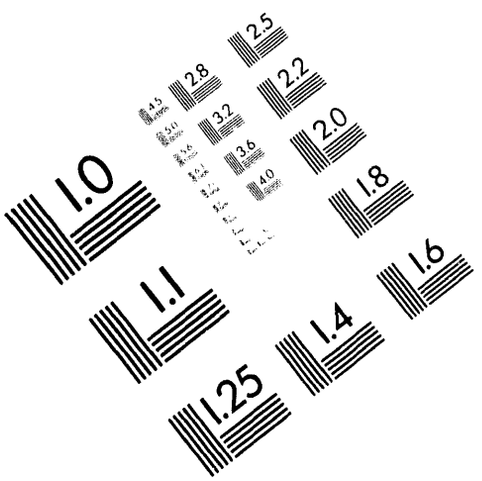

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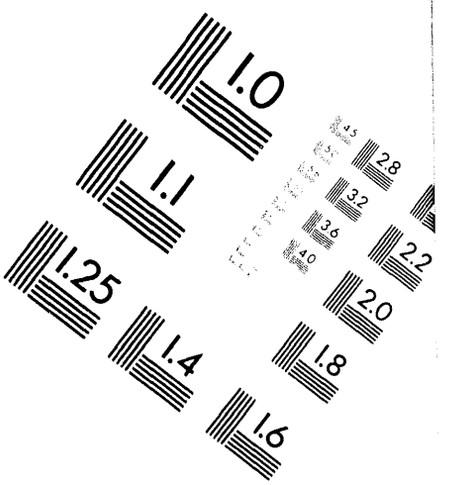

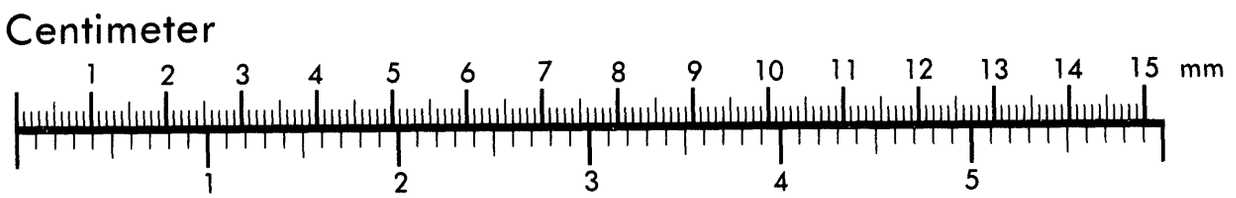

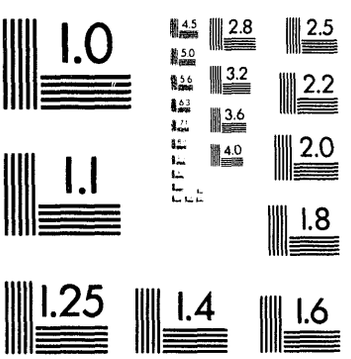

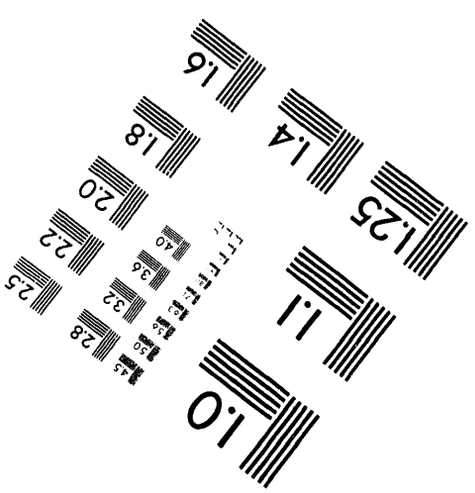

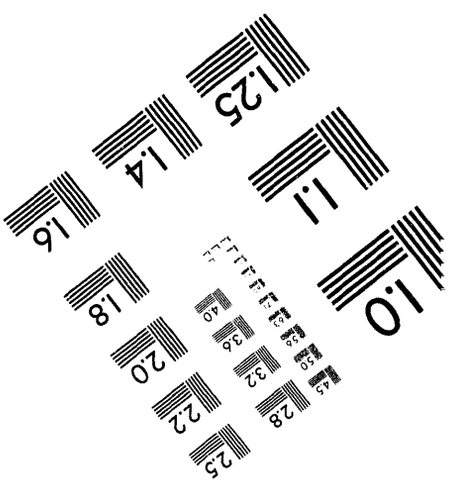

1 of 1

MIXED WASTE INTEGRATED PROGRAM

QUALITY ASSURANCE REQUIREMENTS PLAN

April 15, 1994

Prepared for
U.S. DEPARTMENT OF ENERGY
OFFICE OF TECHNOLOGY DEVELOPMENT
Washington, D.C. 20585

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for the
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APPROVALS:

for

6/22/94
Date

DOE Environmental Restoration and Waste Management,
Office of Technology Development, Waste Management
Division, Mixed Waste Integrated Program Manager, EM-542

6-22-94
Date

DOE Environmental Restoration and Waste Management,
Office of Technology Development,
Quality Assurance Program Manager, EM-533

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ACRONYMS AND TERMS

DOE - U.S. Department of Energy

GRS - General Records Schedule

Integrated Program Coordinator - The Management and Operating Contractor organization assigned responsibility by DOE for oversight and integration of MWIP work activities.

M&O - Management and Operating

MWIP - Mixed Waste Integrated Program

NARA - National Archives and Records Administration

Participating Organization - Any organization which performs work for MWIP.

QA - Quality Assurance

QARP - Quality Assurance Requirements Plan

TTP - Technical Task Plan

QUALITY POLICY

The Quality Assurance (QA) Program and its application to Mixed Waste Integrated Program (MWIP) work has the complete approval and support of Office of Technology Development management, including the provision of adequate resources for implementation.

It is the intent and expectation of the Office of Technology Development, Waste Management Division, that all MWIP participating organizations and their suppliers achieve and maintain the highest standards of quality in all their endeavors for the program. A commitment to the highest standards of quality will foster consistency, integration, and disciplined control in all work performed. Achieving quality objectives requires a concerted and consistent effort on the part of all participating organizations; therefore, all personnel performing MWIP work are individually responsible for complying with the requirements of the MWIP QA program as represented in this Quality Assurance Requirements Plan (QARP) and other implementing documents applicable to their work.

All management level personnel will assure that the QA program is adhered to, and will encourage the identification of technical and/or administrative problems and participate in their resolution. MWIP management is responsible for proper implementation of the QA program and all individual staff members are responsible for the quality of their work.

Implementation of the QA program will include consideration of the technical as well as administrative aspects of activities affecting quality. QA program implementation is based on the premise that the quality controls selected for each element of work are consistent with the risk, complexity, duration, importance, and health and safety considerations of performing the work.

for Paul Hart, Program Manager
EM-542, Mixed Waste Integrated Program

6/22/94
Date

INTRODUCTION

MWIP is sponsored by the U.S. Department of Energy (DOE), Office of Technology Development, Waste Management Division. The strategic objectives of MWIP are defined in the Mixed Waste Integrated Program Strategic Plan, and expanded upon in the MWIP Program Management Plan. This MWIP QARP applies to mixed waste treatment technologies involving both hazardous and radioactive constituents.

As a DOE organization, MWIP is required to develop, implement, and maintain a written Quality Assurance Program in accordance with DOE Order 4700.1 *Project Management System*, DOE Order 5700.6C, *Quality Assurance*, DOE Order 5820.2A *Radioactive Waste Management*, ASME NQA-1 *Quality Assurance Program Requirements for Nuclear Facilities* and ANSI/ASQC E4-19xx *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs*. The purpose of the MWIP QA program is to establish controls which address the requirements in 5700.6C, with the intent to minimize risks and potential environmental impacts; and to maximize environmental protection, health, safety, reliability, and performance in all program activities. QA program controls are established to assure that each participating organization conducts its activities in a manner consistent with risks posed by those activities.

The QARP has been developed to fulfill requirements established in the EM Office of Technology Development. The QARP addresses the requirements of DOE Order 4700.1, DOE Order 5700.6C, DOE Order 5820.2A, ASME NQA-1 and ANSI/ASQC E4-1993; and is consistent with the EM-50, Quality Assurance Program Description. It is intended that organizations performing work for MWIP verify their existing QA programs for conformance to the applicable sections of this QARP and enhance their programs when necessary. Participating organizations that do not have a QA program must develop one that conforms to the applicable sections of this QARP.

The QARP provides for both the achievement and the verification of quality. The line organization has total responsibility for meeting requirements, and individuals are responsible for the quality of their work. The line organization is responsible for implementation of the QA program. The line organization and the QA organization share responsibility for the verification of quality. The DOE/HQ MWIP Program Manager retains responsibility for the total QA program.

