



**Office of Defense Nuclear Nonproliferation
Office of Fissile Materials Disposition**

**FISSILE MATERIALS DISPOSITION PROGRAM
QUALITY ASSURANCE REQUIREMENTS DOCUMENT**

September 2004

Revision 1

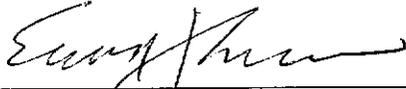
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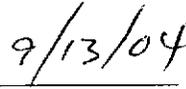
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Agreement

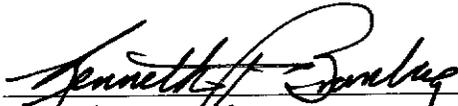
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Edward J. Siskin
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Approving Authority



Date



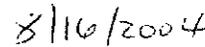
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**Fissile Materials Disposition Program
Quality Assurance Requirements Document (QARD)**

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**Office of Fissile Materials Disposition
Washington, D.C.**

FOREWORD

GENERAL

The National Nuclear Security Administration's (NNSA) Fissile Materials Disposition Program (FMDP) contributes to a reduction in the global nuclear danger associated with inventories of surplus weapons-usable fissile materials by developing strategies and implementing actions to (1) blend down surplus highly enriched uranium to make it non-weapons usable; (2) prepare surplus weapons pits for disposition by designing, constructing, and operating a Pit Disassembly and Conversion Facility (PDCF); (3) design, license, construct, and operate a Mixed Oxide (MOX) Fuel Fabrication Facility to produce MOX fuel from surplus plutonium oxide; (4) upgrade and license existing domestic reactors to irradiate MOX fuel; (5) conduct joint technical activities with Russia in support of efforts to dispose stockpiles of excess Russian plutonium; (6) work with Russia to build a MOX fuel fabrication facility with international contributions; and (7) support efforts to irradiate 34MT of surplus Russian weapons-grade plutonium that has been fabricated into MOX fuel.

The Office of Fissile Materials Disposition (OFMD) plans, manages and assesses work to support and implement Departmental decisions regarding the storage and disposition of surplus weapons-usable fissile materials. This work includes the preparation of technical, environmental and other analyses to support decision making; the performing of research and development activities necessary to assure the viability of disposition technologies; and the implementation of storage and disposition facility design and construction projects.

QUALITY ASSURANCE PROGRAM REQUIREMENTS

All work accomplished by Program participants shall be planned, performed, and assessed in accordance with approved management controls (i.e., quality assurance programs). These management controls shall be developed from specified quality assurance program requirements that have been selected (graded) as appropriate for the work to be performed.

The FMDP mission involves multiple activities. As a result, the FMDP quality assurance program requirements are governed by two federal regulations, one departmental order, and a national consensus standard. The purpose of this Quality Assurance Requirements Document is to help clarify the application of these requirements to the performance of specific work assignments.

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Acronyms & Abbreviations

A/E	Architecture/Engineering Firm
ADA	Assistant Deputy Administrator
ANSI	American National Standards Institute
AOP	Annual Operating Plan
ASME	American Society of Mechanical Engineers
DCS	Duke, Cogema, and Stone & Webster
ASQC	American Society for Quality Control
DOE	United States Department of Energy
EA	Environmental Assessment
EIS	Environment Impact Statement
DNFSB	Defense Nuclear Facilities Safety Board
FMDP	Fissile Materials Disposition Program
HEU	Highly Enriched Uranium
HQ	DOE/NNSA Headquarters
MFFF	MOX Fuel Fabrication Facility
MOX	Mixed Oxide Fuel
MPQAP	MOX Project Quality Assurance Plan
NEPA	National Environmental Policy Act
NQA	Nuclear Quality Assurance
NQA-1	<i>Quality Assurance Program Requirements for Nuclear Facility Applications</i>
NRC	United States Nuclear Regulatory Commission
OFMD	Office of Fissile Materials Disposition
PDCF	Pit Disassembly and Conversion Facility
PIC	Person-in-charge
QA	Quality Assurance
QAP	Quality Assurance Program
QARD	Quality Assurance Requirements Document
SAR	Safety Analysis Report
SRS	Savannah River Site
WGI	Washington Group International, Inc.

