization basis for the design phase for facilities with a categorization of HC 3 nuclear facilities or higher (based on DOE-STD-1027-92, "Hazard Categorization and Accident Analysis Techniques for Compliance," and DOE Order 5480.23, "Nuclear Safety Analysis Report") will include a preliminary DSA, the safety evaluation report (SER), and the feedback from independent design reviews. Authorization for facilities below HC 3 thresholds must be based on a like document (e.g., auditable safety analysis).
- b. Design review as applied to research is accomplished by stakeholder reviews of research plans and by peer review of research results being offered for publication.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

Research activities and the facilities used to support the research are reviewed per *ESH Manual* Section 21.2, "Experiment Safety Review."

- c. Designs of nonradiological facilities must be verified by a technically knowledgeable person who is separate from those who performed the design.

#### 2.2.4 PROCUREMENT

##### 2.2.4.1 Introduction

- a. This section establishes the QA requirements for the Argonne procurement process. Proper implementation ensures that items and services provided by suppliers meet or exceed the requirements and expectations of the end user. It also ensures that requirements are accurately, completely, and clearly communicated.
- b. The procurement process utilizes quality level designations to ensure that the item or service is procured commensurate with the item/service risk importance and safety-related end use.
- c. The procurement documents and contracts for items and services provided to facilities covered by 10 CFR 830 must include a statement informing the supplier or subcontractor that it is subject to 10 CFR 830 and the potential for enforcement action under this regulation.
- d. The design and procurement requirements provided by the design authority must be met during construction, modification, maintenance, and research and development (R&D) activities to ensure that an acceptable item (or service) is delivered on time and maintained until use.
- e. The procurement and receipt inspection process supports the identification and prevention of the introduction of suspect and counterfeit items (S/CI). The system for S/CI detection prior to release for use is detailed in the Argonne *QAPM* Section 2.2, "Suspect and Counterfeit Items."

##### 2.2.4.2 Procurement Documents

- a. Argonne procurement documents must clearly state or reference requirements and acceptance and rejection criteria for purchased items and services as described in the *Procurement Operations Manual* (POM). These documents must include specifications,

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

standards, and other applicable documents referenced in the design documents and must be submitted to the supplier.

b. Procurement documents must specify critical parameters and requirements: Examples are:

- Administrative documents
- Catalog/part number
- Document submittal and approval requirements
- Item or service quality level designation
- Item/material qualifications/certifications
- Performance expectations for service including associated certification and/or statement of conformance submittals
- Personnel qualifications and documentation
- Problem reporting
- Product-related documents
- Quality Program Requirements
- Suspect and Counterfeit Clauses
- Test and inspection requirements and documentation

c. Changes to procurement documents must be managed and controlled in the same manner as the original documents. The process for changes and/or modifications to procurement documents is defined in the *Procurement Operations Manual*.

#### 2.2.4.3 Supplier Evaluation

a. Prospective suppliers must be evaluated to verify their capability to meet quality and technical performance criteria and contract/purchase order schedules. Potential suppliers must be identified early in the design and procurement process to allow sufficient time to evaluate their capabilities.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- b. Supplier evaluation from a quality and technical standpoint is performed by personnel specifically trained and/or qualified.
- c. Evaluation and monitoring of supplier's performance during the life cycle of the purchase order or contract and after contract/purchase award must be performed to ensure that acceptable items are produced and services continue to meet the quality, technical, and performance requirements.
- d. The supplier evaluation and monitoring process is detailed in *QAPM* Section 4.1, "Supplier Evaluation." Training and the qualification requirements for assessment personnel are detailed in *QAPM* Section 3.5, "Lead Assessor."

#### 2.2.4.4 Inspection

- a. Design and procurement documents must specify critical and important acceptance parameters for inspection. Inspections must include verification that specified documentation has been provided by the supplier and the purchased item was not damaged in delivery.
- b. The process for the performance of inspections, measurements, tests, and document reviews to ensure conformance with purchase requirements is described in *QAPM* Section 4.5, "Receipt Inspection." The requesting organization identifies receipt inspections to be performed.
- c. Items that do not meet inspection, test, and performance criteria must be identified and controlled by the inspector to prevent their inadvertent installation and use. Such items must be dispositioned by a design authority prior to installation or use.
- d. Supplier documents such as certificates or statements of conformance, drawings, analyses, test reports, maintenance data, corrective actions, approved changes, waivers, deviations, and nonconformance documentation must be reviewed and/or approved.
- e. The training and/or qualification of personnel performing inspection and acceptance of items and services is also detailed in *QAPM* Section 1.4, "Training and Qualification of Inspection and Test Personnel."
- f. For intercontractor procurements, quality requirements must be established and agreed to in writing with clear definition of responsibilities of each organization.

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### 2.2.4.5 Purchase Requisition Review for Quality Related Items

- a. Quality level A, B, and some C requisitions require items/services to be purchased using the procurement and requisition integrated system (PARIS). Requisitions must be reviewed and approved by the appropriate approval thread, including institutional QA and divisional QAR.
- b. Items purchased through Argonne Materials Ordering System (AMOS) designated as quality level C require review and approval of the divisional and/or institutional QA personnel. If the item is designated as having acceptance criteria or having S/CI clauses applicable to the item, review and approval of the divisional QAR and/or institutional QA personnel are required.
- c. Requisitions for quality level D items for general service, office supplies, food supplies, etc., including off-the-shelf items without specific quality stipulations, require no institutional QA or divisional QAR review or approval. The use of quality level D is limited to products and services for which the risk of noncompliance is acceptable within the stated suppliers' warranty.
- d. The purchase requisition review process must be periodically monitored by EQO and/or QARs to ensure that items and services are properly categorized and appropriate reviews and approvals are performed.

#### 2.2.5 INSPECTION AND ACCEPTANCE TESTING

##### 2.2.5.1 Introduction

This section establishes the minimum requirements for inspections and tests performed at Argonne to verify that physical and functional aspects of items, services, and processes meet requirements and are fit for acceptance and use. The performance expectations, inspections, and tests must be identified and considered early in the design phase and specified in the design output and procurement documents.

##### 2.2.5.2 Inspection and Testing Process

- a. Inspection and testing requirements for items, services, and processes must be identified in design, procurement, facility, maintenance and operations documents. Inspection and test planning considerations must include the following;
  - Application of approved codes and standards;

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Identification of characteristics to be examined;
  - Required qualifications of individuals who perform the examinations;
  - Descriptions of the examination methods, including equipment and calibration requirements;
  - Acceptance and rejection criteria;
  - Suitable environmental conditions;
  - Shelf life limitations;
  - Required safety measures; and
  - Mandatory hold points, if applicable
- b. Inspections and tests must be performed and test results evaluated and verified by technically qualified individuals who have the authority to access appropriate information and facilities. When required, personnel must be used who are independent of the activities being inspected or tested and have the freedom to report the results of the inspections and/or tests.
- c. Qualification requirements for inspection and test personnel are detailed in the *QAPM* Section 1.4, "Training and Qualification of Inspection and Test Personnel." Implementation of inspection and acceptance testing is detailed in *QAPM* Section 2.5, "Inspection and Acceptance Testing." Implementation of receipt inspection is detailed in *QAPM* Section 4.5, "Receipt Inspection."

