

U.S. Department of Energy

Oak Ridge Operations

ORO O 410 Chapter III Chg. 1

DATE: 03-31-98

SUBJECT: QUALITY ASSURANCE

1. PURPOSE. This Chapter relates to DOE 5700.6C, QUALITY ASSURANCE, dated August 21, 1991, by assigning responsibility and accountability and providing administrative and/or contractual guidance to the Oak Ridge Operations (ORO) and its contractors. Nothing in this issuance changes any requirements contained in any DOE Order.
2. CANCELLATION. This Chapter cancels and replaces ORIG 5700.6D, QUALITY ASSURANCE, dated April 19, 1994.
3. APPLICABILITY. The provisions of this Chapter apply to ORO Principal Staff and management and operating contractors.
4. RESPONSIBILITIES. Many ORO contractors have developed Standards/Requirements Identification Documents (S/RIDs) or Work Smart Standards (WSS) sets that may not include requirements referenced or included in DOE 5700.6C or this Chapter. Interpretation and performance of Federal responsibilities outlined below must take into account the approved standards set for each particular contract and must not be deemed to add any requirements to the approved set.
 - a. Director, Nuclear Safety Division (NSD).
 - (1) Coordinates the development of the Management, Performance, and Assessment (MPA) Program as a formal ORO quality assurance plan.
 - (2) Develops and provides initial and periodic training to ORO personnel on the MPA Program and quality assurance management training, including continuous improvement teaming and general quality principles and tools.
 - (3) Assists in performing independent assessments of ORO implementation of the MPA Program.
 - (4) Provides guidance to ORO on the readiness review process.
 - (5) Directs a consolidated management and independent assessment program to ensure ORO line organization implementation of the Self-Assessment Program, the MPA Program, and field inspection of Order compliance.
 - b. Director, Evaluation and Control Division, coordinates and maintains schedules for contractor appraisals and acts as the official office of record in maintaining copies of management assessments and independent assessments.

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INITIATED BY: NUCLEAR SAFETY DIVISION

- c. Principal Staff.
 - (1) Implement the MPA Program (Attachment 2 of this Chapter) within each division to comply with the quality assurance criteria identified in DOE O 416.1, paragraph 9b.
 - (2) Develop training plans and schedules to ensure ORO employees are appropriately qualified/certified.
 - (3) Provide technical assistance to ORO readiness review teams to determine if the equipment/system/facility is ready to operate.
 - (4) As requested by the Q&FSD, provide staff with technical knowledge/expertise to perform independent assessments of ORO organizations.
 - (5) Heads of matrix organizations will conduct independent assessments of ORO contractors in accordance with DOE O 416.1, subparagraph 9b(3)(b), Criterion 10.
 - (6) Designate a Quality Assurance Representative for their principal staff unit or division.
- d. Contracting Officers' Representatives evaluate contractor quality assurance plans to ensure conformance with the criteria in DOE O 416.1, paragraph 9b, and forward to the cognizant Secretarial Officer.

5. REQUIREMENTS AND PROCEDURES. None.

6. REFERENCES.

- a. ORIG 1100.X1B, ORGANIZATION AND FUNCTIONS - OAK RIDGE OPERATIONS, dated May 5, 1994.
- b. ORIG 5482.1D, ENVIRONMENT, SAFETY, HEALTH, AND QUALITY ASSURANCE APPRAISAL PROGRAM, dated January 26, 1994.
- c. ORIG N 1300.X2, OAK RIDGE OPERATIONS STANDARDS/REQUIREMENTS PROGRAM FIELD VERIFICATION PROCESS, dated October 28, 1993.