FISSILE MATERIALS DISPOSITION PROGRAM QUALITY ASSURANCE REQUIREMENTS DOCUMENT

1.0 INTRODUCTION

1.1 Purpose

The purpose of the Fissile Materials Disposition Program (FMDP) quality assurance program requirements is to establish effective management controls (i.e., quality assurance programs) over work performed using specified performance requirements, coupled with technical standards where appropriate, that ensure:

- a. Senior management provides planning, organization, direction, control, and support to achieve FMDP's objectives;
- b. Line organizations achieve and maintain quality;
- c. Each Program participant reviews, evaluates, and improves its overall performance and that of its subcontractors using an aggressive assessment process based upon an approved Quality Assurance Program (QAP).

1.2 Scope

This Quality Assurance Requirements Document (QARD) establishes the quality assurance (QA) requirements for FMDP managed work performed in the United States and is applicable to all FMDP funded work performed by Program participants. Program participants include the Office of Fissile Materials Disposition (OFMD), NNSA Site and DOE Operations Offices, other governmental agencies, National Laboratories, and prime contractors and subcontractors. FMDP work includes the research, development, design, construction, startup, operation, and decontamination and decommissioning of new or modified FMDP facilities and equipment; the design and qualification of MOX fuel; the modification of existing reactors for use of MOX fuel; and, the blend down of surplus highly enriched uranium to make it non-weapons usable.

1.3 Quality Assurance Program Basis

The FMDP QAP is based on the following fundamental principles:

- a) The extent to which management controls are specified and implemented will reflect the anticipated risks (both the probability and the consequences) of an event adversely affecting the public or workers' health and safety, the environment, or the FMDP mission.

- b) The principles and practices specified in this document apply to all aspects of work performed for the FMDP.
- c) The achievement of quality is a personal responsibility wherein each manager, supervisor, and worker is individually accountable for the quality of his or her work.
- d) Quality achievement needs to be verified or validated by individuals or groups other than those who performed the work.
- e) The assurance of quality involves the interaction of many organizational components and should not be regarded as the sole responsibility of any single group.
- f) The implementation of effective management controls will ensure that work is planned, performed and assessed to verify quality and process effectiveness together with a system for improvement.

1.4 Quality Assurance Program Requirements Applicability

This QARD identifies and amplifies the QAP federal regulations and NNSA/DOE order requirements that are applicable to participants and their contractors performing FMDP work. For activities potentially affecting public or worker health and safety or the environment, the quality assurance program requirements are specified by federal regulations. The applicable regulations are 10 CFR 50, Appendix B, *Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants*, for NRC regulated nuclear facilities and 10 CFR 830, Subpart A - *Quality Assurance Requirements*, for non-NRC regulated nuclear facilities. Specific QAP requirements associated with the Mixed Oxide (MOX) Fuel Project-related activities are found in the NRC-approved MOX Project Quality Assurance Plan (MPQAP).

Work associated with the design and construction of non-NRC regulated nuclear facilities shall be performed in accordance with the applicable criteria of 10 CFR 830.122, *Quality Assurance Criteria*, supplemented with the requirements of ASME NQA-1-1997 (or subsequent edition), *Quality Assurance Requirements for Nuclear Facility Applications*. OFMD requires that FMDP participants' activities be conducted in accordance with an OFMD-approved QAP.

Work not directly affected by the regulations referenced in the previous paragraphs [e.g., NNSA Headquarters (OFMD), NNSA Site and DOE Operations Offices, and their supporting contractors] shall be conducted in accordance with the applicable QAP criteria contained in DOE Order 414.1B, (or subsequent revision) *Quality Assurance*, supplemented, where necessary, by the more prescriptive requirements of ASME NQA-1-1997 (or subsequent edition), *Quality Assurance Requirements for Nuclear Facility Applications*.