#### 2.2.5.3 Suspect and Counterfeit Items

Argonne has established a process for the identification, control, and disposition of suspect/counterfeit items (S/CIs). Implementation of the S/CI program can be found in the *QAPM* Section 2.2, "Suspect/Counterfeit Items."

#### 2.2.5.4 Control of Nonconforming Items

- a. The nonconformance report (NCR) process provides controls to ensure that items that do not conform to specified requirements are controlled to prevent their inadvertent installation or use. These controls must include identification, documentation, evaluation,

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

segregation (when practical), item disposition (reject, repair, rework, use-as-is) and notification of affected organizations.

- b. The NCR process is implemented through the following:

*QAPM* Section 2.1, "Nonconformance Process"

*QAPM* Section 1.2, "Corrective Action Development"

#### 2.2.5.5 Control of Measuring and Test Equipment (M&TE)

- a. Measuring and test equipment (M&TE) used for inspections, tests, monitoring, and data collection must be calibrated, maintained, and controlled using documented processes that include testing, retesting, adjusting, and recalibrating of the equipment. Prior to use, the equipment must be checked to ensure that it is the proper type, range, accuracy, and precision and is uniquely identified and traceable to its calibration records. Control and calibration of M&TE is detailed in the *QAPM* Section 2.7, "Control of Measuring and Test Equipment."
- b. M&TE must be calibrated at specified intervals and to standards traceable to the National Institute of Standards and Technology or other nationally or internationally recognized measurement standards when appropriate. Where no recognized standard exists, the basis for calibration must be defined and documented. Consideration must be given to computer programs that are part of the calibration of the equipment when calibrating and/or checking the equipment for use.
- c. When M&TE or calibration standards are found to be out of tolerance, appropriate evaluations must be performed to assess any adverse impact on inspection, testing, or calibration performed using that equipment or standard, and appropriate notifications made.

#### 2.2.5.6 Records

- a. Inspection and test records, at a minimum, must identify;
- The item inspected/tested;
  - Date of inspection/test;
  - Inspection/test method and acceptance criteria;

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

- Inspector, tester, or data recorder;
  - Results and acceptability; and
  - Action taken concerning problems noted.
- b. The inspection and/or test status of items, services, and processes requiring examination must be clearly and plainly identified to ensure that only those with acceptable inspection and test results are used. The process provides for review and reinspection or retesting of items whose parameters have changed.

## 2.3 ASSESSMENTS

### 2.3.1 MANAGEMENT ASSESSMENTS

#### 2.3.1.1 Introduction

Managers must assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

Management assessment is the process used by an organization to evaluate its own management processes and their implementation in an effort to identify good and noteworthy practices, uncover issues, identify corrective actions, and ensure that the work being performed is satisfactory and in accordance with Argonne requirements, the regulatory environment, and the mission. Each division must implement a management assessment process in accordance with *QAPM* Section 3.1, "Management Assessments."

#### 2.3.1.2 Assessment Results

Results from assessments must be evaluated for reportability under the Price-Anderson Amendments Act (PAAA) and/or the Occurrence Reporting and Processing System (ORPS) programs (*ESH Manual* Sections 1.2 and 1.7, respectively). Issues that are identified as a result of management assessments require a corrective action plan, disposition, follow-up, and verification and validation. Improvement opportunities require disposition, and where appropriate, corrective action. Corrective actions must be recorded and tracked to closure in accordance with the corrective action procedure, *QAPM* Section 1.2, "Corrective Actions Development," and *QAPM* Section 1.3, "iCatch."

## Quality Assurance Requirements and Description

### Chapter 2 QUALITY PROGRAM ELEMENTS

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### 2.3.1.3 Determining the Adequacy of the Management Assessment Program

EQO must monitor the adequacy of the management assessments and the progress of corrective actions through triennial evaluations. The ALDs and ESH/QA representatives must monitor the progress of actions in their ALDships on a periodic basis and ensure that the actions are finalized with appropriate objective evidence.

#### 2.3.2 INDEPENDENT ASSESSMENTS

##### 2.3.2.1 Introduction

- a. Independent assessments must be conducted by qualified individuals that are not directly involved in the work being assessed. Independent assessments also include assessments conducted by outside agencies, (e.g., DOE-ASO, DOE HQ, IEPA, or other customers, etc.).
- b. Institutionally, the group performing independent assessments is coordinated by the EQO Assessments Program manager. DD/DHs may sponsor independent assessments in their areas outside the EQO process. Personnel performing independent assessments must be given sufficient authority and freedom to carry out the activities necessary to conduct the assessments effectively. The *QAPM* Section 3.2, "Independent Assessments," defines the minimum requirements and responsibilities for conduct of independent assessments.
- c. DOE and other external assessments are conducted at Argonne to provide objective oversight by outside organizations. Section 2.3.2.4 identifies the support of those assessments.

##### 2.3.2.2 Assessment Results

Documented assessment results must be presented to the organization that was assessed and provided to the appropriate levels of management for review. Issues that are identified as a result of independent assessments require a corrective action plan, disposition, follow-up, and verification and validation. Improvement opportunities require disposition, and where appropriate, corrective action taken. Corrective actions must be recorded and tracked to closure in accordance with the corrective action procedure, *QAPM* Section 1.2, "Corrective Actions Development."

## Quality Assurance Requirements and Description

### Chapter 2      QUALITY PROGRAM ELEMENTS

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

#### **2.3.2.3 Follow-Up Action**

The EQO Assessments Program manager must take follow-up action to verify that corrective actions are identified and accomplished as necessary to address weaknesses discovered that have Argonne-wide implications.

#### **2.3.2.4 Support of DOE and Other External Assessments**

Argonne must provide accommodations (i.e., access, administrative support, facility space) for DOE and other external assessment teams.

Findings and report response actions for DOE assessments will be in accordance with the Contractor Requirements Document (CRD) of DOE O 470.2B, "Independent Oversight and Performance Assurance Program."

Findings and report response actions for other external assessment teams (i.e., IEPA, sponsor audits) will be discussed and agreed on between the external assessment team and the assessed organization.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.1 Definitions

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

### APPENDIX 3.1 DEFINITIONS

**as-built drawings** - drawings that are maintained to show the current configuration of the vital structures, systems, and components (VSSC). These drawing do not have to show the measured data for tolerance dimensions; however, they should identify all known deviations from the original approved drawings and show all modifications.

