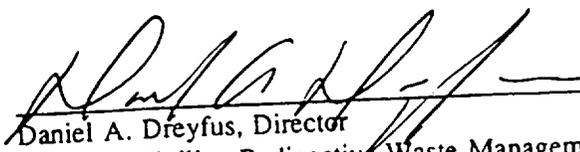


U.S. DEPARTMENT OF ENERGY  
OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT  
QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION  
FOR THE  
CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM



Donald G. Horton, Director  
OCRWM Office of Quality Assurance

7/11/94  
Date



Daniel A. Dreyfus, Director  
Office of Civilian Radioactive Waste Management

7/11/94  
Date

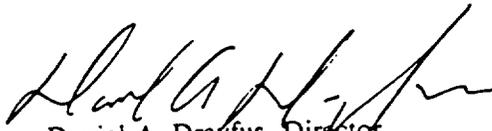
## Policy Statement

The U.S. Department of Energy (DOE) is authorized by the Nuclear Waste Policy Act, as amended, to site, construct, and safely operate a geologic repository and a monitored retrievable storage facility. The Act also instructs the DOE to provide for the safe transportation of spent fuel to either the MRS or the geologic repository and transportation of high level radioactive waste to the geologic repository.

The Act established the Office of Civilian Radioactive Waste Management (OCRWM) within the DOE to carry out this mission. Central to our mission is the protection of the health and safety of the public and workers, and the quality of the environment.

As the Director of OCRWM, I have established the quality assurance requirements necessary to ensure these vital protections. This document, the *Quality Assurance Requirements and Description*, embodies these requirements. These requirements apply to every level of every organization participating in this mission.

The quality assurance provisions described in the *Quality Assurance Requirements and Description* have my unqualified support. All organizations performing work for OCRWM will use and comply with the *Quality Assurance Requirements and Description* to develop and implement a quality assurance program.

  
Daniel A. Dreyfus, Director  
Office of Civilian Radioactive  
Waste Management

Date 7/11/94



# Office of Civilian Radioactive Waste Management

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### REVISION HISTORY

#### REVISION

#### REVISION DESCRIPTION

0

Initial issue. This document consolidates the *Quality Assurance Requirements Document* and the *Quality Assurance Program Description Document* into one document.

1

Revised Section 1.0. Organization. to reflect OCRWM reorganization.



# Office of Civilian Radioactive Waste Management

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# Office of Civilian Radioactive Waste Management

## *Quality Assurance Requirements and Description*

Title: ORGANIZATION

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### 1.1 GENERAL

This section establishes requirements for creating and maintaining an organizational structure to implement the Quality Assurance Program for the Civilian Radioactive Waste Management Program. This section also provides a description of the OCRWM organization and other affected organizations.

### 1.2 REQUIREMENTS

Each affected organization shall prepare controlled documents, accepted by the responsible organization with immediate authority over the affected organization (next-higher-level organization), that describe internal and external organizational interfaces, organizational structures, requirements, and responsibilities for its scope of work.

#### 1.2.1 Line Management

Each affected organization shall identify the responsibilities and authorities of those organizations and management positions responsible for achieving and maintaining quality.

#### 1.2.2 Quality Assurance Management

Each affected organization shall identify the management position within the organization responsible for performing quality assurance functions. This position shall be occupied by an individual with appropriate knowledge and experience in management and quality assurance. The position shall:

- A. Be at the same or higher organization level as the highest line manager directly responsible for performing work subject to QARD requirements.
- B. Be sufficiently independent from cost and schedule considerations.
- C. Have the organizational freedom to effectively communicate with other senior management positions.
- D. Be responsible for interpreting and approving quality assurance program requirements as they apply to the affected organization's scope of work.
- E. Have no other assigned responsibilities unrelated to the quality assurance program that would prevent full attention to quality assurance matters.
- F. Be responsible for identifying quality problems, initiating, recommending, or providing solutions to quality problems, and verifying solutions to quality problems.