SECTION 1 - PROGRAM

Each MWIP participating organization will develop, implement, and maintain a written Quality Assurance (QA) Program. The QA Program will describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work. The QA Program will describe the management system, including planning, scheduling, and cost control considerations.

1.1 QUALITY ASSURANCE PROGRAM

MWIP management has developed and approved this QARP in order to provide uniform direction to all participating organizations concerning QA program requirements applicable to the technology development work which is the core of the MWIP mission. The QARP is based on the requirements of DOE Order 4700.1 *Project Management System*, DOE Order 5700.6C, *Quality Assurance*, DOE Order 5820.2A *Radioactive Waste Management*, ASME NQA-1 *Quality Assurance Program Requirements for Nuclear Facilities* and ANSI/ASQC E4-1993 *Specifications and Guidelines for Quality Systems for Environmental Data Collection and Environmental Technology Programs.* The QARP is formatted to follow the structure of DOE Order 5700.6C. The QARP includes cross reference tables which provide a visual linkage from the QARP to each standard (APPENDIX I). The MWIP DOE/HQ Program Manager is committed to implementation of the QA program and requires the participation of each organization performing work under its sponsorship. The hierarchy of QA program requirements is illustrated in Figure 1.

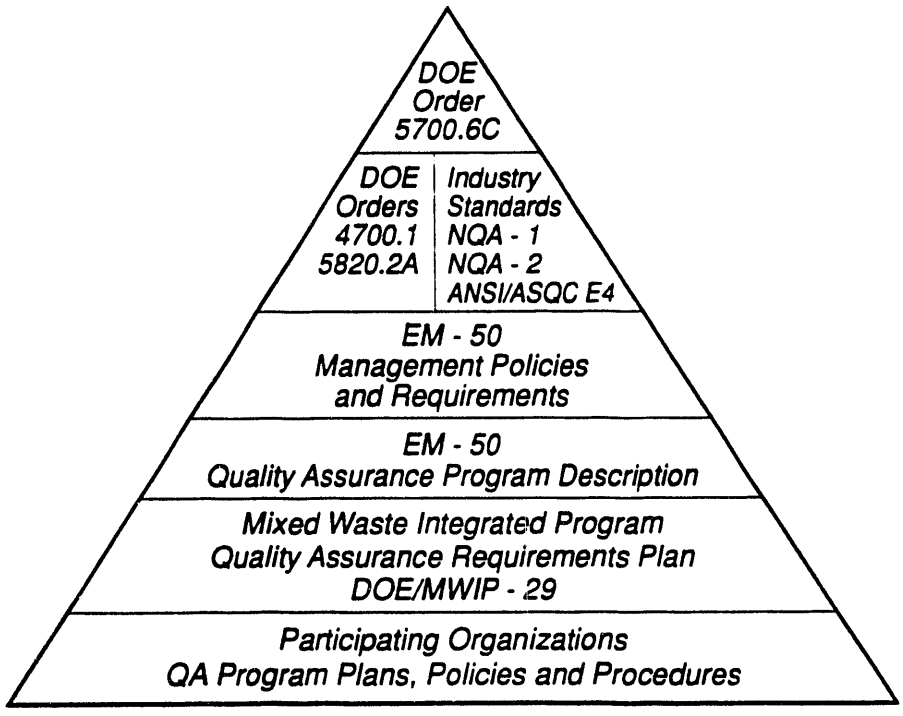

Figure 1. Hierarchy of Requirements

1.1.1 Participating Organizations QA Programs

Each organization participating in MWIP is required to have a written QA program, the relevant portions of which are implemented for MWIP work. For the purpose of this QARP, a participating organization is any organization which is contracted to perform work for the DOE/HQ Mixed Waste Program, e.g., Management and Operating (M&O) contractors, private sector contractors, and universities. Controls established in participating organization's QA programs for MWIP work will include provisions for DOE Orders and other Federal codes, standards, and laws which affect technology development associated with mixed waste management.

In the spirit of 5700.6C, MWIP management is not mandating any specific structure for the participating organization's QA programs nor that participating organizations develop additional QA documents if they are not needed. MWIP does, however, require each participating organization to complete a QA Requirements Analysis Matrix (APPENDIX II) to demonstrate how the participating organization's existing QA program meets MWIP requirements, or to provide justification as to why certain requirements are not applicable for specific tasks. APPENDIX II is provided to each participating organization, by issue of this QARP, with the requirement that each participating organization complete the matrix, obtain approval by the participating organization's responsible management, and return it to the Integrated Program Coordinator's office. Where documentation already exists which demonstrates that a participating organization's QA program meets the requirements shown in Figure 1 as appropriate to the specific work activities, the participating organization may substitute that documentation for APPENDIX II.

Participating organizations will assure that their QA programs are binding on all personnel performing MWIP work, and also on any suppliers of items or services which affect the quality of MWIP work.

Each participating organization's QA program will:

- include a written quality assurance policy statement, by senior management, which commits the organization to implement a formal QA program.
- discuss how the quality of items and services are assured to an extent consistent with their risk.
- describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of MWIP work.
- describe the management system, including planning, scheduling, and cost control considerations.
- promote effective and efficient achievement of performance objectives.

- be binding on all personnel, including those having responsibility for planning and scheduling.
- describe the onsite and offsite organizational elements that function within the scope of the QA program.
- establish criteria for developing individual QA programs or combining similar work under a single QA program, when appropriate.
- adopt a common vocabulary that is consistent and representative of the work being performed.
- define key terminology and assure that personnel indoctrination includes appropriate definitions to assure consistent understanding and communication.
- establish methods to assure that work assigned to parties outside the organization is identified; and that management controls are established, responsibilities assigned, lines of communication identified, and QA requirements are clearly communicated for assigned work.
- establish methods to assure that initial estimates used in planning are based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity.

1.1.2 Graded QA Controls

Each participating organization is expected to evaluate work performed for MWIP and to implement the QA controls established in the participating organization's QA Program based on the risks involved in the specific activities. The intent is to minimize risks and potential environmental impacts; and to maximize environmental protection, health, safety, reliability, and performance in the conduct of MWIP work. Therefore, each participating organization must determine which QA controls apply to their work and implement them in accordance with their respective QA programs. Each participating organization's QA program should promote the effective and efficient achievement of MWIP performance objectives as established in the participating organization's Technical Task Plan (TTP). The TTP, based on approved budgets, outlines the scope of work and the level of funding for an activity.

1.1.3 QA Program Familiarization

Participating organizations will assure that all personnel performing MWIP work under their direction, are familiar with the applicable requirements of the QA program. This includes suppliers that may be providing items or services which affect the quality of the participating organization's work. Familiarization will also include MWIP-specific terminology which is important to consistent understanding of the work, and communication among participating organizations.

1.1.4 Acronyms and Terms

Acronyms and terms which are useful to understanding this QARP are found at the beginning of this QARP.

1.1.5 Readiness Review

Each participating organization's work planning will include provisions for completing readiness reviews prior to the conduct of major MWIP activities such as testing or demonstrations, and prior to restart should any activities be shut down. Readiness reviews will be documented along with any corrective actions resulting from the reviews.

As a minimum, readiness reviews will assure that: a) work prerequisites have been satisfied; b) detailed technical and QA procedures have been reviewed for adequacy and appropriateness; c) personnel have been suitably trained and qualified; and d) the proper equipment, material, and resources are available.

1.2 ORGANIZATION

1.2.1 Structure and Interfaces

The structure and interfaces of the MWIP organization are illustrated in APPENDIX III. The organization consists of DOE-Headquarters staff, DOE Management and Operating Contractors, private industry, and other government entities such as the National Governors Association and the Western Governors Association. To facilitate the MWIP mission, DOE-Headquarters has also established an MWIP Integrated Program Coordinator to oversee and integrate the efforts of the various participating organizations.

1.2.2 Responsibility

1.2.2.1 DOE/HQ MWIP program management retains overall responsibility for the MWIP QA Program and is responsible for development and approval of the MWIP QARP, and revisions thereto.

1.2.2.2 The MWIP Integrated Program Coordinator is responsible for coordinating and integrating the efforts of the various MWIP participating organizations, and assisting DOE/HQ MWIP program management in assuring that the QA Program is fully implemented.

Specific responsibilities include:

- Approval of participating organization's QA Requirements Analysis Matrix.
- Assessment of QA program implementation.
- Assurance that required corrective actions are effective and complete.

1.2.2.3 Participating organizations senior management at each site is responsible for implementation, assessment, and improvement of an effective quality program. Specific responsibilities include:

- Approval and implementation of the participating organization's QA program.
- Assurance that the QA Requirements Analysis Matrix (or other compliance documentation is completed and transmitted to the MWIP Integrated Program Coordinator.
- Assessment of QA program implementation.
- Assurance that required corrective actions are effective and complete.
- Implementation of a management system which assures that planning, scheduling, and cost control are effectively implemented.