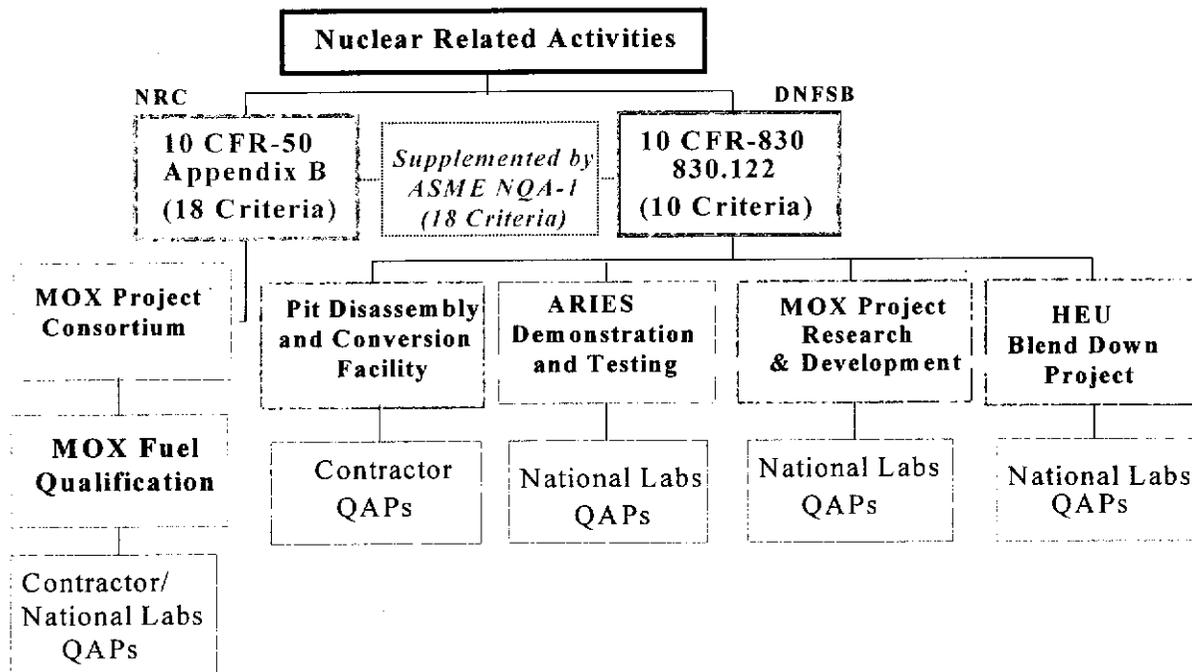
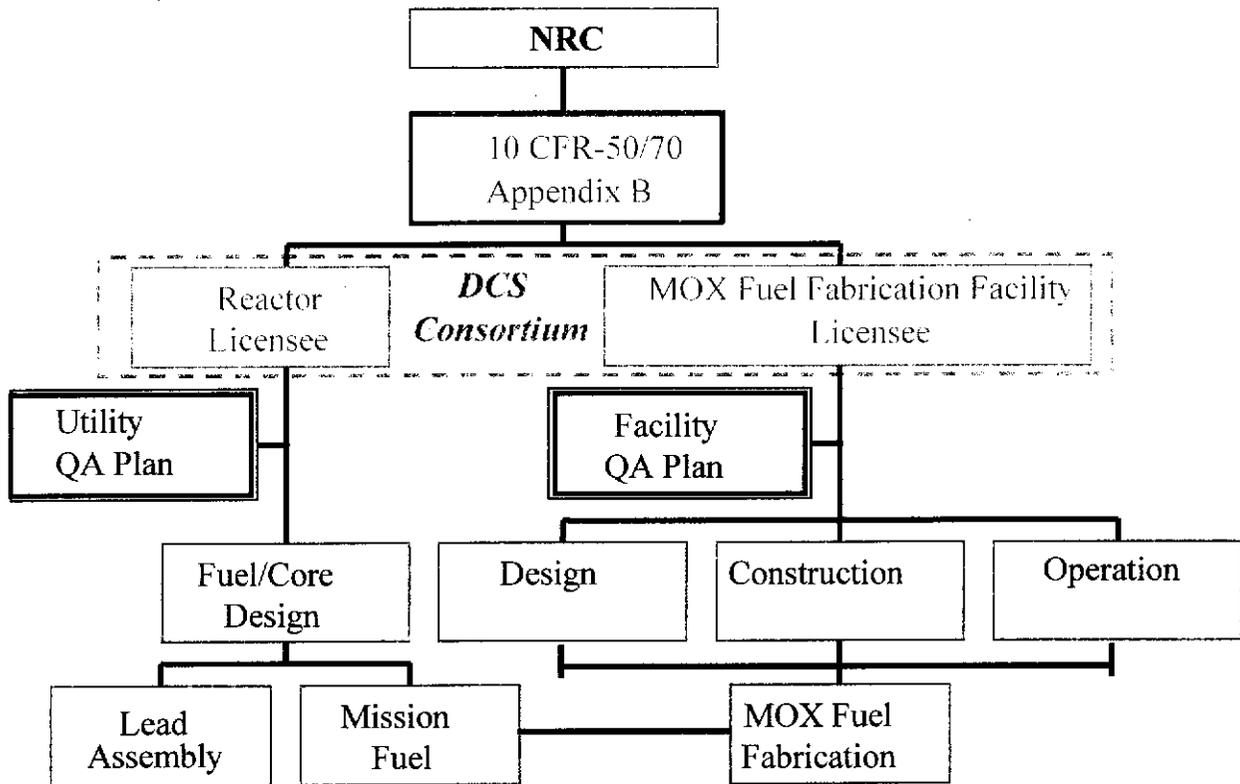