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- G. Be responsible for verifying the proper establishment and execution of the quality assurance program.
- H. Have the authority to stop work when significant conditions adverse to quality warrant such action.

## 1.2.3 Responsibility for Quality

Quality shall be achieved and maintained by those who have been assigned responsibility for performing work. Quality achievement shall be verified by persons or organizations not directly responsible for performing the work.

## 1.2.4 Delegation of Work

Positions or organizations responsible for establishing and executing the quality assurance program may delegate work to other organizations. The positions or organizations making the delegation shall retain overall responsibility for the delegated work.

## 1.2.5 Resolution of Quality Disputes

Differences of opinion involving quality assurance program requirements shall be brought to the attention of the appropriate management and, if not resolved, shall be elevated progressively to successively higher levels of management.

## 1.3 DESCRIPTION

### 1.3.1 General Description of the Office of Civilian Radioactive Waste Management

- A. OCRWM is comprised of the Office of the Director; the Offices of Quality Assurance; Waste Acceptance, Storage and Transportation; Program Management and Integration; Human Resources and Administration; and the Yucca Mountain Site Characterization Office. The Yucca Mountain Site Characterization Office is headed by a Project Manager. The remaining offices are headed by Office Directors. The Project Manager and Office Directors report to the Director, OCRWM. The OCRWM organization is illustrated in Figure 1-1.
- B. OCRWM's functions are described in official mission and function statements, approved by the Assistant Secretary, Office of Human Resources and Administration.
  - 1. All references to OCRWM responsibilities and functions in the QARD are intended only as summarizations of those official functions and are in no way intended to replace or supplement the official statements.
  - 2. Any substantial OCRWM reorganization of descriptions or functions of the offices described herein, will require a revision to this document.

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### **1.3.2 Specific Civilian Radioactive Waste Management Offices**

#### **A. Office of the Director**

The Office of the Director has been delegated overall responsibility for carrying out the functions of the Secretary of Energy as prescribed in the Nuclear Waste Policy Act, as amended.

#### **B. Office of Quality Assurance (OQA)**

1. The OQA is responsible for providing guidance and direction to the line organization on quality assurance matters relating to OCRWM activities, developing the OCRWM quality assurance program and managing the quality concerns program. The OQA is also responsible for the overview of work subject to QARD requirements and environmental, safety and health activities. This overview includes the verification of the OCRWM line organization's achievement and quality of work through audits, surveillances, or other means of verification, as appropriate.
2. The OQA is responsible for reporting the overview findings to senior management.

#### **C. Office of Waste Acceptance, Storage and Transportation (OWAST)**

The OWAST is responsible for managing the standard contracts for disposal of spent nuclear fuel and/or high level radioactive waste; collection of data to support the acceptance and transportation of spent nuclear fuel from contract holders; studies to determine technical waste acceptance criteria; environmental assessments; Nuclear Regulatory Commission (NRC) license application for OCRWM operated storage facilities; cask design, testing, certification and acquisition; economic and engineering analysis for transportation system development; and transportation operations support, including cask maintenance. The OWAST is also responsible for developing and coordinating the implementation of safeguards and security for the OCRWM program.

#### **D. Office of Program Management and Integration (OPMI)**

The OPMI is responsible for program control and project management system policy, requirements, and guidance; the overall OCRWM program Work Breakdown Structure (WBS); development of overall OCRWM budgets; OCRWM systems engineering activities and technical baselines at the program level; configuration management system and OCRWM Change Control Boards; supporting the system elements/project in identifying and resolving site suitability and licensing regulatory issues related to the Monitored Retrievable Storage (MRS) facility or Mined Geologic Disposal System (MGDS) license application, and cask/canister certifications; integrating the MGDS with the multipurpose canister (MPC) and transportation elements of the OCRWM program; program wide system to provide reporting on commitments made by or to OCRWM, to or from the NRC.