7. DEFINITIONS. See Appendix 1, Attachment 2 of this Chapter.

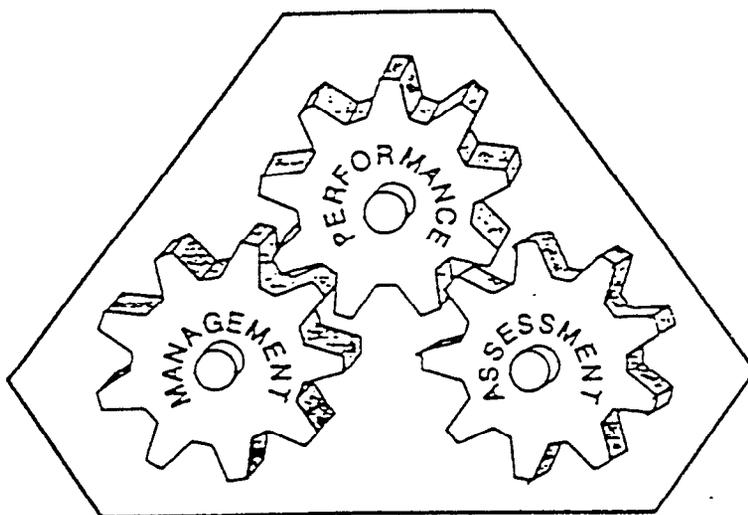
8. CONTRACTOR REQUIREMENTS DOCUMENT. See Contractor Requirements Document, Attachment 1 of this Chapter.
9. ATTACHMENTS.
 - a. Attachment 1 - Contractor Requirements Document.
 - b. Attachment 2 - DOE/OR/1084, "Management, Performance, and Assessment Program," dated June 1993.

CONTRACTOR REQUIREMENTS DOCUMENT

Contractors that are identified in paragraph 3 of this Chapter shall accomplish the following:

1. Develop and implement a quality assurance program that conforms to the requirements of DOE O 416.1, paragraph 9 and Attachment 1.
2. Submit changes to an existing quality assurance plan, on an annual basis, to the COR for review and approval in accordance with DOE O 416.1, subparagraph 9a(4).

Management, Performance, and Assessment Program

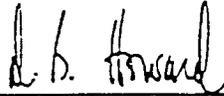


Oak Ridge
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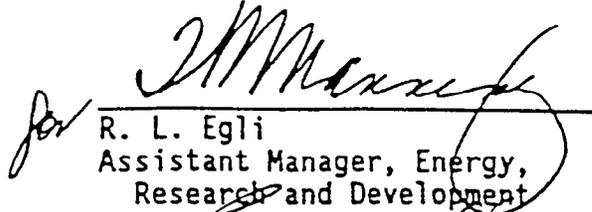


UNITED STATES DEPARTMENT OF ENERGY
OAK RIDGE OPERATIONS OFFICE
MANAGEMENT, PERFORMANCE, AND ASSESSMENT PROGRAM

CONCURRENCE:



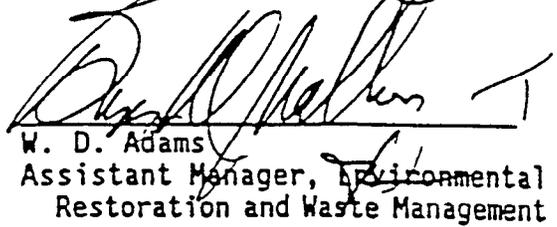
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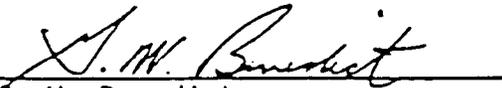
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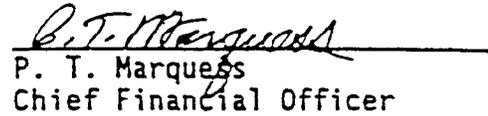
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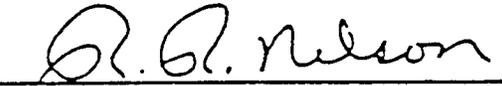
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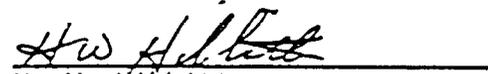
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DATE

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Appendix 1 DEFINITIONS

LIST OF ACRONYMS

CFR	Code of Federal Regulations
DOE	Department of Energy
ECD	Evaluation and Control Division
ESH&QA	Environment, Safety and Health, and Quality Assurance
FMFIA	Federal Managers' Financial Integrity Act
M&O	Management and Operating
MPA	Management, Performance, and Assessment
ORO	Oak Ridge Operations Office
ORIG	Oak Ridge Implementation Guidance
OSA	Office of Self-Assessment
OSHA	Occupational Safety and Health Act
PCD	Procurement and Contracts Division
QA	Quality Assurance
QI	Quality Improvement
QRD	Quality and Reliability Division

I. -INTRODUCTION

A. POLICY STATEMENT

It is the policy of the Oak Ridge Operations Office (ORO) to establish, implement, and maintain a program that provides a structured management system for efficient, cost-effective accomplishment of mission objectives to a rising standard of quality. This program represents ORO's commitment to excellence.