Figure 1 - FMDP Quality Assurance Requirements for Nuclear Related Activities

NNSA’s nuclear-safety related activities are either under the oversight of the Defense Nuclear Facilities Safety Board (DNFSB) or regulated by the Nuclear Regulatory Commission (NRC). Figure 1 graphically depicts the relationship of these agencies to FMDP activities, and identifies the applicable QAP requirements. Figure 2 graphically depicts the relationship between the FMDP, the NRC, and the MOX fuel fabrication and irradiation services provided by a consortium comprised of Duke, Cogema, and Stone & Webster (DCS).

Risk is the fundamental consideration in determining the extent to which the QAP requirements are selected for application. Risk is a quantitative and/or qualitative expression of possible loss which considers both the probability of the event occurrence causing harm or the loss and the consequences of that event. The degree to which management controls are applied to an item or process (termed “grading”) is to be determined by the responsible technical staff during the planning stages, using, where available, proven risk-related information. Critical items or processes (e.g., those that may impact environmental, safety and health (ES&H), or mission accomplishment) may require extensive controls throughout all stages of development. Less critical items or processes may require only limited controls.

Figure 2 - NRC Quality Assurance Requirements



The selection of appropriate management controls should be commensurate with factors such as the probability and consequences of failure; MOX fuel qualification, fabrication, and irradiation activities and related facilities that are licensed by the NRC; NNSA nuclear facilities and processes that are monitored by the DNFSB; a supplier’s product quality history; the importance of data to be generated; the complexity or uniqueness of a design or fabrication process; the ability to demonstrate compliance with specified requirements during receipt inspection; potential impact on the environment; and the potential for adverse effects on FMDP objectives, such as performance, schedule and/or costs.

Participants’ technical staffs, with the support of quality assurance personnel, shall determine the management controls necessary to provide an appropriate level of confidence that the work to be performed will result in a product that meets or exceeds FMDP specified requirements. Using the appropriate quality assurance program requirements document, as shown in Figure 1, the staff shall select (grade) appropriate management controls (a quality assurance program) required to ensure, with a desired level of confidence, that the resulting product satisfies all specified requirements.