1.2.2.4 Line management in each participating organization is responsible for the following:

- achievement of quality
- implementing the planning, scheduling, and cost control functions designated for use by senior management.

1.2.2.5 Individual staff members (e.g. Principal Investigators) are responsible for the following:

- quality of their work
- implementing the applicable sections of their site QA programs.

1.2.3 Authority

DOE/HQ MWIP program management delegates authority to participating organizations to implement site QA programs which meet the requirements of this QARP. The MWIP Integrated Program Coordinator is delegated the authority by MWIP program management to conduct assessments of participating organizations' QA programs.

Each individual participating in MWIP activities is delegated the authority to stop work when unsafe conditions are observed, or to initiate stop work in accordance with site procedures when work of inadequate quality is discovered. Stop work authority will not be mitigated by planning, scheduling, or cost considerations.

1.3 WORK PLANNING

MWIP tasks are assigned by the DOE/HQ MWIP Program Manager and are documented in TTPs. The TTPs capture the technical, cost, and schedule information needed to manage MWIP and serve as the basis for developing work plans for MWIP activities.

SECTION 2 - PERSONNEL TRAINING AND QUALIFICATION

All personnel assigned to MWIP tasks are required to be trained and qualified to assure that they are capable of performing their work. Participating organizations' training programs will also provide for continuing training to assure that individual proficiency is maintained. As an overriding principle, training will emphasize correct performance of work, i.e., "doing it right the first time," and will stress the potential consequences of improper work practices. Specific areas for participating organizations to address are as follows:

2.1 Training Programs

Participating organizations' QA programs will include a training component that assures the initial capability of individuals to perform assigned tasks prior to beginning work, and provides for continuous training to assure that proficiency is maintained. Training programs will include education in the principles of an activity and enhancement of the skills and practices necessary to perform the activity. Training will provide not only knowledge of correct work procedures, but also an understanding of the fundamentals of the work and the context (i.e., specific work scope and physical environment) within which it is performed.

Training provided for MWIP must assure that personnel responsible for performing tasks understand the limitations of the processes and tools involved in the activity, such as: measuring and test equipment, process control instrumentation, and computer hardware and software. In addition to technical training, the participating organization's management will assure that staff are familiarized with the QA program and provided an understanding of why QA program controls are necessary. Training plans will also address professional development of staff and stimulate an interest in professional growth. For management personnel, training will include an emphasis on professional, managerial, communication, and interpersonal skills.

Participating organizations will evaluate their training programs to assure that the curricula meet the needs of MWIP activities.

2.2 Qualification of Personnel

Participating organizations will have a system for determining the qualifications necessary for positions assigned to MWIP work activities. Personnel assigned to each position must then meet the established position qualifications for work they perform and will be qualified prior to performing that work. Qualification requirements will be documented and maintained as project records, as well as the qualifications of individuals who meet those requirements and perform work for MWIP. The use of performance-based training will help assure that personnel demonstrate their proficiency. Training programs will also include a system for periodic requalification of personnel to assure that individual skills are updated and meet current practices.

2.3 Qualification of Instructors

Participating organizations will assure that training is provided by instructors who are technically knowledgeable and proficient in the subject matter being presented. Instructor qualifications will be documented and maintained.

2.4 Training Program Maintenance and Upgrade

The participating organizations' management will assure that training programs are regularly reviewed to determine the effectiveness of training presented to staff working on MWIP tasks. When such reviews indicate the need for improvements, the participating organizations' management will assure that modifications are made to improve the training program.

SECTION 3 - QUALITY IMPROVEMENT

Each MWIP participating organization will establish and implement processes for detecting quality problems and for quality improvement. Participating organizations will assure that items and processes used in MWIP work which do not meet established requirements, are identified and controlled, and that such items and processes are corrected. Participating organizations will identify the cause of problems and implement measures to prevent recurrence. Participating organizations will also review and analyze information collected as part of MWIP work to identify items and processes which need improvement. Specific areas for participating organizations to address are as follows:

3.1 Management Commitment

Each participating organization's management must make a commitment to fostering a "no-fault" attitude which encourages staff to identify nonconforming items and processes without fear of retaliation. Management must also be committed to personal involvement in the quality improvement process to assure that the proper focus is given, adequate resources are allocated, and difficult issues are resolved. Each participating organization's management must make a commitment to the concept that each individual participating in MWIP activities (as noted in paragraph 1.8 above) is granted the authority to stop work when unsafe conditions are observed, or to initiate stop work in accordance with site procedures when work of inadequate quality is discovered.

3.2 Quality Improvement Programs

Participating organizations will establish and implement processes with the objective of preventing problems and improving quality. Examples of processes which could be used on MWIP tasks are: peer reviews, design reviews, probabilistic risk assessments, Safety Analysis Reports, and Reliability, Availability, Maintainability analyses. The focus of quality improvement activities will be to reduce the variability of processes which affect the quality of MWIP technology development.

Participating organizations will establish and implement processes to promote continuous improvement, including the identification of expected performance standards and associated performance measures. The focus of quality improvement will be on reducing the variability of every process which influences the quality of the product. Performance data, internal and external failure costs, prevention costs, and other quality-related information will be analyzed to identify trends that adversely impact quality, and to identify opportunities to improve items and processes. To identify commonalities, this analysis will consider information from external sources and not be limited to one type of work, one facility, or one contractor. Quality improvement processes will incorporate actions from lessons learned.

Participating organization's quality improvement processes will include provisions for resolving professional differences of views and opinions.

3.3 Nonconformances

All personnel supporting MWIP tasks will have the authority to identify nonconforming items and processes, will have a process for doing so, and will also be encouraged by management to identify and suggest improvements which affect MWIP work. Participating organizations will assure that items and processes which do not meet established requirements or goals, or do not result in the anticipated level of quality are promptly identified, documented, analyzed, resolved, and followed up in accordance with the participating organization's nonconformance reporting system.

Nonconforming items and processes will be properly controlled by each participating organization to prevent their inadvertent test, installation, or use. Nonconformances will be reviewed by the organization that originally reviewed and approved the items or processes, or by a designated organization that is qualified and knowledgeable; and the justification for disposition will be appropriately documented. Reworked, repaired, and replacement items and processes will be inspected and tested by the participating organizations in accordance with original requirements or specified alternatives.

Participating organization's nonconformance systems will include provisions to assure that personnel responsible for analyzing and dispositioning nonconformances have an adequate technical understanding of the area in which they are working and have access to pertinent background information relative to the nonconformance.

3.5 Root Cause Analysis

The extent of cause analyses performed by participating organizations for nonconforming items and processes will be commensurate with the importance or significance of the problem.

SECTION 4 - DOCUMENTS AND RECORDS

Each participating organization will have a system to assure that MWIP documents are prepared, reviewed, approved, issued, used, and revised in order to prescribe processes, specify requirements, or establish design for their work. Participating organizations will also have a system to assure that MWIP project records are specified, and that those records are prepared, reviewed, approved, and maintained. Specific areas for participating organizations to address are as follows:

4.1 Document Control

Each participating organization's document control process will address the methods used to prepare, review, approve, issue, use, and revise documents which have been identified for control, and will determine the scope of the document control system as it applies to MWIP work. Controlled documents will be distributed by participating organizations in accordance with established systems, and used by personnel performing MWIP work. Participating organization's document control processes will include measures for control of superseded or cancelled documents which also provide assurance that only correct documents are in use.

A participating organization's document control systems will include provisions to assure that revisions to controlled documents are reviewed and approved by the organization that originally reviewed and approved the documents, or that an alternative organization is

designated to review and approve controlled documents, based on competence and capability.

Participating organization's document control systems will include timeliness guidelines for distribution of new or revised controlled documents, and record copies will be marked "superseded" or "cancelled" and kept for a specified retention period.

4.2 Project Records

Each participating organization will establish and implement a process to assure that sufficient records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed MWIP work. The maintenance of records will include provisions for retention, protection, preservation, traceability, accountability, and retrievability.

The MWIP Integrated Program Coordinator has established and implemented a Records Management Plan which includes provisions for quality assurance records. The Records Management Plan incorporates the requirements of the General Records Schedule (GRS) published by the National Archives and Records Administration (NARA) and is applicable to MWIP participating organizations. Participating organizations will refer to the MWIP Records Management Plan for guidance on retention and disposition of records.

When a participating organization's task generates records that require special processing and control, such as computer codes or information on high density media or optical disks, the participating organization will assure that the hardware and/or software required to maintain and access such records is controlled so that the records are useable. Active records requiring special handling, storage, and processing controls will not be sent to records holding facilities.