The ORO management program embraces and promotes the following principles:

- People are our most important resource; and are at the heart of quality.
- Quality is essential; it is doing the job right the first time.
- Quality is everybody's job; quality results from pride in work and continuous improvement of work processes.
- Quality requires disciplined adherence to sound procedures and practices which assure safe, secure, economical and environmentally sound operations.
- Employees will actively strive for identification and elimination of flaws within our systems where the root causes of most quality problems exist.
- ORO staff must take full ownership for the quality, effectiveness, and cost efficiency of their assigned tasks and for reporting nonconforming items and conditions to management.

Program requirements are identified in DOE Order 5700.6C, "Quality Assurance." In accordance with this Order, a written management program is required for DOE offices and contractors. The Quality and Reliability Division (QRD) staff will disseminate requirements, and provide counsel and technical support. Organization managers are responsible for developing and implementing plans, procedures, and actions within their areas to support the principles and policies of this program.

B. MISSION

ORO is responsible for the administration and management of programs for production of special nuclear material, other special materials, uranium enrichment, research and development, waste management, and environmental cleanup activities. These activities are to be carried out in compliance with laws, regulations, and DOE-Headquarters Orders and policies.

C. PURPOSE

This document establishes the program description for ORO as required by DOE Order 5700.6C, "Quality Assurance." It embraces the requirements set forth by that order and, with the various implementing procedures, forms a management system with emphasis on continuous improvement of processes within ORO.

The objectives of the ORO management system are to ensure that senior management provides planning, organization, resources, direction, control, and support to achieve the organization's objectives, and that overall performance is reviewed and evaluated using a rigorous assessment process.

Management and Operating contractors and their subcontractors at ORO are also required by contract and DOE Order 5700.6C to develop and implement an effective program unique to their organization and scope of work. Contractors' programs are required to be reviewed and receive concurrence by ORO and to be approved by the appropriate Headquarters organization.

D. SCOPE

The management system described herein applies to ORO programs, functions, and activities which affect the ORO mission, including oversight of contractor activities.

Some activities, such as records maintenance and computer support, may be performed by qualified contractors, but ORO retains responsibility for the delegated functions and activities. Oak Ridge Implementation Guidance (ORIG) 5700.6C, "Quality Assurance," contains specific roles and responsibilities.

E. ORGANIZATION

Specific organizational elements and responsibilities are documented in the ORO Directives System.

II. REQUIREMENTS

A. MANAGEMENT

1.0 QUALITY ASSURANCE PROGRAM

1.1 Implementation

ORO provides information concerning implementation of DOE policies and orders through the ORO Directives System. This system is used to identify functional responsibilities at the operations office and provide a central control point for the dissemination of directives from Headquarters. It is comprised of many parts, including Oak Ridge Implementation Guides (ORIGs), operations office-level procedures,

policies, and memoranda of agreement, etc. Additional policies and procedures are controlled at lower levels in the organization. They exist at the assistant manager's office, site office and/or division level, as warranted.

When dictated by specific organizational, functional, or programmatic objectives and requirements, these documents will be revised or expanded. Figure 1 shows the requirements implementation process.

1.2 Graded Approach

Since all items, processes, and services do not have the same effect on safety and reliability, a graded approach is to be taken to determine the degree of rigor to be applied when implementing new or revised requirements. The guidelines for applying a graded approach are contained in the ORO Directives System.

1.3 Readiness Reviews and Stop Work Authority

Readiness Reviews shall be conducted prior to selected scheduled or planned work and shall verify, as a minimum, that work prerequisites have been satisfied, that the equipment/system/facility is ready, that technical and quality-related procedures are reviewed for adequacy and appropriateness, that personnel are trained and qualified, and that proper ancillary equipment, materials, and resources are available. Selection criteria shall be described/controlled in assistant manager, site office, and/or division-level procedures. Associated responsibilities are detailed in the ORO Directives System.

Provisions for stopping/restarting work are contained in the ORO Directives System.

2.0 PERSONNEL TRAINING AND QUALIFICATION

2.1 General

NOTE: Implementing this element is particularly sensitive to funding.