**assessment** - an appraisal of any type (review, evaluation, inspection, test, check, surveillance, or audit) to determine and document whether items, processes, systems, or services meet specific requirements and are performing effectively.

**certification** - the process by which Argonne facility management provides written endorsement of the satisfactory achievement of qualification of a person for a position.

**design authority** - the organization responsible for establishing the design requirements and ensuring that design output documents appropriately and accurately reflect the design basis. The design authority is responsible for design control and ultimate technical adequacy of the design process. These responsibilities are applicable whether the process is conducted fully in-house, partially contracted to outside organizations, or fully contracted to outside organizations.

**design change** - any modification that will alter a structure, system, or component function, method of performing the function, or design configuration.

**design control** - activities have the level of detail necessary to permit the design process to be carried out in a correct and organized manner, and to permit verification that the design meets the requirements.

**design input requirements** - a technically correct and complete collection of all the requirements resulting from contractual requirements and customer expectations.

**design request** - a formal written agreement between the facility manger and the design authority providing the design input and constraint requirements for any new or modified system, structure, or component.

**design review** - a systematic review of project design to ensure that it is meeting the requirements of the objective.

**document control** - the process by which information is prepared, reviewed, and approved in accordance with established procedures, has controlled distribution, and is subject to revision and voidance control.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.1 Definitions

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

**engineering order (EO)** - a document used to request services from the document control center for such activities as assigning project identifiers or drawing numbers, executing document changes or revisions, distributing documents, etc.

**facility** - land, buildings, and other structures, their functional systems and equipment, and other fixed systems and equipment installed therein, including site development features outside the plant, such as landscaping, roads, walks, and parking areas; outside lighting and communication systems; central utility plants; utilities supply and distribution systems; and other physical features.

**graded approach** - the process of ensuring that the level of analysis, documentation, and actions used to comply with requirements is commensurate with the hazard level of the activity.

**hazard** - a source of danger (i.e., material, energy source, or operation) with the potential to cause illness, injury, or death to a person or damage to a facility or to the environment (without regard to the likelihood or credibility of accident scenarios or consequence mitigation).

**hazard analysis** - a documented process to systematically identify the hazards of a given operation; describe and analyze the adequacy of measures taken to eliminate, control, or mitigate the hazards and risks of normal operation; and identify and analyze potential accidents and their associated risks.

**intercontractor procurement (ICP)** - a subcontract-level purchase transaction between two or more DOE management and operating contractors or site integrating contractors.

**issue** - generic term including, but not limited to, an identified problem, deficiency, finding, concern, nonconformance, alert, regulatory or contractual noncompliance, or other condition that requires: 1) evaluation by management; and 2) corrective action.

**item** - an all-inclusive term used in place of appurtenance, assembly, component, equipment, material, module, part, structure, product, software, subassembly, subsystem, system, unit, or support systems.

**Job and Hazard Questionnaire (JHQ)** - is a document used to identify the hazards an employee encounters on the job. JHQ responses are used to determine and assign environment, safety, health, and quality assurance training requirements related to an individual by identifying their responsibilities and potential for hazard exposure. In addition, the JHQ provides information that assists with such functions as medical evaluations and surveillance, exposure monitoring, hazard assessment, and certifications. The JHQ is a dynamic document that is updated as appropriate to ensure compliance with changing policies and regulations.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.1 Definitions

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

**line management** - the chain of authority and responsibility in any branch of the Argonne organizational structure, originating with the Laboratory director and linked to associate Laboratory directors and division directors, facility/project managers, first-line supervisors, and employees.

**management assessment** - process used by an organization to evaluate its own management processes.

**qualification** - the completion of the training requirements that have been established for a specific job, including written and oral examinations and operational evaluations.

**quality** - the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

**quality assurance** - all the planned and systematic activities implemented within a system that can be demonstrated to provide confidence a product or service will fulfill requirements for quality.

**record** - documented information received, created, or maintained by an Argonne organization or an Argonne employee in the transaction of business, research, or the conduct of affairs at Argonne, regardless of its medium (paper, digital, tape, film, etc.).

**safety class (SC) structures, systems, or components (SSC)** - structures, systems, and components including primary environmental monitors and portions of process systems, whose failure could adversely affect the environment, or safety and health of the public as identified by safety analyses.

**safety-significant (SS) structures, systems, or components (SSC)** - structures, systems, or components not designated as safety-class but whose preventive or mitigative function is a major contributor to defense-in-depth (i.e., prevention of uncontrolled material releases) and/or worker safety as determined from hazard analysis.

**safety software** - includes safety system software, safety and hazard analysis software, and design software and safety management and administrative controls software (source DOE O 414.1C).

**safety structures, systems, or components (SSC)** - the set of structures, systems, and components that includes both safety class and safety significant.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.1 Definitions

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

**software quality assurance (SQA)** - a planned and systematic pattern of all actions necessary to provide adequate confidence that an item or product conforms to established technical requirements.

**subject matter expert (SME)** - an individual recognized as knowledgeable about the professional standards, requirements, and practices used within the discipline he/she represents.

**supplement** - a document that provides additional data, information, or other requirements to augment an institutional procedure in the *QAPM*.

**supplier** - a term used to refer to any vendor, contractor, firm, offeror, bidder, individual, or a legal entity doing business with the Laboratory.

**suspect/counterfeit items (S/CI)** as defined by DOE -

- A suspect item is one in which visual inspection, testing, or other means indicate that it may not conform to established government or industry-accepted specifications or national consensus standards; or one whose documentation, appearance, performance, material, or other characteristics may have been misrepresented by the supplier or manufacturer.
- A counterfeit item is a suspect item that has been copied or substituted without legal right or authority to do so or one whose material, performance, or characteristics are misrepresented by the supplier or manufacturer. An item that does not conform to established requirements is not normally considered an S/CI if the nonconformity results from one or more of the following conditions, which are controlled by site procedures as nonconforming items:
  - Defects resulting from inadequate design or production quality control;
  - Damage during shipping, handling, or storage;
  - Improper installation;
  - Deterioration during service;
  - Degradation during removal;
  - Failure resulting from aging or misapplication; or

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.1 Definitions

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

- Other controllable causes.

**training management system (TMS)** - the mechanism to acquire, process, store, retrieve, and analyze data for the Laboratory's training programs to document both compliance and accomplishments.

**validation (for design)** - design and development validation is to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use, where known.

**verification (for design)** - the act of reviewing the results of one of the following or a combination of the following activities: monitoring, testing, checking, and auditing is used to ensure that the results meet the requirements of a specification, standards, and codes that are associated with a project and/or quality program.