SECTION 5 - WORK PROCESSES

MWIP work processes focus on the two broad technical areas of technology development and infrastructure for demonstrations. Participating organizations supporting these areas will have systems in place to assure that their work processes are controlled in accordance with technical standards and administrative controls. Participating organizations will implement approved procedures, instructions, or other appropriate methods utilized in their quality programs to assure that work is performed under controlled conditions. Items used in accomplishing MWIP work will be identified and controlled to assure their proper use; and such items will be maintained to prevent damage, loss, or deterioration. Participating organizations using equipment for process monitoring or data collection will assure that the equipment is calibrated to appropriate standards and maintained in accordance with approved instructions. Specific areas for participating organizations to address are as follows:

5.1 Conduct of Work

As stated in the Quality Policy, all personnel performing work for the MWIP are responsible for the quality of their work. Each participating organization will assure that individuals are knowledgeable of the requirements for the work they perform, and understand the capability of the tools and processes they use. Each participating organization's management will assure that personnel working under their supervision are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Each participating organization's management will establish the criteria which describe acceptable work performance for each staff member.

Participating organizations will implement a process for management to review work and related information to assure that the desired quality is being achieved. Management will also identify areas needing improvement.

Participating organizations will assure that MWIP work is planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of a detail commensurate with the complexity and risk of the work. Work-related instructions, procedures, and other forms of direction prepared by the participating organization for MWIP work will be developed, verified, validated, and approved by technically competent personnel.

5.2 Identification and Control of Items

Participating organizations will establish and implement processes to identify, control, and maintain items used in MWIP work. Identification of these items will be maintained to assure appropriate traceability.

Consumables and items with limited shelf-life will be controlled in accordance with processes established and implemented by the participating organization to prevent the use of incorrect or defective items, and to control samples.

5.3 Handling, Storage, Packaging and Shipping

Participating organizations will establish and implement processes to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration. When required, special protective measures will be specified and provided by participating organizations to maintain acceptable quality.

Throughout packaging, shipping, handling, and storage operations, participating organizations will assure that marking and labeling of items is maintained, and that marking and labeling provides sufficient information to identify items and provides instructions or special controls to preserve the integrity of such items.

For off-site transportation, participating organizations will implement processes which meet the transportation requirements in the Office of Technology Development (EM-50), Management Policies and Requirements document.

5.4 Calibration and Control of Measuring and Test Equipment

Monitoring and data collection equipment used by participating organizations will be of a type and will have a degree of accuracy suitable for their intended use. Participating organizations will assure that the types of equipment included in MWIP work processes are specified.

Participating organizations will establish and implement processes to control the calibration, maintenance, and use of measuring and test equipment used for MWIP monitoring and data collection activities. Equipment used will have calibration certifications traceable to national standards, where possible.

SECTION 6 - DESIGN

Participating organizations will assure that design personnel use sound engineering/scientific principles and appropriate standards during the design of items and processes for MWIP tasks. Participating organizations will assure that design work, including changes, incorporates requirements and design bases applicable to MWIP. Design interfaces will also be identified and controlled during the design process.

Participating organizations will assure that the adequacy of design products is verified or validated by individuals or groups other than those who performed the design, and that verification and validation work is completed before approval and implementation of the design. Specific areas for participating organizations to address are as follows:

6.1 Design Process

Participating organizations will establish and implement a process for design of items and processes which is based on sound engineering/scientific principles and appropriate standards, such as the General Design Criteria (DOE 6430.1A). The established design process will include how the participating organization controls design requirements, inputs, processes, outputs, changes, records, and organizational interfaces.

The participating organization's design process will include provisions for how design inputs (such as design bases, reliability requirements, and fire protection requirements) are correctly translated into design output (such as specifications, drawings, procedures, and instructions).

The participating organization's design process will include provisions to assure that changes to final designs, field changes, modifications, and nonconforming items dispositioned "use-as-is" or "repair" are justified and subject to design control measures commensurate with the original design. The design process will also include methods to assure that the design analyses for the items remain valid after changes or acceptance of nonconforming items. The participating organization's design process will assure that changes are approved by the original design organization or a technically qualified, designated alternate organization.

6.2 Design Interfaces

The participating organization's design process will include provisions to assure that design interfaces are identified and controlled, and that design efforts are coordinated among and within MWIP participating organizations. Established interface controls will include the assignment of responsibility and establishment of procedures among participating design organizations.

6.3 Design Verification and Validation

The participating organization's design process will include provisions to assure that the acceptability of design work and documents (including design inputs, processes, outputs, and changes) is verified and documented. The participating organization's design process will include methods to assure that computer programs used in design work are proven through previous use, or validated through testing or simulation prior to use.

Participating organizations will assure that design verification is performed by a qualified individual or group other than those who performed the original design. Personnel assigned to perform design verification may, however, be from the same organization. The design process used by the participating organization will include provisions to assure that the extent of verification is based on the complexity, risk, and uniqueness of the specific design. The participating organization's design process will include established verification methods such as design reviews, alternate calculations, and qualification testing which are implemented and documented during the design process. The participating organization's design process will also include provisions for determining if separate verification is not needed for multiple uses of identical or previously proven designs, unless those designs are intended for different applications or have different performance criteria.

Where testing is used to verify or validate acceptability of a specific design feature, the tests selected must demonstrate acceptable performance under conditions that simulate the most adverse design conditions. Test planning will give consideration to operating or test modes and environmental conditions in which items must perform satisfactorily to determine the most adverse conditions appropriate to the test.

The participating organization's design process will include controls which assure that design verification has been completed before design output is used by other organizations; or is used to support other work, such as procurement, manufacturing, construction, or experimentation. When this timing cannot be achieved, the unverified portion of the design will be identified and controlled by the participating organization. In all cases, design verifications will be completed before relying on the design item to perform its function and before installation becomes irreversible.

6.4 Design Records

Design records collected and maintained by the participating organization to provide evidence that the design was properly accomplished, will include not only the final design output and its revisions, but also important design steps and sources of input that support the final output. Records will be maintained in accordance with the MWIP Records Management Plan (Section 4.0 of the QARP).

SECTION 7 - PROCUREMENT

The participating organization's procurement processes will include provisions to assure that items and services procured for MWIP meet established requirements and perform as specified, that prospective suppliers are evaluated and selected on the basis of specified criteria, and that approved suppliers can continue to provide acceptable items and services. Specific areas for participating organizations to address are as follows:

7.1 Procurement Planning

Each participating organization will establish and implement a planning process as part of its procurement activities which includes methods to assure that items and services purchased for MWIP meet established requirements (including QA requirements) and perform as expected.

The participating organization's planning process will assure that applicable technical and administrative requirements, such as specifications, codes, standards, tests, and inspections are identified and invoked for procurement of items and services; and that procurement documents include applicable acceptance criteria.

The participating organization's procurement system will include appropriate controls for the selection, determination of suitability, evaluation, and receipt of all purchased items and services, including commercial-grade items, to assure that procured items and services perform as expected.

7.2 Supplier Qualification

The participating organization's procurement system will include provisions for evaluation of prospective suppliers to assure that only qualified suppliers are selected to supply items and services used in MWIP tasks. The procurement system will include provisions for periodic monitoring of qualified suppliers and, as necessary, sub-tier suppliers to assure that acceptable items and services continue to be supplied.

7.3 Acceptance of Items and Services

The participating organization's procurement system will include specified methods for acceptance of purchased items and services. Such methods will be implemented to assure that procurement specification, inspection, and test requirements are satisfied and nonconformances properly dispositioned before a procured item is used or placed in service for an MWIP task. Actual performance of items will be compared with original performance criteria.

Personnel responsible for procurement will review such information as user group surveys, supplier evaluations, inspection and test results, and performance data to determine the effectiveness of the participating organization's procurement process.

The participating organization's procurement system will include provisions for determining the interval at which the quality of purchased items and services is verified to a degree consistent with the complexity, risk, quantity, and frequency of procurement of the item or service.

The participating organization's procurement system will also include provisions to forward information to the DOE Office of Inspector General in cases where there are indications that suppliers knowingly supplied items and services of substandard quality for MWIP work.

SECTION 8 - INSPECTION AND ACCEPTANCE TESTING

Each participating organization will establish and implement methods to assure that inspection and acceptance testing of specified items and processes is conducted using established acceptance and performance criteria. Equipment used by participating organizations for inspections and tests will be calibrated and maintained in accordance with work processes which are established in Section 5.0. Specific areas for participating organizations to address are as follows:

8.1 Inspection

Each participating organization will establish and implement an inspection process which includes provisions to assure that inspection planning is accomplished in accordance with the work process criteria described in Section 5.0 of this QARP. Planning will identify item characteristics and processes to be inspected, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing inspections.

The inspection process will include provisions which specify what types of inspections are required for specified items and processes, and when inspections are to occur. Established inspection processes will also include administrative controls and status indicators to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of an item or process prior to inspection.

The inspection process will allow for implementation by or for the organization performing the work to be inspected, with the provision that personnel may not inspect their own work for the purpose of acceptance.