Individuals shall be qualified, indoctrinated and/or trained to an extent commensurate with the scope, complexity, and nature of the activities they perform. Qualifications are determined by the knowledge and skills necessary to perform assigned job related tasks. In relaying performance criteria, the integration of quality into all task-related activities will be emphasized.

Indoctrination/training shall be conducted prior to performance of all job related and quality-impacting activities. This training will be based on a documented minimum-training matrix and on training plans which outline development, including schedule, and define curricula to

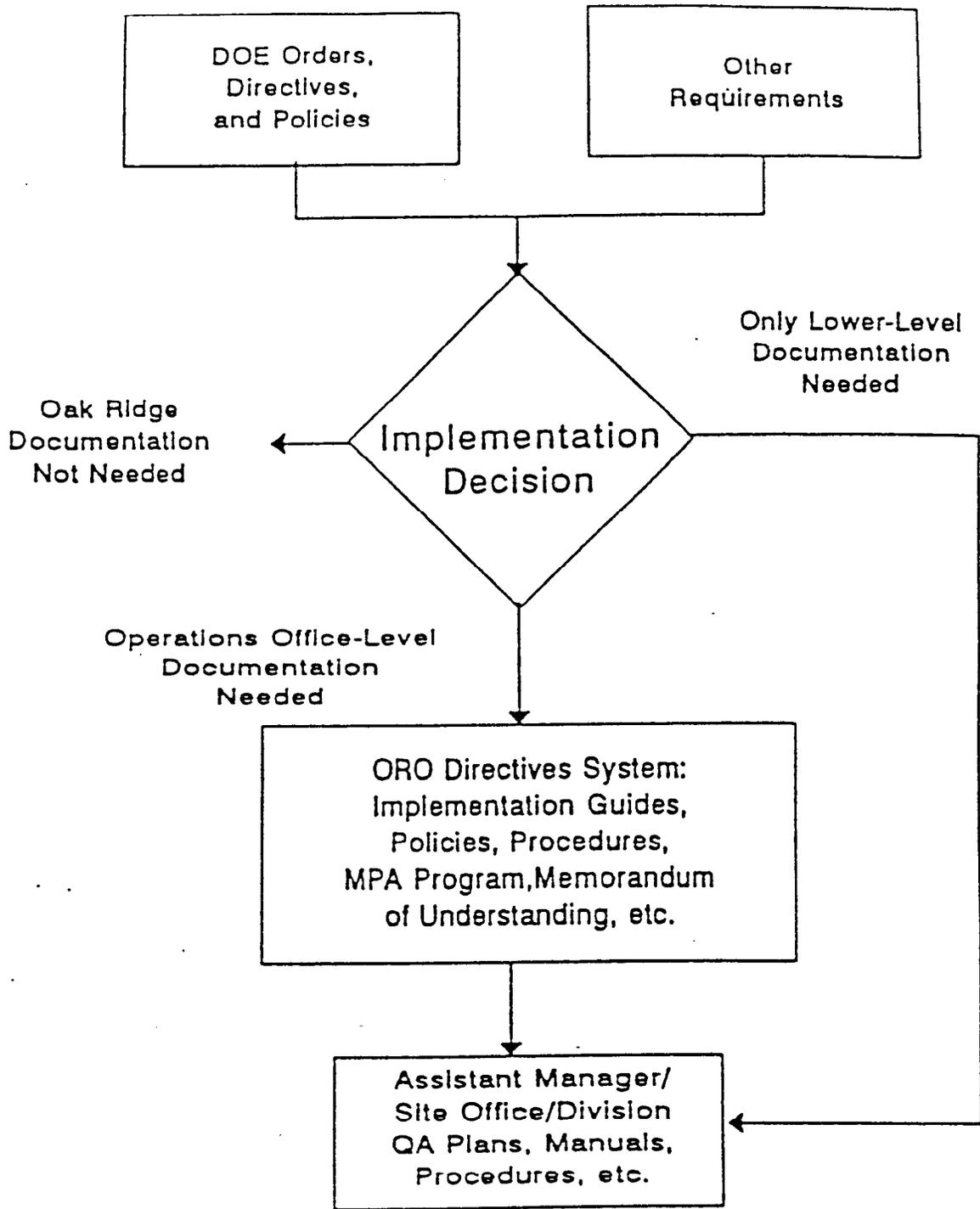


Figure 1. Requirements Implementation Process

address specific needs. The plans and their implementation will be a continuous and iterative process to ensure improvements, thus enhancing effectiveness of the training program. Associated responsibilities are detailed in the ORO Directives System.