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### E. Office of Human Resources and Administration (OHRA)

The OHRA is responsible for headquarters training program; verification of OCRWM personnel qualifications; program wide Total Quality Management (TQM) program; coordinating the OCRWM Ombudsman Program; OCRWM Information Systems; OCRWM Headquarters Records Management System, the Central Records Facility, and the Quality Records Center. In addition, the OHRA manages the procurement/business activities associated with the management and operating contract and all other OCRWM contracts program-wide and overseeing and administering the award fee process for the Management and Operating Contractor.

### F. Yucca Mountain Site Characterization Office (YMSCO)

The YMSCO is responsible for directing the Yucca Mountain Site Characterization Project (YMP); scientific evaluations needed to determine whether the Yucca Mountain candidate site is suitable for a geologic repository; waste-package and repository design and development; integrating the MGDS with the waste acceptance storage and transportation elements of the OCRWM program; MGDS Environmental Impact Statement (EIS); and the preparation and submittal to the NRC of a license application for the MGDS should the Yucca Mountain Site be found suitable. The YMSCO is also responsible for YMP information resources management and records management programs; YMP training program; and the YMP radiological program.

### 1.3.3 Other Affected Organizations

#### A. DOE Operations Offices

1. The Idaho and Oak Ridge Operations Offices are responsible for overall line management and implementation of assigned tasks. These Operations Offices establish a management organization and delegate responsibility and authority for management and direction of Program tasks. These Operations Offices have direct, primary responsibility and accountability for the execution and implementation of Program work; are points of contact for the flow of information to and from the Director, OCRWM and other affected organizations; and are responsible for complying with the QARD requirements.

a. The Idaho Operations Office provides support for waste transportation cask development.

b. The Oak Ridge Operations Office provides geoscience, shielding, systems integration, operations, and public relations support.

2. The other Operations Offices are contract holders through management agreements and have administrative responsibility only. Technical direction is performed by OCRWM. These Operations Offices are:

a. Richland Operations Office - The Richland Operations Office provides administrative support for the work performed by Pacific Northwest Laboratories (PNL);

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- b. Albuquerque Operations Office - The Albuquerque Operations Office provides administrative support for work performed by Los Alamos National Laboratory (LANL) and Sandia National Laboratories (SNL);
- c. Oakland Operations Office - The Oakland Operations Office provides administrative support for work performed by Lawrence Livermore National Laboratory (LLNL) and Lawrence Berkeley Laboratory (LBL).

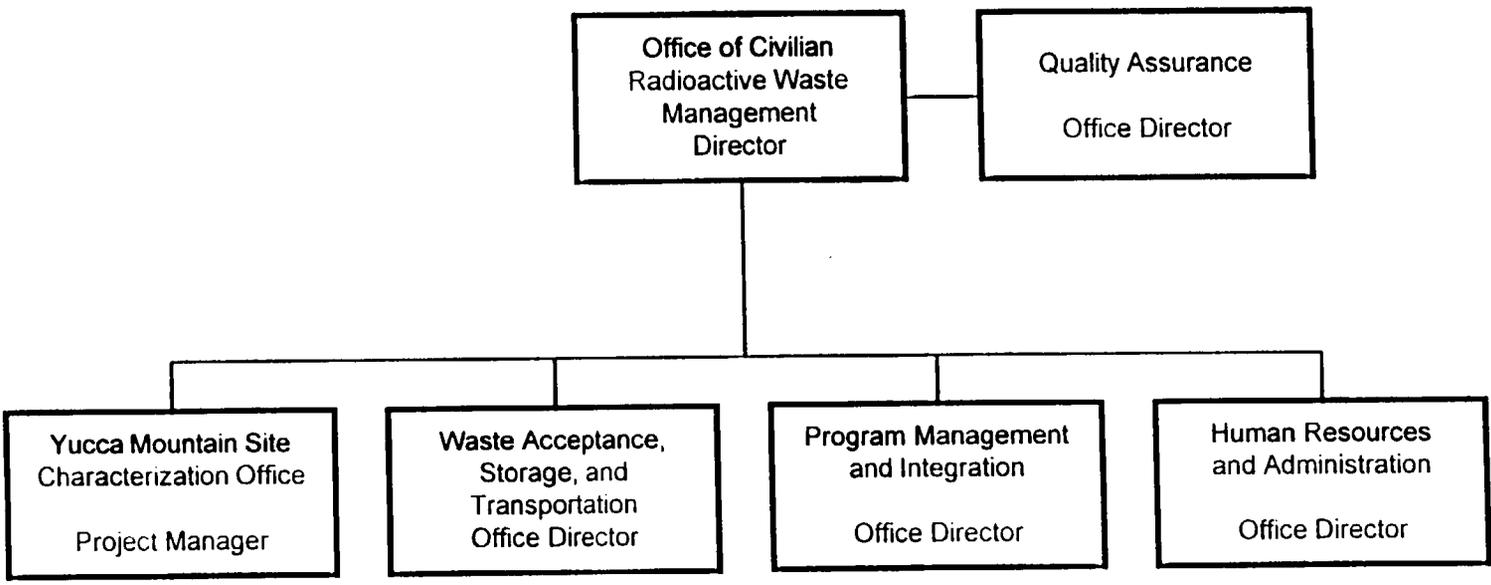
### B. OCRWM-Managed Affected Organizations