**work** - a defined task or activity such as research and development; operations; environmental remediation; maintenance and repair; administration; safety software development, validation, testing, and use; inspection; safeguards and security; or data collection and analysis.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.2 Acronyms

Last revised: August 1, 2007

Last reviewed: August 1, 2007

### APPENDIX 3.2 ACRONYMS

<b>AHJ</b>	authority having jurisdiction
<b>ALD</b>	associate Laboratory director
<b>AMOS</b>	Argonne Materials Ordering System
<b>CASD</b>	<i>Contractor Assurance System Description</i>
<b>CEO</b>	chief executive officer
<b>CFR</b>	Code of Federal Regulations
<b>CMP</b>	<i>Configuration Management Program</i>
<b>CRD</b>	contractor requirements document
<b>DA</b>	design authority
<b>DD/DH</b>	division directors/department heads
<b>DOE</b>	Department of Energy
<b>DOE HQ</b>	Department of Energy, Headquarters
<b>DOE-ASO</b>	Department of Energy-Argonne Site Office
<b>DSA</b>	documented safety analysis
<b>EO</b>	engineering order
<b>EQO</b>	Environment, Safety, Health/Quality Assurance Oversight
<b>EQO-OCC</b>	Oversight Coordinating Committee
<b>EQO-QA</b>	EQO-Quality Assurance
<b>ESH/QA</b>	Environment, Safety and Health/Quality Assurance
<b>HC</b>	hazard category
<b>HR</b>	Human Resources Division
<b>iCATCH</b>	Issues, Corrective Action Tracking, and Commitment Handling
<b>IEPA</b>	Illinois Environmental Protection Agency
<b>ISMS</b>	Integrated Safety Management System
<b>JHQ</b>	Job Hazard Questionnaire
<b>M&amp;TE</b>	measuring and test equipment
<b>NCR</b>	nonconformance report
<b>OJT</b>	on-the-job training
<b>ORPS</b>	Occurrence Reporting and Processing System
<b>PAAA</b>	Price Anderson Amendments Act
<b>PARIS</b>	Procurement and Requisition Integrated System
<b>PD</b>	position description
<b>POM</b>	<i>Procurement Operations Manual</i>
<b>QA</b>	quality assurance
<b>QAPM</b>	<i>Quality Assurance Procedures Manual</i>
<b>QAR</b>	quality assurance representative
<b>QARD</b>	<i>Quality Assurance Requirements and Description</i>
<b>QM</b>	quality management system

**Quality Assurance Requirements and Description****Chapter 3 APPENDICES****Appendix 3.2 Acronyms**

---

*Last revised: August 1, 2007**Last reviewed: August 1, 2007*

---

<b>R&amp;D</b>	research and development
<b>S/CI</b>	suspect/counterfeit items
<b>SQA</b>	software quality assurance
<b>SSC</b>	structures, systems or components
<b>SSQA</b>	safety software quality assurance
<b>SS-SSC</b>	safety significant structure, system, or component
<b>SC-SSC</b>	safety class structure, system, or component
<b>TMS</b>	Training Management System
<b>TSR</b>	technical safety requirements
<b>USQ</b>	unreviewed safety question
<b>VSSC</b>	vital structures, systems, and components

**Quality Assurance Requirements and Description****Chapter 3 APPENDICES****Appendix 3.3 References**

---

*Last revised: August 1, 2007**Last reviewed: August 1, 2007*

---

**APPENDIX 3.3 REFERENCES**

Prime Contract DE-AC02-06CH11357

10 CFR 830, Subpart A, "Quality Assurance Requirements"

10 CFR 851, "Worker Safety and Health Program"

ANSI/ASQ Z1.13, "Quality Guidelines for Research"

ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications"

DOE G 414.1-2A, "Quality Assurance Management System Guide for Use with 10 CFR 830 Subpart A, Quality Assurance Requirements, and DOE O 414.1C, Quality Assurance"

DOE G 414.1-4, "Safety Software Guide"

DOE N 203.1, "Software Quality Assurance"

DOE O 226.1, "Implementation of DOE Oversight Policy"

DOE O 231.1A, "Occurrence Reporting and Processing System"

DOE O 414.1C, "Quality Assurance"

DOE O 470.2B, "Independent Oversight and Performance Assurance Program"

DOE O 5480.23, "Nuclear Safety Analysis Reports"

DOE Order 420.1B, "Facility Safety"

DOE P-450-4, "Management System Policy"

DOE/RW-0333P, "Quality Assurance Requirements and Description from the Office of Civilian Radioactive Waste Management"

DOE-STD-1027-92, "Hazard Categorization and Accident Analysis Techniques for Compliance with DOE O 5480.23, Nuclear Safety Analysis Reports"

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.3 References

---

*Last revised: August 1, 2007*

*Last reviewed: August 1, 2007*

---

DOE-STD-1073-2003, "Configuration Management"

Price Anderson Amendments Act (PAAA)

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### APPENDIX 3.4 REQUIREMENT BASIS TABLE (MUST, SHALL AND WILL STATEMENTS)

##### Forward, Introduction, Section 1.1 Purpose and Scope, and 1.2 Graded Approach

Section	Basis	Citation
Intro	For substantive changes, "comments will be solicited from representatives from each ALDship"	Argonne <i>Policy Manual</i> Chapter 2, Section 2.2.
Intro	Submit a QAP to DOE for approval before beginning work under a DOE contract. . . Submit QAP changes made the previous year annually to DOE for review and approval. In the submittal, identify the changes, the reason for the changes, and the basis for concluding that the revised QAP continues to satisfy the requirements of this CRD.	DOE 414.1C CRD 2b. and 10 CFR 830.121
1.1.2	"Compliance with the <i>QARD</i> is mandatory for Argonne organizations. Additional requirements imposed on those Argonne activities that support a customer with QA requirements must be implemented."	Argonne management decision
1.2.1	Multiple DOE directives and guides provide for using a graded approach.	DOE 414.1C CRD 2a1 10 CFR 830.7.
1.2.2	The graded approach process <u>must not</u> be used to "grade to zero."	DOE G 414.1-2A Sect 4.1.3

#### QA CRITERIA SECTIONS

##### Section 2.1.1 Program

Section	Basis	Citation
2.1.1	"Applies additional standards, where practicable and consistent with contractual or regulatory requirements and as necessary to address unique/specific work activities..."	DOE 414.1C CRD 2 a(3)
2.1.1	<u>Quality Guidance Usage</u> . The contractor must consider QA guidance in developing and implementing a QAP.	DOE 414.1C CRD 2c
2.1.1	If divisions must follow requirements in addition to those established in the <i>Quality Assurance Procedures Manual (QAPM)</i> , the division must write a supplement(s).	Argonne management choice to fulfill overall requirements of DOE Rule for QA program.
2.1.1.3c	Each ALD must appoint an ESH/QA representative.	<i>ESH Manual</i> Section 1.1.3
2.1.1.3e	Each division director must appoint one or more quality assurance representatives (QAR).	<i>ESH Manual</i> Section 1.1.3 and appendix A.
2.1.1.3g	Employees must inform their immediate supervisors of any conditions that are noncompliant with Argonne policies and requirements.	<i>ESH Manual</i> Section 1.16
2.1.1.3g	"Employees must report environment, safety, and health noncompliances and/or technical concerns to their immediate manager/supervisor."	HR Procedure 1300.2