2.2 Plans and Schedules

Training plans and schedules are developed at the assistant manager and/or division level to ensure that individuals are appropriately qualified/certified and that their proficiency and progressive improvement are maintained.

2.3 Monitoring and Tracking

An operations office-wide training tracking system is maintained to ensure that the training program can be monitored and that records are auditable.

3.0 QUALITY IMPROVEMENT

3.1 Improvement Process

ORO maintains a quality improvement (QI) process for all elements of OR. The QI process includes individual and team efforts and encourages the use of data and evaluations to determine root causes, corrective actions, preventive measures, and alternatives for improvement. QI teams include a mix of management and staff based upon the task under review. QI activities are selected using self-assessment reports, performance indicators, trends, employee suggestions, and other sources. QI implementation guidance is located in the ORO Directives System.

3.2 Performance Reporting and Corrective Action Tracking System

Management recognizes and supports nonconformance reporting as a quality improvement tool, fostering a "no-fault" philosophy to encourage reporting. ORO implements the requirements of DOE Order 5000.3A, "Occurrence Reporting System," through the ORO Directives System. Corrective actions shall be tracked through completion, and selected actions evaluated for effectiveness. Guidance is provided in the ORO Directives System and implementation is through assistant manager, site office and/or division procedures. A Requirements and Self Assessment Database is used to track order compliance issues through completion.

3.3 Lessons Learned

A system to provide lessons learned, both positive and negative, to operations office and contractor personnel where appropriate, is used. A lessons-learned procedure is included in the ORO Directives System. Some ORO staff also have access to the computerized lessons learned-system operated by one of our M&O contractors.

4.0 DOCUMENTS AND RECORDS

4.1 Documents

Information critical to the performance of mission activities is controlled to ensure that only current documents are used. A document control procedure is included in the ORO Directives System with implementation through assistant manager, site office, and/or division-level procedures.

4.2 Records

Records at ORO are subject to the National Archives and Records Administration requirements set forth in 36 CFR Parts 200 to end and DOE Orders 1324.2A, "Records Disposition," and 1324.5, "Records Management Program." ORO responsibilities are included in the ORO Directives System. Record retention periods are determined from General Records Schedules, site specific schedules, or documented on DOE 1324.6, "Request for Records Disposition Authorization," for new project records.

B. PERFORMANCE

5.0 WORK PROCESSES

5.1 Control of Work

Individuals within ORO are responsible for achieving quality in the work they and their contractors perform. Qualitative and quantitative criteria describing acceptable work performance shall be described in employee Performance Evaluation Plans. Guidelines for preparation of procedures are in the ORO Directives System.

5.2 Identifying, Handling, Storing, Shipping and Controlling Items

Government-owned equipment (e.g., computers, etc.) shall be identified, handled, stored, cleaned, packaged, shipped, and preserved to prevent damage, loss, or deterioration, and to ensure that only correct and accepted items are used or installed.

5.3 Monitoring and Data Collecting Equipment

Monitoring and data collecting equipment shall be controlled, maintained, serviced, and calibrated according to procedures maintained by the organization possessing and using the equipment. Calibration shall be traceable to certified reference standards. Monitoring and data collection equipment shall be of the accuracy and type suitable for the intended use.

5.4 Information Resources (Hardware and Software)

ORO assigns responsibilities for the control of unclassified computer software and hardware through the ORO Directives System. Orders and manuals covering classified computer software and hardware contain sufficient information concerning functional responsibilities.

A critical computer program (software) shall not be used until its performance has been properly verified as appropriate for the intended purpose. These programs shall only be used for the intended purpose and by personnel qualified in their use. This applies to both standard-purchase and custom-design software.

Actions to be taken to reduce risk or consequence of software failure shall be consistent with the impact of such failure. Software determined to have serious adverse impact in case of failure will have a Software Quality Assurance Plan prepared. This requirement will be identified in the appropriate contractual documents by the purchaser and user.

6.0 DESIGN

6.1 General

ORO is responsible for quality planning during design activities. The selection of design activities and the extent of control are determined by the design oversight organization during the planning process, using a graded approach.