OCRWM-managed affected organizations perform work subject to QARD requirements in accordance with the controls established in their respective implementing documents. The QARD requirements for each OCRWM-managed affected organization are identified in the appropriate procurement documents. OCRWM provides an overview of affected organization work subject to QARD requirements by using appropriate verification methods.

### C. OCRWM Direct-Support Affected Organizations

OCRWM direct-support organizations perform work subject to QARD requirements in accordance with controls established in OCRWM implementing documents.

- D. For affected organizations performing work in accordance with Memoranda of Understanding (MOUs) or Memoranda of Agreement (MOAs) rather than in accordance with procurement documents, appropriate technical and Quality Assurance requirements shall be incorporated into the MOU or MOA.



OCRWMORG 136/6-27-94

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT

Figure 1 1

**U.S. DEPARTMENT OF ENERGY**

**OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT**

**QUALITY ASSURANCE REQUIREMENTS AND DESCRIPTION**

**FOR THE**

**CIVILIAN RADIOACTIVE WASTE MANAGEMENT PROGRAM**



Donald G. Horton, Director  
OCRWM Office of Quality Assurance

1/30/95  
Date



Daniel A. Dreyfus, Director  
Office of Civilian Radioactive Waste Management

2/3/95  
Date



# Office of Civilian Radioactive Waste Management

## *Quality Assurance Requirements and Description*

Title: REVISION HISTORY

Effective Date:

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### REVISION HISTORY

#### REVISION

#### REVISION DESCRIPTION

- |   |   |
|---|---|
| 0 | Initial issue. This document consolidates the <i>Quality Assurance Requirements Document</i> and the <i>Quality Assurance Program Description Document</i> into one document.       |
| 1 | Revised Section 1.0, Organization, to reflect OCRWM reorganization.   |
| 2 | Revised Section 7.0, Control of Purchased Items and Services, to accommodate the transfer of responsibility for the performance of audits from affected organizations to OCRWM OQA. |

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### 7.1 GENERAL

This section establishes requirements for planning and executing procurements to ensure that purchased items and services meet specified requirements. This section does not apply to direct-support services used for staff augmentation.