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.1.1.3g	"Employees with concerns regarding their or another employee's failure to observe the requirements of this Statement are expected to report such concerns to their supervisors, division management, Human Resources (252-2960), the Legal Department (252-3040), or the ethics and compliance officer (ethicsofficer@anl.gov; 1-630-252-6376); or to the Argonne ethics and compliance line (1-877-587-2449); these calls may be made anonymously."	HR Policy 1050
----------	--	----------------

#### Section 2.1.2 Personnel Training and Qualifications

Section	Basis	Citation
2.1.2.1	Train and qualify personnel to be capable of performing their assigned work.	DOE 414.1C CRD 3b1 and 10 CFR 830.122 (b)(1) Criterion 2
2.1.2.1	Personnel shall possess the experience, knowledge, skills and abilities that are necessary to discharge their responsibilities.	DOE P 450.4 Component 2, Competence Commensurate with Responsibilities.
2.1.2.1b.2	Contractors/subcontractors/service contractors who are not escorted at all times must at a minimum attend Contractor Safety Orientation (CSO).	<i>ESH Manual</i> Sect. 1.5.3
2.1.2.1b.3	Training may be waived if the contractor will be in the presence of a qualified escort at all times.	<i>ESH Manual</i> Sect. 1.5.3
2.1.2.1c	Access is controlled with a combination of general laboratory orientation and the use of qualified escorts trained for the specific radiological areas.	<i>ESH Manual</i> Sect. 5.3.5
2.1.2.1	Similar requirement for laser controlled areas.	<i>ESH Manual</i> Sect. 6.2
2.1.2.1 2.1.2.2	The supervisor and the employee are jointly responsible to ensure that the JHQ is updated within 90 days of assignment to new duties. During this time the employee must work under the direct supervision of an employee who is trained and qualified in the new duties and control of their associated hazards.	<i>ESH Manual</i> Sect 1.5.6
2.1.2.2	Division directors and department heads have primary responsibility for ensuring that their employees and visitors to their facilities have the appropriate training to work properly, safely, and efficiently. Training will be implemented, as appropriate, including on-the-job training.  Managers/supervisors are responsible for knowing the training requirements of their employees.	HR Policy 5100.1 HR Procedure 5100.2
2.1.2.2	Final selection of a candidate must be based on credentials, interview feedback, applicable references, and overall suitability for the position.	HR Procedure 2200.2

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.1.2.2	(DD/DH) ensures that employees complete required environment, safety and health training, that JHQs are completed, reviewed, and updated, and that job-specific environment, safety and health training is provided for site-specific hazards.”	<i>ESH Manual</i> Section 1.5
2.1.2.3	For courses with an "ESH" prefix, course completion documentation, electronic and hard copy, is maintained by EQO-TR. Electronic completion data is stored on TMS. For courses with prefixes other than "ESH," hard copies of course completion data are maintained by the division that owns the training. Electronic documentation of the training is maintained on TMS and entered by the course keeper of the division that owns the training.	<i>ESH Manual</i> Section 1.5.7
2.1.2.4	Managers/supervisors are responsible for keeping the employee Job Hazard Questionnaire current as this drives both training and the level of medical evaluations being provided.	HR Policy 9100.1, "Fitness for Duty"
2.1.2.6	The Laboratory provides training that supports its strategic initiatives and it supports each employee in performing his/her job effectively and efficiently and in full compliance with existing regulations.	HR Policy 5100.1
2.1.2.6	Incorporate DOE and contractor lessons learned into operations, training, maintenance and work planning, work processes, and design and construction.	DOE O 210.2 CRD 2f.
2.1.2.6	Division directors and department heads have primary responsibility for ensuring that their employees and visitors to their facilities have the appropriate training to work properly, safely, and efficiently.	HR Policy 5100.1
2.1.2.6	The supervisor and the employee are jointly responsible to ensure that the JHQ is updated within 90 days of assignment to new duties.	<i>ESH Manual</i> 1.5.6

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### Section 2.1.4 Controlling Documents and Records

Section	Basis	Citation
2.1.4.1a	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	DOE 414.1C CRD 3 d(1)  10 CFR 830.122 (d)(1) Criterion 4
2.1.4.1a	The contractor must have a formal policy that endorses the use of configuration management and defines key roles and responsibilities.	DOE STD 1073-2003,
2.1.4.1a	A configuration management process must be established that controls changes to the physical configuration of project facilities, structures, systems, and components.	DOE O 413.3A, CRD 9
2.1.4.1d	Integrates, where practicable and consistent with contract or regulatory requirements, quality management system requirements as defined in this CRD, the S/CI prevention process (Paragraph 4) and Safety Software Quality Requirements (Paragraph 5) with other quality or management system requirements in DOE directives and external requirements ...	DOE O 414.1C CRD 2.a.(4)
2.1.4.2	(1) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (2) Specify, prepare, review, approve, and maintain records.	DOE O 414.1C CRD 3.d(1)  10 CFR 830.122 (d)(1) Criterion 4

#### Section 2.2.1 Work Processes

Section	Basis	Citation
2.2.1.3a	Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.	DOE 414.1C CRD 3.e(1)
2.2.1.3a	Evaluate and select prospective suppliers on the basis of specified criteria.	DOE 414.1C CRD 3.g(2)
2.2.1.3a	Inspect and test specified items, services, and processes using established acceptance and performance criteria.	DOE 414.1C CRD 3.h(1)
2.2.1.4a	Identify and control items to ensure proper use. . . Maintain items to prevent damage, loss, or deterioration.	DOE 414.1C CRD 3 e. (2.) & (3.)
2.2.1.5a	Calibrate and maintain equipment used for inspections and tests.	DOE 414.1C CRD 3.h. (2.)