The inspection process will also include provisions for determining the level of inspection and degree of independence of inspection personnel required based on the risk and complexity of the item or process to be inspected.

When acceptance criteria are not met, the participating organization's inspection process will include provisions such that deficiencies are resolved and reinspection completed, as required for the item or process.

8.2 Acceptance Testing

Each participating organization will establish and implement a testing process to demonstrate that items and processes perform as intended. Testing will be structured so that proving designs should not be confused with verifying the adequacy of work.

The testing process used will allow for implementation by or for the organization performing the work to be tested with the provision that personnel may not test their own work for the purpose of acceptance.

The participating organization's group responsible for design will provide or approve item or process test requirements and acceptance criteria. Established test processes will also include administrative controls and status indicators to preclude inadvertent bypassing of required tests and to prevent inadvertent operation of an item or process prior to testing.

Test procedures developed by participating organizations will include:

(a) instructions and prerequisites to perform the test;
(b) completeness and accuracy of data;
(c) use of test equipment;
(d) acceptance criteria;
(e) inspection hold points; and
(f) test article configuration.

When acceptance criteria are not met, the participating organization's testing process will include provisions such that deficiencies are resolved and retesting is completed, as required for the item or process.

8.3 Calibration and Control of Measuring and Test Equipment

Participating organizations will establish and implement a process to control calibration, accountability, and use of equipment utilized to control any process parameter which influences the quality of an item's characteristics or which is used for in-process inspection of an item. The process established will include provisions to assure that the types of equipment to be used, such as instruments, tools, gauges, reference and transfer standards, and nondestructive examination equipment are defined.

Measuring and test equipment used by participating organizations for MWIP work will be calibrated at specified intervals, or immediately before and after use, on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance. The process used to control measuring and test equipment will include provisions for labeling, tagging, or otherwise controlling the equipment to indicate its calibration status and assure traceability to calibration test data.

Each participating organization's measuring and test equipment will be calibrated against standards having an accuracy which will assure that the equipment being calibrated is within required tolerances. Where nationally recognized calibration standards exist, the calibration standards used for MWIP work will be traceable to such standards.

The participating organization's process will include provisions to assure that measuring and test equipment found to be out-of-calibration or out-of-tolerance will be tagged or segregated and not used until it is successfully recalibrated. The participating organization will determine the acceptability of items or processes previously measured, inspected, or tested with an out-of-tolerance device.

SECTION 9 - MANAGEMENT ASSESSMENT

Each participating organization will establish and implement a process to assure that management at all levels periodically assesses the integrated quality assurance program and its performance. Problems found which hinder the organization from achieving its objectives will be identified and corrected. Specific areas for participating organizations to address are as follows:

9.1 Conduct of Assessments

The participating organization's management assessment process will be structured to assure that planned and periodic assessments are established and implemented as a way to improve quality and health. Management assessments will focus on how well the participating organization's integrated quality assurance program is working and identify management problems that hinder the organization from achieving its objectives in accordance with the quality, safety, and environmental requirements established for MWIP work. Results of management assessments will be documented.

The participating organization's assessment process will include provisions to assure that senior management retains overall responsibility for management assessments and engages direct participation by senior management during management assessments. The management assessment process implemented by the participating organizations will involve all levels of management, as appropriate.

9.2 Corrective Action

The participating organization's assessment process will include provisions to assure that senior management takes prompt action and documents decisions made in response to recommendations resulting from the management assessment process. Follow-up on corrective actions will include an evaluation of the effectiveness of management actions.

SECTION 10 - INDEPENDENT ASSESSMENT

Each participating organization will establish and implement a process to assure that planned and periodic independent assessments are conducted to measure item quality and process effectiveness and to promote improvement. The participating organization's management will assure that the organization assigned to perform independent assessments is given sufficient authority and freedom from the line organization it is assessing to carry out its responsibilities. Persons selected to conduct independent assessments will be technically qualified and knowledgeable in the areas assessed. Specific areas for participating organizations to address are as follows:

10.1 Conduct of Assessments

The participating organization's independent assessment process will be structured to assure that planned and periodic independent assessments are established and implemented by an independent assessment organization. Provisions will be included in the process to assure that independent assessments focus on improving items and processes by emphasizing the line organizations' achievement of quality.

Participating organizations will charge independent assessment personnel with the responsibility to monitor work performance, identify abnormal performance and precursors of potential problems, identify opportunities for improvement, report results to a level of management having the authority to effect corrective action, and verify satisfactory resolution of problems. Independent assessment personnel will also act in a management advisory function for the participating organization.

The participating organization's independent assessment process will include provisions for conducting assessments using criteria that describe acceptable work performance and will promote improvement of work processes.

Participating organizations will base the scheduling of assessments and allocation of resources on the status, risk, and complexity of the item or process being assessed. Scheduling will be flexible and additional attention will be given to areas of questionable performance.

10.2 Qualification of Assessment Personnel

Participating organizations will assign personnel to perform independent assessments who are technically knowledgeable in the area assessed, and will assure that the assessment focuses on improving the quality of the processes that lead to MWIP products.

The assessment process will include provisions to assure that personnel performing independent assessments do not have direct responsibilities in the areas they are assessing.

10.3 Corrective Action

The participating organization's assessment process will include provisions to assure that assessment results are tracked and that identified problems are resolved by management having responsibility in the area assessed. When necessary, the process used will include follow-up reviews of deficient areas.

The assessment process will include provisions to assure that responses to assessments include the following as applicable: action to correct the deficiency; cause identification; actions to prevent recurrence; lessons learned; and actions to be taken for improvement.

APPENDIX I

QA REQUIREMENTS CROSS REFERENCE MATRICES

QA Requirements Cross Reference Matrix

ANSI/ASQC - E4 \ MWIP QARP		Program	Personnel Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection and Acceptance Testing	Management Assessment	Independent Assessment
		1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
Management and Organization	2.1	●									
Quality System and Description	2.2	●									
Personnel Qualification and Training	2.3		●								
Procurement of Items and Services	2.4							●			
Documents and Records	2.5				●						
Computer Hardware and Software	2.6					●			●		
Planning	2.7	●				●					
Implementation of Work Processes	2.8					●			●		
Assessment and Response	2.9									●	●
Quality Improvement	2.10			●							
Planning and Scoping	3.1	●				●					
Design of Data Collection Operations	3.2						●				
Implementation of Planned Operations	3.3					●			●		
Assessment and Response	3.4									●	●
Assessment and Verification of Data Useability	3.5					●			●		
Planning	4.1	●				●					
Design of Systems	4.2						●				
Construction /Fabrication of Systems and Components	4.3					●			●		
Operation of Systems	4.4					●			●		
Assessment and Response	4.5									●	●
Verification and Acceptance of Systems	4.6								●		

QA Requirements Cross Reference Matrix

DOE Order 5820.2A and NQA-1		Program 1.0	Personnel Training and Qualification 2.0	Quality Improvement 3.0	Documents and Records 4.0	Work Processes 5.0	Design 6.0	Procurement 7.0	Inspection and Acceptance Testing 8.0	Management Assessment 9.0	Independent Assessment 10.0
Organization	1	●		●							
QA Program	2	●	●							●	
Design Control	3						●				
Procurement Document Control	4							●			
Instructions, Procedures, and Drawings	5				●	●					
Document Control	6				●						
Control of Purchased Items and Services	7							●			
Identification and Control of Items	8					●					
Control of Processes	9					●					
Inspection	10								●		
Test Control	11								●		
Control of Measuring and Test Equipment	12					●			●		
Handling, Storage, and Shipping	13					●					
Inspection, Test, and Operating Status	14								●		
Control of Nonconforming Items	15			●							
Corrective Action	16			●						●	●
QA Records	17				●						
Audits	18										●

NQA-2

Computer Software	2.7						●				

QA Requirements Cross Reference Matrix

DOE Order 4700.1 (Chap. III, Part D) / MWIP QARP		Program	Personnel Training and Qualification	Quality Improvement	Documents and Records	Work Processes	Design	Procurement	Inspection and Acceptance Testing	Management Assessment	Independent Assessment
		1.0	2.0	3.0	4.0	5.0	6.0	7.0	8.0	9.0	10.0
QA Organization	a.	●									●
QA Plan	b.	●	●								
Design Control	c.						●				
Procurement Control	d.							●			
Instructions, Procedures, and Drawings	e.				●						
Document Control	f.				●						
Control of Purchased Material, Equipment, and Services	g.							●			
Identification, Control, & Traceability of Materials, Parts, & Components	h.					●					
Control of Special Processes	i.					●					
Inspection	j.								●		
Test Control	k.								●		
Calibration and Control of Test & Measurement Equipment	l.					●			●		
Handling, Storage, Shipping, and Preservation	m.					●					
Inspection, Test, and Operating Status	n.								●		
Nonconforming Material, Parts, or Components	o.			●							
Corrective Action	p.			●						●	●
QA Records	q.				●						
Audits	r.										●

APPENDIX II

PARTICIPATING ORGANIZATIONS QA REQUIREMENTS ANALYSIS MATRIX

The QA Requirements Analysis Matrix is the initial step in demonstrating compliance of the participating organization's QA program with MWIP requirements. A completed matrix gives the DOE/HQ MWIP Program Manager and the Integrated Program Coordinator a road map through the participating organization's QA program plan, policies, and procedures, and allows the participating organization to demonstrate where its QA program meets MWIP requirements and to justify exceptions where appropriate.