### 7.2 REQUIREMENTS

#### 7.2.1 Procurement Planning

Procurements shall be planned and documented to ensure a systematic approach to the procurement process. Procurement planning shall:

- A. Identify procurement methods and organizational responsibilities.
- B. Identify what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.
- C. Identify and document the sequence of actions and milestones needed to effectively complete the procurement.
- D. Provide for the integration of the following activities:
  1. Procurement document preparation, review, and change control according to the requirements of Section 4.0.
  2. Selection of procurement sources.
  3. Proposal/bid evaluation and award.
  4. Evaluation of supplier performance.
  5. Verifications including any hold and witness point notifications.
  6. Control of nonconformances.
  7. Corrective action.
  8. Acceptance of the item or service.
  9. Identification of quality assurance records.

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- E. Be accomplished as early as possible, and no later than at the start of those procurement activities which are required to be controlled.
- F. Be performed relative to the level of importance, complexity, and quantity of the item or service being procured and the supplier's quality performance.
- G. Include the involvement of the quality assurance organization.

## **7.2.2 Source Evaluation and Selection**

- A. Supplier selection shall be based on an evaluation, performed before the contract is awarded, of the supplier's capability to provide items or services in accordance with procurement document requirements.
- B. The organizational responsibilities for source evaluation and selection shall be identified and shall include the quality assurance organization. If a source evaluation board is established, then the quality assurance organization shall have a voting member.
- C. Measures for evaluating and selecting procurement sources shall include one or more of the following elements:
  - 1. Evaluation of the supplier's history for providing an identical or similar product which performs satisfactorily in actual use.
  - 2. Evaluation of supplier's current quality assurance records supported by any documented qualitative and quantitative information.
  - 3. Evaluation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and quality assurance program implementation.
- D. The results of procurement source evaluation and selection shall be documented.

## **7.2.3 Proposal/Bid Evaluation**

- A. The proposal/bid evaluation process shall include a determination of the extent of conformance to the procurement document requirements. This evaluation shall be performed by designated, technically qualified organizations including the quality assurance organization and shall include the following subjects consistent with the importance, complexity, and quantity of items or services being procured.
  - 1. Technical considerations.
  - 2. Quality assurance program requirements.
  - 3. Supplier personnel.

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4. Supplier production capability.
  5. Supplier past performance.
  6. Alternatives.
  7. Exceptions.
- B. Before the contract is awarded, the purchaser shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.
- C. Supplier quality assurance programs shall be evaluated either before or after contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to QARD requirements.
- D. Supplier quality assurance programs shall be accepted by the purchaser before the supplier starts work subject to QARD requirements.

### 7.2.4 Supplier Performance Evaluation

- A. The purchaser of items and services shall establish measures to interface with the supplier and to verify supplier's performance. The measures shall include:
1. Establishing an understanding between the purchaser and supplier of the requirements and specifications identified in the procurement documents.
  2. Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.
  3. Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements.
  4. Identifying and processing necessary change information.
  5. Establishing the method to be used to document information exchanges between purchaser and supplier.
  6. Establishing the extent of source surveillance and inspection.
- B. The extent of verifications shall be a function of the relative importance, complexity, and quantity of items or services being procured, and the supplier's quality performance.

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- C. Verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement. Verifications shall include supplier audits used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the supplier's quality assurance program.

## 7.2.5 Control of Supplier Generated Documents

- A. Supplier generated documents shall be controlled, processed, and accepted in accordance with the requirements established in the procurement documents.
- B. Measures shall be implemented to ensure that the submittal of these documents is accomplished in accordance with the procurement document requirements. These measures shall provide for the acquisition, processing, and recorded evaluation of technical, inspection, and test data compared against the acceptance criteria.

## 7.2.6 Acceptance of Items or Services

- A. Methods for accepting supplier furnished items or services shall include one or more of the following, as appropriate to the items or services being procured:
1. Evaluating the supplier certificate of conformance.
  2. Performing one or a combination of source verification, receiving inspection, or post-installation test.
  3. Technical verification of the product produced.
  4. Surveillance or audit of the work.
  5. Review of objective evidence (such as certifications, stress reports, or personnel qualifications) for conformance to the procurement document requirements.
- B. The supplier shall verify that furnished items or services comply with the purchaser's procurement requirements before offering the items or services for acceptance.
- C. The supplier shall provide the purchaser objective evidence that items or services conform to procurement documents. The documentation shall be available at the purchaser's facility before the item is installed or before the service is accepted.