The ORO organization providing design service and/or oversight develops and maintains procedures for their activities. Examples include the "OR System Design Methodology" for information resources projects, and the "Project Management Procedures, Volumes 1 and 2," for construction projects.

Design control activities include the assignment of qualified individuals to review and approve concepts and criteria for design inputs/outputs; the identification and documentation of design interfaces; the establishment and implementation of design review and evaluation of architect-engineer and M&O contractor designs; the development and application of a graded approach for design change control and configuration management; and the verification, where appropriate, of contractor design through analyses or the use of alternate calculations.

6.2 Input/Output

Design input, such as the design bases and reliability requirements shall be correctly translated into design output, such as specifications, drawings, procedures, and instructions.

6.3 Interfaces

Design interfaces are identified and controlled and design efforts are coordinated among and within participating organizations. Interface controls include the assignment of responsibility and establishment of procedures among participating design organizations.

6.4 Review and Approval

Management and Operating (M&O) contractor-initiated design requirements inputs and architect engineer outputs and changes thereto are reviewed and approved as appropriate by ORO. Design change control and configuration management are applied using a graded approach.

6.5 Verification

The acceptability of design work and documents, including design inputs, processes, outputs and changes shall be verified. Designs shall be verified prior to their release for the procurement, manufacture, construction, or release to another design organization by qualified individuals. These verifications include the use of computer programs and peer reviews to perform or verify by alternate calculations.

7.0 PROCUREMENT

7.1 General

Procured items and services shall meet established requirements and perform as specified. Suppliers of items and services are selected, approved, monitored, evaluated and controlled in accordance with Federal Acquisition Regulations and Department of Energy Acquisition Regulations.

7.2 Procedures/Instructions

ORO implements procurement requirements through Oak Ridge Procurement Letters, Standard Practices and Procedures, and Policy Information Bulletins.

7.3 Reviews

Contractor Procurement System Reviews are coordinated by the Procurement and Contracts Division (PCD), utilizing resources from throughout ORO.

8.0 INSPECTION AND ACCEPTANCE TESTING

The inspection and acceptance testing activities have been delegated to contractors.

C. ASSESSMENT

9.0 MANAGEMENT ASSESSMENT

9.1 General

Management assessments encompass those activities by which ORO organizations collect and evaluate information on their own performance. Management assessments also encompass those activities by which ORO line organizations collect and evaluate information on the performance of their contractors. In many instances the line organizations use matrix support to carry out management assessments of their contractors.

Examples of management assessments include, self-assessments, functional appraisals of contractors, reviews to support the annual Federal Managers' Financial Integrity Act (FMFIA) assurance report, and award fee determinations.

9.2 Self-Assessment

ORO management maintains a self-assessment program for site offices and divisions. The self-assessment program includes ongoing assessments of how performance criteria are being met using such tools such as trends, functional appraisals, walk-downs, audits, surveillances, external inputs, customer responses, etc. Focused assessments are performed to cover special topics of management concern or to target an opportunity for continuous improvement.

9.3 Management Control Systems

ECD manages this program to assure operations office compliance with the FMFIA. Specific tasks include: conducting training in the requirements of the Act; assuring that the required vulnerability assessments and management control evaluations are scheduled and conducted; and preparing the Manager's annual FMFIA report to Headquarters, maintaining the tracking system for corrective actions, and validating reported closures for both ORO and contractor corrective actions.

9.4 Award Fee Determinations

ORO uses a three-tiered structure consisting of the Fee Determination Official, the Award Fee Board, and Performance Evaluation Committees to produce award fee determinations. The functional responsibilities are described in the ORO Directives System. Award fee plans are developed to cover six-month periods and contain performance objectives and criteria, including specific milestones.

A total contractor appraisal process, from planning through conducting, reporting, following up on recommendations, and verification of corrective actions, is maintained.

Award fee assessments utilize information gathered through the self-assessment program, the contractor appraisal process, the vulnerability assessments, the management control evaluations, the independent assessment programs and special assessments in evaluating contractor performance against the documented expectations in the award fee plans.

9.5 Accident Investigations

Those accident investigations not chartered by the Manager are performed by teams established by the cognizant line organization. Guidance for the formation and performance of accident investigation teams is contained in the ORO Directives System.