The matrix is to be completed as follows. The participating organization evaluates its QA plan, policies, and procedures against each requirement stated in the far left column of the matrix. Based on that evaluation, place a check mark in the appropriate column under Compliance indicating full, partial or N/A. Where full or partial are checked, fill in the corresponding sections of the columns titled "Part. Org. QA Plan Section(s)" and "Part. Org. Applicable Procedure(s)" which meet the requirement. Where a requirement is not applicable, the N/A column is checked and a justification is provided under the Comments column.

The "Comments" column is provided for the following purposes:

- to allow for any additional explanation needed
- to provide justification as to why a particular requirement is not applicable to a participating organization's scope of work.
- to explain partial compliance when necessary, to describe the impact on the quality of the work, and to project when full compliance will be achieved.

The MWIP QA requirements listed in Appendix II are a combination of the Quality Assurance Criteria from section 9 and the implementation guidance in Attachment I of DOE Order 5700.6C.

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 1 - Program **(1-a)** Organizations will develop, implement, and maintain a written Quality Assurance program.						
(1-b) Senior management will develop and issue a written quality assurance policy statement which commits the organization to implement a formal Quality Assurance program.						
(1-c) Appropriate standards will be used, wherever applicable, to develop and implement Quality Assurance programs.						
(1-d) The Quality Assurance program will include a discussion of how the criteria will be satisfied. The quality of items and services will be assured to an extent consistent with their risk.						
(1-e) Senior management will retain and exercise responsibility for the scope and implementation, assessment, and improvement of an effective QA program. Line management will be responsible for the achievement of quality. Each individual will be responsible for the quality of his/her work.						
(1-f) The Quality Assurance program will promote effective and efficient achievement of performance objectives.						
(1-g) The Quality Assurance program will be binding on all personnel, including those having responsibility for planning and scheduling.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 1 - Program (cont'd) **(1-h)** Management will take the necessary actions to assure that the Quality Assurance program is understood and implemented.						
(1-i) The Quality Assurance program will describe the organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing adequacy of work.						
(1-j) The description will include the onsite and offsite organizational elements that function within the scope of the Quality Assurance program.						
(1-k) The organization will establish criteria for developing individual Quality Assurance programs or combining similar work under a single Quality Assurance program, when appropriate.						
(1-l) A common vocabulary that is consistent and representative of the work being performed will be adopted.						
(1-m) Key terminology will be defined. Personnel indoctrination will include appropriate definitions to assure consistent understanding and communication.						
(1-n) Work assigned to parties outside the organization will be identified. For assigned work, management controls will be established, responsibilities assigned, and lines of communication identified.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 1 - Program (cont'd) **(1-o)** The Quality Assurance program will describe the management system, including planning, scheduling, and cost control considerations.						
(1-p) Initial estimates used in planning will be based on sound data and assumptions relating to personnel, material/service costs, availabilities, and productivity.						
(1-q) Readiness reviews will be performed prior to major scheduled or planned work and will be performed to verify at least the following characteristics: - Work prerequisites have been satisfied; - Detailed technical and QA procedures have been reviewed for adequacy and appropriateness; - Personnel have been suitably trained and qualified; and - The proper equipment, material, and resources are available.						
(1-r) Responsibility and authority to stop unsatisfactory work will be assigned such that planning and schedule considerations do not override safety considerations.						
(1-s) A readiness review will be performed prior to restarting work.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 2 - Personnel Training and Qualification **(2-a)** Personnel will be trained and qualified to assure they are capable of performing their assigned work.						
(2-b) Qualification requirements will be established for specific job categories, such as operators, designers, managers, supervisors, inspectors, welders, engineers, scientists, and independent personnel.						
(2-c) Training includes both education in principles and enhancement of skills and practices.						
(2-d) Training will assure the worker understands the processes and tools he/she is using, the extent and sources of variability in those processes and tools, and the degree to which he/she does and does not have control over that variability.						
(2-e) Training will emphasize correct performance of work and provide understanding of why quality requirements exist.						
(2-f) Training will provide an understanding of the fundamentals of the work and its context.						
(2-g) Training instruction will address potential consequences of improper work and focus attention on "doing it right the first time."						

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 2 - Personnel Training and Qualification (cont'd) (2-h) Training plans will address and stimulate professional development. Training plans for management personnel will include professional, managerial, communication, and interpersonal skills.						
(2-i) Personnel performing work that requires special skills or abilities will be qualified prior to performing work.						
(2-j) Training will provide curricula that address specific needs, and it will be presented by qualified instructors.						
(2-k) Personnel will be provided continuing training to assure that job proficiency is maintained.						
(2-l) Training plans will provide for maintenance of proficiency and progressive improvement and will not be limited to attainment of initial qualification.						
(2-m) Qualification will include demonstrated proficiency of each candidate and will be preformed periodically thereafter to maintain skills to meet current practices.						
(2-n) Training will be subject to on-going review to determine program and instruction effectiveness.						

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 2 - Personnel Training and Qualification (cont'd) (2-o) Training and qualification will be upgraded whenever needed improvements or other enhancements are identified.						
Section 3 - Quality Improvement (3-a) The organization will establish and implement processes to detect quality problems and to assure quality improvement.						
(3-b) Processes will be established and implemented with the objective of preventing problems and improving quality (e.g., peer reviews, design reviews, probabilistic risk assessments, Safety Analysis Reports, and Reliability/Availability/ Maintainability analyses.)						
(3-c) The focus of quality improvement will be to reduce the variability of every process which influences the quality of the product.						
(3-d) Processes will be established and implemented to promote continuous improvement including the identification of expected performance standards and associated performance measures.						
(3-e) Items and processes that do not meet established requirements will be identified, controlled, and corrected. Correction will include identifying the causes of problems and preventing recurrence.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 3 - Quality Improvement (cont'd) (3-f) All personnel will identify nonconforming items and processes, and will be encouraged by management to identify and suggest improvements.						
(3-g) All personnel will be granted the freedom and authority to stop work until effective corrective action is taken.						
(3-h) Items and processes that do not meet established requirements, goals, or do not result in the anticipated quality will be promptly identified, documented, analyzed, resolved, and followed up.						
(3-i) The extent of cause analyses for nonconforming items and processes will be commensurate with the importance or significance of the problem.						
(3-j) Management, at all levels, will foster a "no-fault" attitude to encourage the identification of nonconforming items and processes.						
(3-k) Management will be involved in the quality improvement process to assure that the proper focus is given, adequate resources are allocated, and difficult issues are resolved.						
(3-l) A process for resolving professional differences of views and opinions will be established and implemented.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 3 - Quality Improvement (cont'd) (3-m) Nonconforming items and processes will be properly controlled to prevent their inadvertent test, installation, or use. They will be reviewed by the organization that originally reviewed and approved the items or processes, or by a designated organization that is qualified and knowledgeable; and the justification for disposition will be appropriately documented.						
(3-n) Reworked, repaired, and replacement items and processes will be inspected and tested in accordance with original requirements or specified alternatives.						
(3-o) Item reliability, process implementation, and other quality-related information will be reviewed and the data analyzed to identify items and processes needing improvement.						
(3-p) Performance data, internal and external failure costs, prevention costs, and other quality-related information will be analyzed to identify trends that adversely impact quality and to identify opportunities to improve items and processes.						
(3-q) To identify commonalities, this analysis will consider information from external sources and not be limited to one type of work, one facility, or one contractor.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 3 - Quality Improvement (cont'd) **(3-r)** Personnel responsible for analyzing and dispositioning nonconformances will have an adequate technical understanding of the area in which they are working and have access to pertinent background information relative to the nonconformance.						
Section 4 - Documents and Records **Documents** **(4-a)** Documents will be prepared, reviewed, approved, issued, used, and revised to prescribe processes, specify requirements, or establish design.						
(4-b) A process will be established and implemented to control preparation, review, approval, issuance, use, and revision of documents that establish policies, prescribe work, specify requirements, or establish design.						
(4-c) The scope of the document control system will be defined.						
(4-d) Revisions to controlled documents will be reviewed and approved by the organization that originally reviewed and approved the documents.						
(4-e) An alternative organization may be designated based on competence and capability.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 4 - Documents and Records (cont'd) **(4-f)** Timeliness guidelines will be implemented for distribution of new or revised controlled documents.						
(4-g) Controlled documents will be distributed and used by personnel performing work.						
(4-h) Control of superseded or cancelled documents will include measures to assure that only correct documents are in use.						
Records **(4-i)** Records will be specified, prepared, reviewed, approved, and maintained.						
(4-j) Record copies will be marked "superseded" or "cancelled" and kept for a specified retention period.						
(4-k) A process will be established and implemented to assure that sufficient records are specified, prepared, reviewed, approved, and maintained to accurately reflect completed work.						
(4-l) The maintenance of records will include provisions for retention, protection, preservation, traceability, accountability, and retrievability.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 4 - Documents and Records (cont'd) **(4-m)** For records that require special processing and control, such as computer codes or information on high density media or optical disks, hardware and software required to maintain and access such records will be controlled to assure records are useable.						
(4-n) Active records requiring special handling, storage, and processing will not be sent to records holding facilities. Users will refer to the MWIP Records Management Plan for guidance on retention and disposition of such records.						
(4-o) Use of the General Records Schedule published by the National Archives and Records Administration (NARA), and the DOE unique schedules approved by the NARA are mandatory. Participating organizations will refer to the MWIP Records Management Plan for guidance on retention and disposition of task records.						
Section 5 - Work Processes **Work** **(5-a)** Work will be performed to established technical standards and administrative controls, and under controlled conditions using approved instructions, procedures, or other appropriate means.						