## 7.2.7 Certificate of Conformance

When a certificate of conformance is used to accept an item or service:

- A. The certificate shall identify the purchased item or service to the specific procurement document.

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- B. The certificate shall identify the specific procurement requirements met by the purchased item or service. The procurement requirements identified shall include any approved changes, waivers, or deviations applicable to the item or service.
- C. The certificate shall identify any procurement requirements that have not been met together with an explanation and the means for resolving the nonconformances.
- D. The certificate shall be signed or otherwise authenticated by a person who is responsible for this quality assurance function and whose responsibilities and position are described in the supplier's quality assurance program.
- E. The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's quality assurance program.
- F. Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted at intervals commensurate with the past quality performance of the supplier.

### **7.2.8 Source Verification**

The purchaser may accept an item or service by monitoring, witnessing, or observing activities performed by the supplier. This method of acceptance is called source verification.

- A. Source verification shall be implemented consistent with the supplier's planned inspections, examinations, or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item.
- B. Documented evidence of acceptance of source verified items or services shall be furnished to the receiving destination of the item, to the purchaser, and to the supplier.
- C. Source verification shall be performed by personnel qualified in accordance with the applicable QARD requirements for the item or service being procured.

### **7.2.9 Receiving Inspection**

When receiving inspection is used to accept an item:

- A. The inspection shall consider the results of source verifications and audits and the demonstrated quality performance of the supplier.
- B. The inspection shall be performed in accordance with established inspection implementing documents.

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- C. The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical, and other characteristics; freedom from shipping damage; and cleanliness.
- D. The inspection shall be planned and executed according to the requirements of Section 10.0.
- E. Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.

### **7.2.10 Post-installation Testing**

When post-installation testing is used as a method of acceptance, then post-installation test requirements and acceptance documentation shall be mutually established by the purchaser and supplier.

### **7.2.11 Control of Supplier Nonconformances**

The purchaser and supplier shall establish and document the process for disposition of items that do not meet procurement document requirements according to the following requirements.

- A. The supplier shall evaluate nonconforming items according to the requirements of Section 15.0.
- B. The supplier shall submit a report of nonconformance to the purchaser including supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by the purchaser, shall be submitted to the purchaser for approval whenever one of the following conditions exists:
  - 1. Technical or material requirements are violated.
  - 2. A requirement in supplier documents, which have been approved by the purchaser, is violated.
  - 3. The nonconformance cannot be corrected by continuation of the original manufacturing process or by rework.
  - 4. The item does not conform to the original requirement even though the item can be restored to a condition such that the capability of the item to function is unimpaired.
- C. The purchaser shall disposition the supplier's recommendation.
- D. The purchaser shall verify implementation of the disposition.

### **7.2.12 Commercial Grade Items**

Where design specifies the use of commercial grade items, the following requirements are an acceptable alternative to other requirements of this section.

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- A. The commercial grade item shall be identified in an approved design output document. An alternate commercial grade item may be applied, provided the responsible design organization provides verification that the alternate commercial grade item will perform the intended function and will meet design requirements applicable to both the replaced item and the application.
- B. Supplier evaluation and selection, when determined necessary by the purchaser based on the complexity and importance to safety, shall be in accordance with the requirements of the subsection entitled *Source Evaluation and Selection*.
- C. Commercial grade items shall be identified in the procurement document by the manufacturer's published product description.
- D. After receipt of a commercial grade item, the purchaser shall ensure that:
  - 1. Damage was not sustained during shipment.
  - 2. The item received was the item ordered.
  - 3. Inspection or testing is accomplished, to the extent determined by the purchaser, to ensure conformance with the manufacturer's published requirements.
  - 4. Documentation, as applicable to the item, was received and is acceptable.