10.0 INDEPENDENT ASSESSMENT

10.1 General

Independent assessments are those performed by personnel who are technically knowledgeable in the function being assessed, but who have no direct responsibilities in the activity being assessed. They are initiated by the assessing organization, or by the Manager/Deputy Manager, and are coordinated with the cognizant ORO organization. They use criteria that describe acceptable work performance, identify abnormalities and precursors of potential problems, report results, verify satisfactory resolution of problems, and focus on improving products and processes.

The assessing organization maintains schedule flexibility, selects areas to be reviewed based on such factors as risk, complexity, cost, and program impact, and utilizes pertinent expertise from throughout the operations office. This independent assessment program is expected to be much less resource intensive than the management assessment program described in section 9.

10.2 Independent Assessment of ORO Organizations

The Quality and Facility Safety Division oversees the independent assessment activities of ORO to ensure adequate assessment activities are performed. Resources to support this activity are provided from independent ORO organizations. In order to avoid duplication of effort, consolidated assessments are performed that cover applicable requirements of the Self-Assessment Program, the Management, Performance, and Assessment Program, and management aspects of the OSHA inspection program. (OSHA inspections of ORO-occupied facilities are carried out by the Safety and Health Division.)

The Evaluation and Control Division (ECD) provides assurance to ORO management that the contractor appraisal program is working effectively.

10.3 Independent Assessment of Contractor Organizations

The responsibility for inspecting contractor facilities and activities is delegated to the Safety and Health Division.

In accordance with DOE Order 5482.1B, "Environment, Safety, and Health Appraisal Program," dated September 23, 1986, ORO performs management appraisals of contractor ES&H programs. The appraisal teams are independent of the ORO organization having line responsibility for the contractor being appraised and are led by a senior ORO manager.

An independent assessment of contractors is conducted on an as-needed basis by ORO matrix organizations covering functional and management activities, including applicable requirements of the Self-Assessment Program and the Management, Performance, and Assessment Program. These assessments supplement management assessments and focus on specific areas of concern, as identified by the assessing organization. The Quality and Reliability Division maintains cognizance of these activities and conducts additional assessments of ORO contractor management, performance, and assessments programs, as needed.

The Evaluation and Control Division (ECD) performs comprehensive financial management reviews of integrated contractor financial management practices as required by the Chief Financial Officers Act of 1990 as implemented by DOE Order 2200.13. ECD also performs independent evaluations of contractor operations, methods, systems, procedures, and practices, with emphasis on the economy and effectiveness of operations and the accomplishment of programmatic objectives.

10.4 Accident Investigations

Those accident investigations chartered by the Manager are performed by teams independent of cognizant line management. Guidance for the formation and performance of accident investigation teams is contained in the ORO Directives System.

APPENDIX 1. DEFINITIONS

1. Assessment/Verification. The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in DOE 5700.6C, are synonymous; their use is determined by who is performing the work. Assessments are performed by or for senior management. Verifications are performed by the line organization.
2. Design. The process of utilizing inputs, project bases and objectives, and site specific data to formulate facility, system and component requirements for producing output documents required to procure, manufacture, fabricate, construct and test products, systems, processes and facilities.
3. Design Input. Design requirements that govern the design of project structures, systems, components and processes. Design input includes standards, interface requirements, and reliability requirements. Inputs are developed and included in feasibility studies, systems requirements documents, conceptual designs, and design criteria.
4. Design Output. The documents required to implement the design including procurement, manufacture, fabrication, construction and testing of a product, system or process. Output includes drawings, data sheets, specifications, bills of material, cost estimates and procedures.
5. Design Interfaces. Well defined organizational and physical interfaces required to successfully complete a design. These include the interfaces required to transfer information and data, provide support services, review and evaluate design, provide communications and assure that designs and modifications to designs do not adversely impact safe and reliable operation.
6. Graded Approach. A methodology for deciding the level of effort to be applied based upon risk, probability, etc.
7. Item. An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts, or data.
8. Management, Performance, and Assessment Program. The program developed by the U.S. Department of Energy Oak Ridge Operations Office to implement DOE Order 5700.6C, "Quality Assurance."
9. Oak Ridge Directives System. Mechanism used to relate policies, requirements, and functional responsibilities to ORO organizations. These include implementation guides, operations office-level procedures, policies, memorandum of understanding and/or agreement, manuals, etc.