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 5 - Work Processes (cont'd) **(5-b)** Personnel performing work are responsible for the quality of their work. The individual worker will be knowledgeable of requirements for work performed and the capability of the tools and processes used.						
(5-c) Line managers will assure that personnel working under their supervision are provided the necessary training, resources, and administrative controls to accomplish assigned tasks. Criteria describing acceptable work performance will be defined for the worker.						
(5-d) Line managers will review work and related information to assure that the desired quality is being achieved and to identify areas needing improvement.						
(5-e) Work will be planned, authorized, and accomplished under controlled conditions using technical standards, instructions, procedures, or other appropriate means of a detail commensurate with the complexity and risk of the work.						
(5-f) Work-related instructions, procedures, and other forms of direction will be developed, verified, validated, and approved by technically competent personnel.						
Identification and Control of Items **(5-g)** Items will be identified and controlled to assure their proper use.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 5 - Work Processes (cont'd) **(5-h)** Processes will be established and implemented to identify, control, and maintain items.						
(5-i) Identification of items will be maintained to assure appropriate traceability.						
(5-j) Processes will be established and implemented to control consumables and items with limited shelf-life, prevent the use of incorrect or defective items, and control samples.						
Handling, Storing, and Shipping **(5-k)** Items will be maintained to prevent their damage, loss, or deterioration.						
(5-l) A process will be established and implemented to control the handling, storage, shipping, cleaning, and preservation of items to prevent damage, loss, or deterioration.						
(5-m) Marking and labeling of items will be maintained throughout packaging, shipping, handling, and storage.						
(5-n) Marking and labeling will provide information to identify items and provide instructions or special controls to preserve their integrity.						
(5-o) Requirements for off-site transportation will be established and implemented.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 5 - Work Processes (cont'd) **(5-p)** Special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperatures and moisture levels) will be specified and provided when required to maintain acceptable quality.						
Calibration and Maintenance of Monitoring and Data Collection Equipment **(5-q)** Equipment used for process monitoring or data collection will be calibrated and maintained.						
(5-r) A process will be established and implemented to control the calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection.						
(5-s) Monitoring and data collection equipment will be of the accuracy and type suitable for the intended use. The types of equipment included will be specified.						
(5-t) Equipment will have calibration certifications traceable to national standards, where possible.						
Section 6 - Design **(6-a)** A process will be established and implemented for design using sound engineering/scientific principles and appropriate standards, such as the General Design Criteria (DOE 6430.1A)						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 6 - Design (cont'd) **(6-b)** Provisions will include control of design requirements, inputs, processes, outputs, changes, records, and organizational interfaces.						
(6-c) Design records, maintained to provide evidence that the design was properly accomplished, will include not only the final design output and its revision, but also important design steps and sources of input that support final output.						
(6-d) Design work, including changes, will incorporate applicable requirements and design bases.						
(6-e) Design input, such as design bases, reliability requirements, and fire protection requirements, will be correctly translated into design output, such as specifications, drawings, procedures, and instructions.						
(6-f) Changes to final designs, field changes, modifications and nonconforming items dispositioned "use-as-is" or "repair" will be justified and subject to design control measures commensurate with the original design; and will include assurance that the design analyses for the items are still valid.						
(6-g) Changes will be approved by the original design organization or a technically qualified designate.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 6 - Design (cont'd) **(6-h)** Design interfaces will be identified and controlled.						
(6-i) Design efforts will be coordinated among and within participating organizations.						
(6-j) Interface controls will include the assignment of responsibility and establishment of procedures among participating design organizations.						
(6-k) The adequacy of design products will be verified or validated by individuals or groups other than those who performed the work.						
(6-l) The acceptability of design work and documents, including design inputs, processes, outputs, and changes, will be verified. Computer programs will be proven through previous use, or validated through testing or simulation prior to use.						
(6-m) Design verification will be performed by qualified individual(s) or group(s) other than those who performed the original design - but who may be from the same organization. The extent of verification will be based on the complexity, risk, and uniqueness of the design.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 6 - Design (cont'd) **(6-n)** Verification methods include but are not limited to, design reviews, alternate calculations, and qualification testing. Separate verification may not be needed for multiple uses of identical or previously proven designs, unless they are intended for different applications or different performance criteria.						
(6-o) Testing to verify or validate acceptability of a specific design feature will demonstrate acceptable performance under conditions that simulate the most adverse design conditions. Operating or test modes and environmental conditions in which items must perform satisfactorily will be considered in determining the most adverse conditions.						
(6-p) Verification and validation work will be completed before approval and implementation of the design.						
(6-q) Design verification will be completed before design output is used by other organizations or to support other work, such as procurement, manufacturing, construction, or experiment.						
(6-r) When this timing cannot be achieved, the unverified portion of the design will be identified and controlled. In all cases, design verifications will be completed before relying on the design item to perform its function and before installation becomes irreversible.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 7 - Procurement (7-a) The organization will establish and implement a process to assure that procured items and services meet established requirements and perform as specified.						
(7-b) Applicable technical and administrative requirements, such as specifications, codes, standards, tests, and inspections will be invoked for procurement of items and services.						
(7-c) Procurement documents will include acceptance criteria.						
(7-d) Appropriate controls for the selection, determination of suitability, evaluation, and receipt of all purchased items, including commercial-grade items, will be imposed to assure that they perform as expected.						
(7-e) Purchased items and services will be accepted using specified methods (such as review of manufacturing process control data, source verification, receipt inspection, pre-installation and post-installation tests, certificates of conformance, or a combination of these methods).						
(7-f) Before a procured item is used or placed in service, procurement specification, inspection, and test requirements are to be satisfied and nonconformances properly dispositioned.						
(7-g) The actual performance of items will be compared with original performance criteria.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 7 - Procurement (cont'd) **(7-h)** User group surveys, supplier evaluations, inspection and test results, and performance data will be reviewed to determine procurement effectiveness.						
(7-i) The quality of purchased items and services will be verified at intervals to a degree consistent with the item's or service's complexity, risk, quantity, and frequency of procurement.						
(7-j) In cases where there are indications that suppliers knowingly supplied items and services of substandard quality, this information will be forwarded to the DOE Office of Inspector General.						
(7-k) Prospective suppliers will be evaluated on the basis of specified criteria to assure that only qualified suppliers are selected.						
(7-l) The organization will assure that qualified suppliers and as necessary, sub-tier suppliers, are monitored periodically to assure that acceptable items and services can continue to be supplied.						
Section 8 - Inspection and Acceptance Testing **Inspection** **(8-a)** Inspection and acceptance testing of specified items and processes will be conducted using established acceptance and performance criteria.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 8 - Inspection and Acceptance Testing (cont'd) **(8-b)** A process will be established and implemented to specify when and what type of inspections (source, in-process, receipt, maintenance, and in-service, for example) are required.						
(8-c) Administrative controls and status indicators will be used to preclude inadvertent bypassing of required inspections and to prevent inadvertent operation of the item or process.						
(8-d) Inspections may be implemented by or for the organization performing the work to be inspected.						
(8-e) Personnel may not inspect their own work for acceptance.						
(8-f) The level of inspection and degree of independence of inspection personnel will be based on risk and complexity.						
(8-g) Provisions to assure inspection planning is properly accomplished will be established.						
(8-h) Planning will identify item characteristics and processes to be inspected, inspection techniques, acceptance criteria, hold points, and the organization responsible for performing inspection.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 8 - Inspection and Acceptance Testing (cont'd) **(8-i)** When acceptance criteria are not met, deficiencies will be resolved and reinspection will occur as required.						
Acceptance Testing **(8-j)** Testing processes will be established and implemented to demonstrate that items and processes will perform as intended.						
(8-k) Testing will be structured so that proving designs will not be confused with proofing the adequacy of work.						
(8-l) Testing may be implemented by or for the organization performing the work to be tested.						
(8-m) When an organization performs its own testing, personnel with the organization will not test their own work for acceptance.						
(8-n) Item and process test requirements and acceptance criteria will be provided by or approved by the organization responsible for design.						
(8-o) Administrative controls and status indicators will be used to preclude inadvertent bypassing of required tests or operation of the item or process.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 8 - Inspection and Acceptance Testing (cont'd) (8-p) Test procedures will be developed and include: (a) instructions and prerequisites to perform the test; (b) completeness and accuracy of data; (c) use of test equipment; (d) acceptance criteria; (e) Inspection hold points (f) test article configuration.						
(8-q) Retesting of items or processes to determine that they meet acceptance criteria is required after deficiencies are corrected.						
Measuring and Test Equipment (8-r) Equipment used for inspections and tests will be calibrated and maintained.						
(8-s) A process will be established and implemented to control calibration, accountability, and use of equipment utilized to control any process parameter which influences the quality of an item's characteristics or which is used for in-process inspection of an item.						
(8-t) The types of equipment to be used, such as instruments, tools, gauges, reference and transfer standards, and nondestructive examination equipment will be defined.						