1.5 Implementation

Program participants shall develop a QAP that addresses the appropriate QA requirements document(s) referenced in Section 1.4 which, as a minimum, meets the QA criteria of Section 2.0. Participants' assigned work that is not regulated by the NRC [e.g., Washington Group International, Westinghouse Savannah River Company, Los Alamos National Laboratory, Oak Ridge National Laboratory, designated construction contractors, and the OFMD National Environmental Policy Act (NEPA) support contractor] shall identify, prepare or revise, and submit a Quality Assurance Program (QAP) to the OFMD for concurrence. The QAP shall specify how the applicable requirements of this QARD will be satisfied. The MOX Project QA Plan (MPQAP) will be provided to the OFMD for information purposes only since the NRC has the primary responsibility for accepting the MPQAP.

The participant's QAP development process should consider the risks associated with the authorized work, and how the applicable QARD requirements will be applied to the performance, assessment, and delegation of assigned work. The extent to which management controls are to be applied shall be at the discretion of the responsible technical managers based on a consideration of the risks involved.

Participants shall further develop a set of written technical and QA administrative implementing procedures by which the performance, assessment, and delegation of work will be controlled. Existing or proposed implementing procedures shall be identified by reference or enumerated in the participant's QAP. These procedures or instructions shall specify who is responsible for the work and how it will be controlled. Participant's subcontractors shall prepare and submit a QAP to the participant for concurrence, unless the delegated work is to be performed in accordance with the participant's QAP. In this case, the participant shall identify the relevant QA documents applicable to a subcontractor.

Implementation of the approved QAPs shall be independently assessed in accordance with Paragraph 2.10 of this QARD, by the OFMD or by the participants who delegate or assign the work.

Further guidance regarding the application of each Criterion contained in DOE O 414.1B (or subsequent revision), and 10 CFR 830.122, can be found in DOE G 414.1-2, *Quality Assurance Management System Guide for use with 10 CFR Part 830.120 and DOE O 414.1*.

2.0 Quality Assurance Requirements

Program participants shall develop and implement a QAP which, as a minimum, implements the following DOE O 414.1B (or later revision) basic requirements, and integrates the QA criteria with the Safety Management System, including safety software development, for nuclear-safety related activities. In addition, participants shall selectively apply the supplemental requirements from NQA-1 (1997 or later edition), or other appropriate national or international consensus standard specified in the Order, during the development of their QAPs. Participants shall selectively impose these requirements upon their subcontractors by inclusion or reference in documents such as annual operating plans (AOP), work authorization statements, purchase orders, contracts, specifications, or similar documents which define the work to be performed.

2.1 Criterion 1 – Program

2.1.1 Basic Requirements

Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing the work. Establish management processes, including planning, scheduling, and providing resources for work.

2.1.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the management controls specified in sections 2.1.3, 2.1.4, and 2.1.5, and the more prescriptive management controls of NQA-1, Requirement 1 and Requirement 2 [paragraph 100(a)], shall also apply.

2.1.3 Computer Software Control

Computer software used to calculate or process data, or control the operation of items, shall be verified, validated, and controlled. Each Program participant shall control computer software development, procurement, testing, maintenance, and use in accordance with the requirements of NQA-1, Requirement 3, paragraph 800 & Requirement 11, paragraph 400; NQA-1, Subpart 2.7; or similar consensus standard requirements.

2.1.4 Stop Work

Each individual performing or observing work has the authority and responsibility to request that the person-in-charge (PIC) stop that work when it would: (1) either produce or conceal results not in accordance with significant Program requirements; or (2) produce results considered unacceptable; or (3) cause a significant degradation of either quality or a significant negative impact on cost, schedule, or the achievement of Program goals and objectives; or (4) result in a possible significant rework if work proceeds and is found deficient later.

The PIC shall adequately evaluate the request to reconfirm that the work is being performed as specified. The PIC shall inform the individual, in writing, of the resolution if the work is continued. The PIC shall stop work that is not being performed in accordance with specified requirements. Senior management shall not authorize the resumption of work until appropriate corrective action has been implemented, verified and documented.