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.1.5a	Measuring and test equipment (M&TE) used for inspections, tests, monitoring, and data collection should be calibrated, maintained, and controlled using a documented process. M&TE should be checked before use to ensure that it is of the proper type, range, accuracy, and precision and that it is uniquely identified and traceable to its calibration data. Procedures should be established for testing, retesting, adjusting, and recalibrating M&TE.	DOE G 414.1-2A Section 4.8.5
2.2.1.5b	M&TE should be calibrated to standards traceable to the National Institute of Standards and Technology or other nationally recognized standards when appropriate. Procedures should be established for testing, retesting, adjusting, and recalibrating M&TE.	DOE G 414.1-2A Section 4.8.5
2.2.1.5c	Management/Criterion 5-Work Processes Calibrate and Identify and control items to ensure proper use. Maintain equipment used for process monitoring or data collection.	DOE O 414.1C CRD 3.e. (2) & (4) & and 10 CFR 830.122(e)(2) & (4)
2.2.1.5d	The use of each item of M&TE should be traceable and associated with the item of M&TE. This is because measurements and tests performed with the M&TE may need to be reevaluated if the item of M&TE is subsequently found to be out of its acceptable calibration range.	DOE G 414.1-2A Section 4.8.5

#### Section 2.2.2 Software Quality Assurance

Section	Basis	Citation
2.2.2.1	. . . all software owned or maintained by DOE, as referenced in paragraph 3c, Applicability, is subject to formal quality assurance. . .	DOE N 203.1, and DOE O 414.1C
2.2.2.2a	The contractor must ensure the adequacy of training programs to meet current and future personnel skill needs in the areas of SQA, software engineering, and software user training.	DOE N 203.1 CRD 8
2.2.2.2b	The contractor must ensure the integration of the SQA program planning process with DOE strategic planning, Safety Management System, and budget process, as appropriate, to ensure that SQA program decisions are made, adequately funded, and executed to support DOE organizational and site missions and priorities.	DOE N 203.1 CRD 9
2.2.2.2d	The contractor must conduct systematic reviews to ensure that the requirements of this directive and DOE O 414.1A, "Quality Assurance," are met and determine the need to update its own SQA program. Relative to software, these reviews should also ensure that appropriate safety and security controls are in place, are effective, and reflect currently accepted industry practices.	DOE N 203.1 CRD 7
2.2.2.3a	The contractor must develop, document, and implement an SQA program for projects.	DOE N 203.1 CRD 3, 5, and 6.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.2.3a	The expectation is that this documentation will be completed at the division or organizational level matching the type and importance of each organizational unit's software applications.	Management approach to allow tailoring of implementation to be commensurate with the division software applications.
2.2.2.3a	Each SQA program will consist of an identified focal point of contact, defined authorities, policies, procedures, training, adopted standards, and conventions tailored to local needs. Each program will treat SQA initiatives appropriately, commensurate with their size, complexity, cost, degree of external impact, degree of customization, functions performed, and other factors important to the site's management.	DOE N 203.1 CRD 3
2.2.2.3a	Each SQA program will consist of an identified focal point of contact, defined authorities, policies, procedures, training, adopted standards, and conventions tailored to local needs	DOE N 203.1 CRD 3
2.2.2.3b	The contractor must ensure the SQA processes and procedures are software product and project lifecycle based; documented to provide a baseline for auditing; and applied in a consistent, repeatable, and predictable manner. The contractor must ensure the adequacy of selected processes and practices, as well as their oversight.	DOE N 203.1 CRD 5
2.2.2.3c	The contractor must develop project SQA plans and address testing (e.g., unit, integration, system, acceptance), verification and validation, structured walkthroughs, peer reviews, inspections, audits and any other requirements specified for an application (e.g., by contract).	DOE N 203.1 CRD 6
2.2.2.3c	The contractor must develop project SQA plans and address testing (e.g., unit, integration, system, acceptance), verification and validation, structured walkthroughs, peer reviews, inspections, audits and any other requirements specified for an application (e.g., by contract).	DOE N 203.1 CRD 6
2.2.2.3d	The contractor must ensure that each plan is commensurate with the level of the size, complexity and scope of the software project.	DOE N 203.1 CRD 6
2.2.2.4	These requirements are necessary to ensure that DOE/NNSA safety software in nuclear facilities performs its intended specific functions in relation to structures, systems, or components (SSCs) and that the classification, design, and analysis associated with nuclear facility operations is correct.”  Work processes involving safety software must be developed and implemented using national or international consensus standards.	DOE O 414.1C CRD 5

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### Section 2.2.3 Design

Section	Basis	Citation
2.2.3.1a.	Every project must have a designated project manager who is directly involved, is accountable for overall project control, and ensures successful completion of project objectives.	Argonne <i>Policy Manual</i> Section 4.1.3
2.2.3.1a.	Evaluate and select prospective suppliers on the basis of specified criteria.	DOE O 414.1C CRD 3.g.(2.)
2.2.3.1c.	"Appropriate standards include the following...ANSI/ASQ Z1.13, 1999, <i>Quality Guidelines for Research, (for nonnuclear research activities).</i> "	DOE O 414.1C CRD 2.a.(2.)
2.2.3.3.1	Incorporate applicable requirements and design basis in design work and design changes.	DOE O 414.1C CRD 3.f.(2.) and 10 CFR 830.122(f)(2.) Criterion 6
2.2.3.3.1	Design inputs should be based upon contractual requirements and customer expectations and should be technically correct and complete.	DOE G 414.1-2A Section 4.6.2
2.2.3.3.1	These inputs shall be reviewed for adequacy. Requirements shall be complete, unambiguous, and not in conflict with each other.	ANSI/ISO/ASQ Q9001 Section 7.3.2
2.2.3.3.1	Consideration for schedule, cost, and rigor of quality must be accommodated in the conceptual design phase.	Restatement of "graded approach" to provide balance between constraints and needs.
2.2.3.3.2	Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.	DOE O 414.1C CRD 3.f.(4) and 10 CFR 830.122(f)(4) Criterion 6
2.2.3.3.3a	The PM must conduct the design review meeting. . . Whenever possible, action items must be resolved during the design review meeting. When this is not feasible, the project manager must assign the responsibility and schedule follow-up action. . . He must also verify that the previous design review commitments have been adequately addressed.	Manual of Construction Section 3.5.3 (retired); good practice
2.2.3.3.3b	Design changes, including field changes and nonconforming items dispositioned for "use-as-is" or "repair," should be controlled by measures commensurate with those applied to the original design.	DOE G 414.1-2A Section 4.6.6.
2.2.3.3.5a	The procurement process should be planned and controlled ...	DOE G 414.1-2A Section 4.7.1
2.2.3.3.5b	Documents and Records. (a.) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. (b.) Specify, prepare, review, approve, and maintain records.	DOE O 414.1C CRD Criterion 4, 4.b.(4.) and 10 CFR 830.122(d.)
2.2.3.3.5b	Supplier-generated documents should be accepted through the procurement system and controlled and processed by the end-user organization.	DOE G 414.1-2A Section 4.7.6