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Section 8 - Inspection and Acceptance Testing (cont'd) **(8-u)** Measuring and test equipment will be calibrated at specified intervals, or immediately before and after use, on the basis of the item's required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance.						
(8-v) Measuring and test equipment will be labeled, tagged, or otherwise controlled to indicate its calibration status and assure traceability to calibration test data.						
(8-w) Measuring and test equipment will be calibrated against standards having an accuracy that will assure that equipment being calibrated will be within required tolerances.						
(8-x) If nationally recognized standards exist, calibration standards will be traceable to such standards.						
(8-y) Measuring and test equipment found out-of-calibration or out-of-tolerance will be tagged or segregated and not used until it is successfully recalibrated. The acceptability of items or processes measured, inspected, or tested with an out-of-tolerance device will be determined.						
Section 9 - Management Assessment **(9-a)** Management at all levels will periodically assess the integrated quality assurance program and its performance.						

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	Full	Partial	N/A			
Section 9 - Management Assessment (cont'd) **(9-b)** Planned and periodic management assessments will be established and implemented as a way to improve quality.						
(9-c) Senior management will retain overall responsibility for management assessments. Direct participation by senior management during management assessments is essential. This process will involve all levels of management, as appropriate.						
(9-d) Management assessment results will be documented.						
(9-e) Problems that hinder the organization from achieving its objectives will be identified and corrected.						
(9-f) Management assessments will focus on how well the integrated quality assurance program is working and will identify management problems that hinder the organization from achieving its objectives in accordance with quality, safety, and environmental requirements.						
(9-g) Senior management will take prompt action and document resulting decisions in response to recommendations resulting from the management assessment process. Follow-up will include an evaluation of the effectiveness of management's actions.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

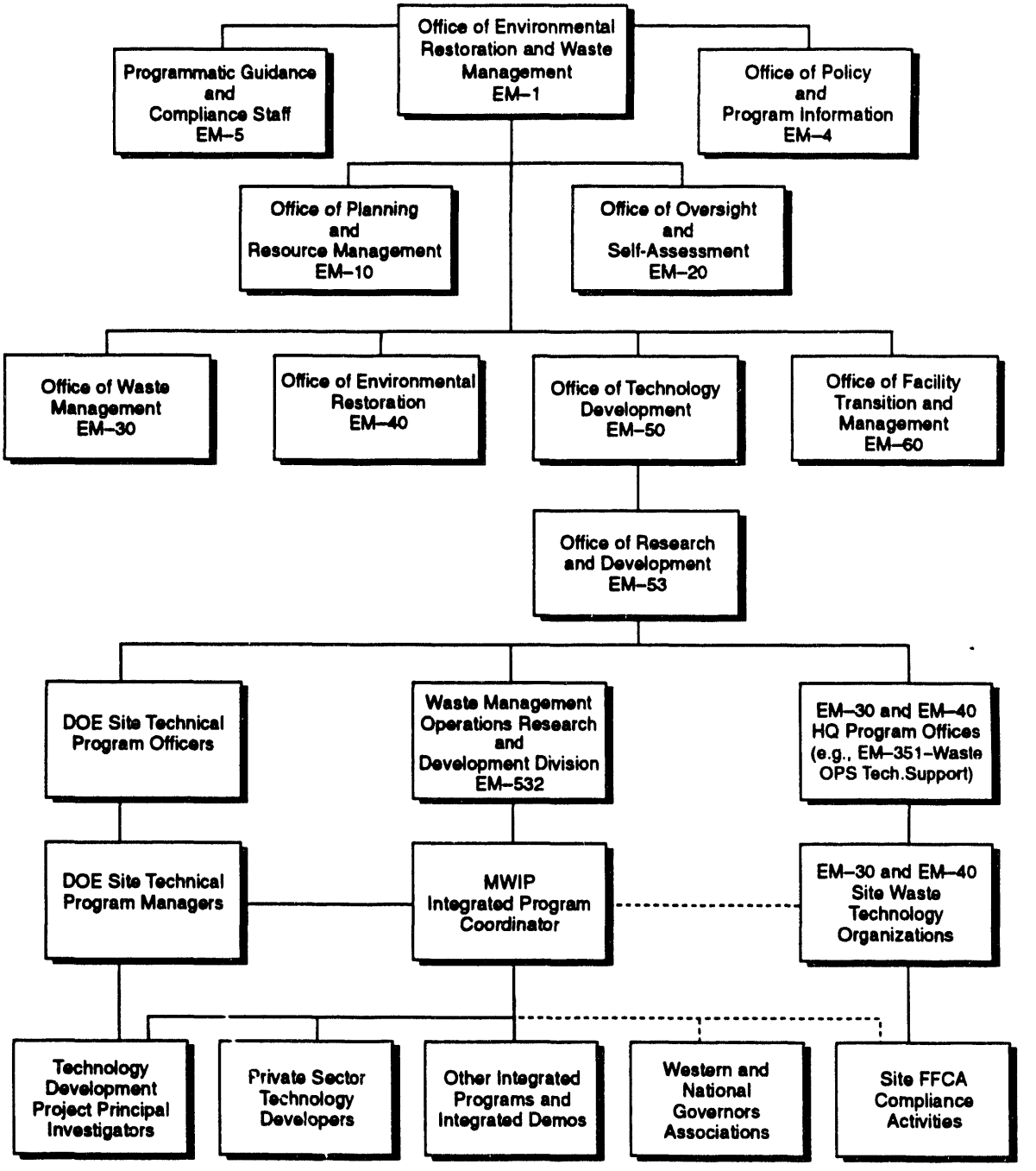
MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 10 - Independent Assessment **(10-a)** Planned and periodic independent assessments will be established and conducted by an independent assessment organization to measure item quality and process effectiveness and to promote improvement.						
(10-b) Independent assessments will focus on improving items and processes by emphasizing line organizations' achievement of quality.						
(10-c) Personnel performing independent assessments will act in a management advisory function.						
(10-d) Their responsibilities are to monitor work performance, identify abnormal performance and precursors of potential problems, identify opportunities for improvement, report results to a level of management having the authority to effect corrective action, and verify satisfactory resolution of problems.						
(10-e) Personnel performing independent assessments will not have direct responsibilities in the area they are assessing.						
(10-f) Independent assessments will be conducted using criteria that describe acceptable work performance and promote improvement.						

Mixed Waste Integrated Program, Participating Organizations QA Requirements Analysis Matrix

MWIP QA Requirements	Compliance			Part. Org. QA Plan Section(s)	Part. Org. Applicable Procedure(s)	Comments
	Full	Partial	N/A			
Section 10 - Independent Assessment (cont'd) **(10-g)** Scheduling of assessments and allocation of resources will be based on the status, risk, and complexity of the item or process being assessed. Scheduling will be flexible and additional attention will be given to areas of questionable performance.						
(10-h) Assessment results will be tracked and resolved by management having responsibility in the area assessed.						
(10-i) Follow-up review of deficient areas will be initiated as necessary.						
(10-j) Responses to assessments will include the following as applicable: action to correct the deficiency; cause identification; actions to prevent recurrence; lessons learned; and actions to be taken for improvement.						
(10-k) The organization performing independent assessments will have sufficient authority and freedom from the line organization to carry out its responsibilities.						
(10-l) Persons conducting independent assessments will be technically qualified and knowledgeable in the areas assessed, and will focus on improving the quality of the processes that lead to the end product.						

APPENDIX III

ORGANIZATION



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