2.1.5 Selection of QA Controls (Grading)

Participants shall develop a process to evaluate assigned work to determine the appropriate level of management controls (grading) based on the risks associated with the work to be performed. The process established for determining task specific management controls shall be submitted to the OFMD for acceptance (10CFR830.7).

Appendix A illustrates how management controls might be applied to items and processes based on the degree of confidence required in the quality of an item or process. The grading information in Appendix A is provided for guidance purposes rather than as a minimum set of QAP requirements. As noted in section 1.5, appropriate management requirements should be determined by the participant's technical management based on consideration of the program risks.

2.2 Criterion 2 – Personnel Training and Qualification

2.2.1 Basic Requirements

Train and qualify personnel to be capable of performing their assigned work. Provide continuing training to personnel to maintain job proficiency.

2.2.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirement 2, [paragraph 100(b) & paragraphs 200 - 500] shall also be applied.

2.3 Criterion 3 – Quality Improvement

2.3.1 Basic Requirements

Establish and implement processes to detect and prevent quality problems. Identify, control, and correct items, services, and processes that do not meet established requirements. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning. Review item characteristics, process implementation, and other quality-related information to identify items, services and processes needing improvement.

2.3.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirements 15 and 16 shall also be applied.

2.4 Criterion 4 – Documents and Records

2.4.1 Basic Requirements

Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design. Specify, prepare, review, approve, and maintain records.

2.4.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirements 5, 6 and 17 shall also be applied.

2.5 Criterion 5 – Work Processes

2.5.1 Basic Requirements

Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, or other appropriate means. Identify and control items to ensure their proper use. Maintain items to prevent their damage, loss, or deterioration. Calibrate and maintain equipment used for process monitoring or data collection.

2.5.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirements 5, 8, 9, 12, 13 & 14 shall also be applied.

2.6 Criterion 6 – Design

2.6.1 Basic Requirements

Design items and processes using sound engineering/scientific principles and appropriate standards. Incorporate applicable requirements and design bases in design work and design changes. Identify and control design interfaces. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work. Verify/validate work before approval and implementation of the design.

2.6.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirement 3 shall also be applied.

2.7 Criterion 7 – Procurement

2.7.1 Basic Requirements

Procure items and services that meet established requirements and perform as specified. Evaluate and select prospective suppliers on the basis of specified criteria. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.

2.7.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirements 4 and 7 shall also be applied.

2.8 Criterion 8 – Inspection and Acceptance Testing**2.8.1 Basic Requirements**

Inspect and test specified items, services, and processes using established acceptance and performance criteria. Calibrate and maintain equipment used for inspections and tests.

2.8.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirements 10, 11, and 12 shall also be applied.

2.9 Criterion 9 – Management Assessment**2.9.1 Basic Requirements**

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

2.9.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1 Requirement 2, [paragraph100(c)] shall also be applied.

2.10 Criterion 10 – Independent Assessment**2.10.1 Basic Requirements**

Plan and conduct independent assessments (audits and surveillance) to measure item and service quality, to measure the adequacy of work performance, and to promote improvement. Establish sufficient authority, and freedom from the line management, for the independent assessment teams. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.

2.10.2 Supplemental Requirements

During the siting, system and component development, design, construction and operations of a nuclear facility, the more prescriptive management controls of NQA-1, Requirement 18 shall also be applied.

3.0 Revision History

<u>Revision</u>	<u>Description</u>	<u>Approval Date</u>
0	Initial Issue	January 4, 1999
1	General updates necessitated by changes to the scope of work managed by the OFMD, editorial changes made to the QAP requirements of 10CFR830.122 and DOE O 414.1B, and clarification of the QAP requirements applicable to the MOX Fuel Project.	September 13, 2004

GLOSSARY

Assessment/Verification. The act of reviewing, inspecting, testing, checking, conducting surveillance, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. The terms assessment and verification, as used in this document, are synonymous; their use is determined by the person who is responsible for the oversight activity. Managers are typically responsible for assessments and verifications are typically conducted by personnel not responsible for the work.