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.3.3.5c 2.2.3.3.5d	When using other than procured items, such as salvage, or customer provided materials, the design authority must be responsible for ensuring the quality of the product.	Responsibility assignment is same as for acquiring items, SSC, or services from conventional vendors and suppliers.
2.2.3.3.6b	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	DOE O 414.1C CRD 3.d. and 10 CFR 830.122(d.) Management/Criterion 4
2.2.3.3.6b	Establish and implement processes to detect and prevent quality problems" and "Identify, control and correct items, services, and processes hat do not meet established requirements.	DOE O 414.1C CRD 3.c.(1.) and (2.) and 10 CFR 830.122(c.), Criterion 3
2.2.3.3.6b	Establish and implement processes to detect and prevent quality problems" and "Identify, control and correct items, services, and processes that do not meet established requirements.	DOE O 414.1C CRD 3.c. (1.) and (2.) and 10 CFR 830.122(c.), Criterion 3
2.2.3.3.6b	<i>design, final</i> ; approved design output documents and approved changes thereto." and " <i>nonconformance</i> ; a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate.	ASME NQA-1 Part I Introduction Section 400
2.2.3.3.6c	Supplier-generated documents should be accepted through the procurement system and controlled and processed by the end-user organization.	See 2.2.3.3.5 b. DOE G 414.1-2A Section 4.7.6
2.2.3.3.7	Section 4.8.1 Inspections and test are accomplished to verify that physical and functional aspects of items, services and processes meet requirements and are acceptable for use.	DOE G 414.1-2A Section 4.8.1
2.2.3.3.8a	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	DOE O 414.1C CRD 3.d. and 10 CFR 830.122(d.) Criterion 4
2.2.3.3.8a	Design changes, including field changes and nonconforming items dispositioned for "use-as-is" or "repair," should be controlled by measures commensurate with those applied to the original design.	DOE G 414.1-2A Section 4.6.6
2.2.3.3.8c	Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	DOE O 414.1C CRD 3.d.and 10 CFR 830.122(d.) Criterion 4
2.2.3.3.8c	Design changes, including field changes and nonconforming items dispositioned for "use-as-is" or "repair," should be controlled by measures commensurate with those applied to the original design.	DOE G 414.1-2A Section 4.6.6
2.2.3.4a	The contractor responsible for a hazard category1, 2, or 3 nuclear facility must establish and maintain the safety basis for the facility.	10 CFR 830.202(a.)

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.3.4a	"Prepare a preliminary documented safety analysis for the facility and ... (b.) Obtain DOE approval of .... (2) The preliminary documented safety analysis before the contractor can procure materials or components or begin construction...."	10 CFR 830.206(a.)
2.2.3.4a	The SER is the document that DOE uses to document their independent review and conclusions on a contractor submitted safety basis.  The USQ process provides same level of control for modifications to an existing nuclear facility.	10 CFR 830.207
2.2.3.4 a.	Exemption from the requirements of 5480.23 does not excuse contractors from doing analysis, where applicable, to evaluate potential significant radiation exposures to workers."	DOE O 5480.23
2.2.3.4 a.	DOE facilities and operations must be analyzed to ensure that structures, systems, and components (SSCs) and personnel will be able to perform their intended safety functions effectively under the effects of NPH.	DOE G 420.1
2.2.3.4 a.	The following items are required of the contractor organization, 1. Safety Assessment Document (SAD).	DOE O 420.2B, Safety of Accelerator Facilities
2.2.3.4 c.	Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.	DOE O 414.1C CRD 3f.(4.) and 10 CFR 830.122(f).(4.) Criterion 6

#### Section 2.2.4 Procurement

Section	Basis	Citation
2.2.4.1c	"The QAP must: ... (4.) Describe how the contractor responsible for the nuclear facility ensures that subcontractors and suppliers satisfy the criteria of paragraph 830.122.	10 CFR 830.121(c.)
2.2.4.1d	"Procure items and services that meet established requirements and perform as specified," "Identify and control items to ensure proper use," and "Maintain items to prevent damage, loss, or deterioration."	DOE O 414.1C CRD 4.b.(7)(a.) and (5)(b. & C.) and 10CFR 830 Criterion 7 and Criterion 5
2.2.4.2 a.	Argonne procurement documents must clearly state or reference requirements and acceptance criteria for purchased items and services as described in the Procurement Operations Manual (POM).	<i>Procurement Operations Manual (POM) Section 2.5</i>
2.2.4.2 b.	Procurement documents should clearly state or reference requirements and acceptance criteria for purchased items and services.	DOE G 414.1-2A, 4.7.2
2.2.4.2 c.	(1.) Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.	DOE O 414.1C CRD 3 d and 10CFR 830.122 (d.) Criterion 4

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.4.3 a.	"Evaluate and select prospective suppliers on the basis of specified criteria." and "Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services."	DOE O 414.1C CRD 3 g. (2) & (3) and 10 CFR 830.122(g)(2&3), Criterion 7
2.2.4.3 a.	The objective of evaluating suppliers is two-fold: 1.) to verify the supplier has implemented a quality assurance program that conforms to contract requirements; and 2.) to verify that the supplier is capable of providing the items or services identified in the contract. Prospective suppliers should be evaluated to verify their capability to meet performance and schedule requirements.	DOE G 414.1-2A, 4.7.3 Supplier Qualification
2.2.4.3 c.	Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.	DOE O 414.1C CRD 3.g (1) and 10 CFR 830.122(g)(1), Criterion 8
2.2.4.4 a.	Inspect and test specified items, services, and processes using established acceptance and performance criteria	DOE O 414.1C CRD 3.h (1.) and 10 CFR 830.122(h.) (1.) Criterion 8
2.2.4.4 a.	The procurement process should provide for identifying inspections and tests to ensure conformance with purchase requirements. Design and procurement documents should specify critical or important acceptance parameters for inspection.	DOE G 414.1-2A, 4.7.5 Inspection
2.2.4.4 c.	Identify, control and correct items, services, and processes that do not meet established requirements. Identify and control items to ensure proper use.	DOE O 414.1C CRD 3 c(2) and 10 CFR 830.122(c)(2) and e(2)
2.2.4.4 d.	Inspections should include verification that specified documentation has been provided by the supplier and that items were not damaged during shipment.	DOE G 414.1-2A, 4.7.5 Inspection
2.2.4.4 f.	For intercontractor procurements, quality requirements must be established and agreed to in writing with clear definition of responsibilities of each organization.	<i>Budget Manual</i> Section 2.1, Inter Entity Work Orders, provides detailed requirements.
2.2.4.5 a.	Quality assurance requirements must be coordinated with and approved by the division quality assurance representative (QAR).	<i>Procurement Operations Manual (POM)</i> Exhibit 2.1-A Matrix of Approvals for Purchase Requisitions
2.2.4.5 a.	A. Requisition Package The buyer/contract specialist shall assure that the following information has been provided, and shall coordinate correction of any deficiencies in the requisition package with the requisitioner, as appropriate: .... 2. The requisition is accompanied by a statement of work (SOW) or product description (PD) that is clear and unambiguous. The SOW or PD shall state the actual minimum needs of the Laboratory. ... 8. Quality assurance level has been identified and approved by the cognizant personnel.	Exhibit 3.2-A Presolicitation And Preaward Guidelines

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.4.5.d.	The purchase requisition review process must be periodically monitored by EQO and/or QARs to ensure that items and services are properly categorized and appropriate reviews and approvals are performed.	Management choice as a way to meet QA Criterion 9 and 10 for management and independent assessment
------------	---	--

#### Section 2.2.5 Inspection and Acceptance Testing

Section	Basis	Citation
2.2.5.1	The performance expectations, inspections, and tests must be identified and considered early in the design phase and specified in the design output and procurement documents.	DOE G 414.1-2A Section 4.8.1
2.2.5.2 a.	Inspection and testing requirements for items, services, and processes must be identified in design, procurement, facility, maintenance and operations documents.	DOE G 414.1-2A Section 4.8.2
2.2.5.2 b.	Inspections and tests must be performed and test results evaluated and verified by technically qualified individuals that have the authority to access appropriate information and facilities	DOE G 414.1-2A Section 4.8.2
2.2.5.2 b.	These qualified personnel should be independent of the activities being inspected/tested and have the freedom to report the results of the inspections/tests.	DOE G 414.1-2A Section 4.8.2
2.2.5.4 a.	Identify, control and correct items, services, and processes that do not meet established requirements.  ALSO e. (2.) Identify and control items to ensure proper use.  <b>Note:</b> DOE does not specify specific document formats for documenting quality problems, deficiencies, nonconformances etc. accept beyond the point where such things need to be reported as ORPs, NTS, etc.	DOE O 414.1C CRD 3 c. (2.) and 10 CFR 830.122(c.)(2.).
2.2.5.5 a.	"Calibrate and maintain equipment used for inspection and tests."	DOE O 414.1C CRD 3.h. (2.) and 10 CFR 830.122(h.) (2.) Criterion 8
2.2.5.5 a.	Measuring and test equipment (M&TE) used for inspections, tests, monitoring, and data collection should be calibrated, maintained, and controlled using a documented process.	DOE G 414.1-2A, 4.7.5 and 4.8.5
2.2.5.5 b.	M&TE must be calibrated at specified intervals and to standards traceable to the National Institute of Standards and Technology or other nationally or internationally recognized measurement standards when appropriate. Where no recognized standard exists, basis for calibration must be defined and documented.	DOE O 414.1C CRD 3.h (1.) and 10 CFR 830.122(h.) (1.) Criterion 8
2.2.5.5 c.	When M&TE or calibration standards are found to be out of tolerance, appropriate evaluations must be performed to assess any adverse impact on inspection, testing, or calibration performed using that equipment, standard, and appropriate notifications made.	DOE O 414.1C CRD 3.h (1.) and 10 CFR 830.122(h.) (1.) Criterion 8

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

2.2.5.6 a.	Inspection and test records should, at a minimum, identify— <ul style="list-style-type: none"> <li>• item tested,</li> <li>• date of test,</li> <li>• test method,</li> <li>• tester or data recorder,</li> <li>• observations,</li> <li>• action results and acceptability, and</li> <li>• action taken concerning problems noted.</li> </ul>	DOE G 414.1-2A, 4.7.5 Inspection and 4.8.4 Records
2.2.5.6 b.	As a result of the inspection/test process, the status of items, services, and processes requiring examination should be clearly and plainly denoted to ensure only those with acceptable inspection and test results are used.	DOE G 414.1-2A, 4.7.5 Inspection and 4.8.4 Records

#### Section 2.3.1 Management Assessments

Section	Basis	Citation
2.3.1.1	Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives	DOE O 414.1C CRD 3.i (1.) and 10 CFR 830.122(i) Criterion 9
2.3.1.2	PAAA reporting is a DOE expectation of the contractor to support DOE Office of Science enforcement responsibilities. It serves to minimize fines for deficiencies that are processed by DOE in accordance with 10 CFR 820 and 851.	Requirements are in <i>QAPM</i> , Section 1.2, Corrective Actions Development and Tracking, and <i>QAPM</i> , Section 1.3, iCATCH. DOE G 414.1-1A Section 5.7.8 provides detailed expectation for corrective action processes. <i>ESH Manual</i> Sections 1.2, 1.7, and 1.12 provide corresponding expectations.
2.3.1.3	EQO must monitor the adequacy of the management assessments and the progress of corrective actions through triennial evaluations. The ALD and ESH/QA representatives must monitor the progress of actions in their ALDships on a periodic basis and ensure that the actions are finalized with appropriate objective evidence.	Management choice. Requirement contained in <i>QAPM</i> Section 3.1.

## Quality Assurance Requirements and Description

### Chapter 3 APPENDICES

#### Appendix 3.4 Requirement Basis Table (Must, Shall and Will Statements)

Last revised: August 1, 2007

Last reviewed: August 1, 2007

#### Section 2.3.2 Independent Assessments

Section	Basis	Citation
2.3.2.1 a.	(2.) Establish sufficient authority and freedom from line management for independent assessment teams.  (3.) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.	DOE O 414.1C CRD 3.j. (2.) & (3.) and 10 CFR 830.122(j) (2.) & (3.) Criterion 9
2.3.2.1 b.	(2.) Establish sufficient authority and freedom from line management for independent assessment teams.	DOE O 414.1C CRD 3.j. (2.) and 10 CFR 830.122(j) (2.) Criterion 9
2.3.2.2	(1.) Plan and conduct independent assessments to measure item and service quality, to measure the adequacy of work performance and to promote improvement. (2.) Establish sufficient authority and freedom from line management for independent assessment teams. (3.) Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.	DOE O 414.1C CRD3.j. (1.) and 10 CFR 830.122(j) Criterion 9
2.3.2.2	Independent Assessment - Senior management should establish and implement a process to obtain an independent assessment of the organization's programs, projects, contractors, and suppliers.	DOE G 414.1-2A, Sect 4.10
2.3.2.2	"Identify, control and correct items, services and processes that do not meet established requirements" and "...identify and correct problems that hinder the organization from achieving its objective.	DOE O 414.1C CRD 3.c (2.) & 3.i and 10 CFR 830.122 (c.) 2 & (i).
2.3.2.3	The assessment program manager must take follow-up action to verify that corrective actions are identified and accomplished as necessary to address weaknesses discovered that have Argonne-wide implications.	QAPM Section 3.2
2.3.2.4	CRD lists detailed requirements for support, access, work space, actions required for imminent danger findings, factual accuracy reviews, a corrective action process and flow down to subcontractors performing security, emergency management and ES&H functions	DOE O 470.2B