Critical. An expression of relative importance based on the function of an item or process in relation to the health and safety of the public and FMDP workers, the environment, and/or the NNSA mission.

Item. An all-inclusive term used in place of any of the following: appurtenance, facility, sample, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, unit, documented concepts, or data.

Line Management (Line). The manager or managers responsible for the day-to-day accomplishment of work associated with the siting, design, development, construction, startup, operation, and decontamination and decommissioning of new or modified facilities and equipment and the blend down of surplus highly enriched uranium to make it non-weapons usable.

Process. A series of actions that achieves an end or result.

Program participant. Any organization which is funded to perform FMDP work is considered a Program participant. Program participants include the OFMD, NNSA Site and DOE Operations Offices, other governmental agencies, Architect/Engineering firms, Construction Contractors, National Laboratories, and their subcontractors.

Quality. The degree to which an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance. Actions that provide confidence that quality is achieved.

Quality Assurance Program. The overall system of management controls established by a Program participant to implement the requirements of this document. The QA Program assigns responsibilities and authorities, defines policies and requirements, and provides for the performance and assessment of work.

Qualification. A formal process that is intended to provide a desired level of confidence that the item meets specified criteria.

GLOSSARY (Continued)

Risk. A quantitative and/or qualitative expression of possible loss which considers both the probability of an occurrence causing harm or loss and the consequences of that event.

Safety Software.

Safety System Software, which performs a safety system function as part of a structure, system, or component (SSC) that has been functionally classified as safety class (SC) or safety significant (SS). Includes human-machine interface software, network interface software, programmable logic controller programming language software, and safety management databases that are not part of an SSC, but whose operation or malfunction can directly affect SS or SC SSC function (see 10CFR830.2).

Safety Analysis and Design Software, which is not part of an SSC but is used in the safety classification, design, and analysis of nuclear facilities to ensure proper accident analysis of nuclear facilities; proper analysis and design of safety SSCs; and proper identification, maintenance, and operation of safety SSCs.

Service. The performance of work, such as design, fabrication, inspection, nondestructive examination, repair, or installation.

Senior Management. The manager or managers responsible for mission accomplishment and overall operations. The NNSA Administrator and the Deputy Administrator for Defense Nuclear Nonproliferation through the Assistant Deputy Administrator (ADA) for Fissile Materials Disposition (FMD), are responsible for mission accomplishment and overall operations. Within the OFMD, senior management includes the Associate ADA for FMD; Director, Office of Disposition Projects; Director, Office of Materials & Conversion; Director, Office of International Programs; Director, Office of Program Integration; and Director, FMD Site Office/SRS. For National Laboratories, and prime and subcontractors, the Director, President, General Manager or similar top position is responsible for mission accomplishment and overall performance in accordance with the requirements of their contracts or other agreements.

Validation. An activity that demonstrates an item or process will perform under conditions of actual use and satisfy requirements of the user.

Work. The process of performing a defined task or activity; for example research and development, operations, maintenance and repair, administration, software development/validation/testing and use, inspection, safeguards and security, data collection, and analysis.

APPENDIX A**Graded Application of Quality Assurance Requirements (Management Controls) For Non-NRC Regulated Facilities and Activities**

The attached table provides guidance information regarding the selection of management controls for work that is managed by the OFMD and monitored by DNFSB. For this work scope, the appropriate QAP requirements documents are the DOE regulation 10CFR Part 830.120, Subpart A for nuclear-related activities) and DOE Order 414.1B (or later revision) for non-nuclear and OFMD management activities. In both QAP requirements documents, the specified management controls have been defined in 10 criteria which are supplemented within the FMDP by the more prescriptive requirements of NQA-1.

The first column on the left of the table lists the 10 management controls criteria. The three columns to the right of the criteria column identify examples of assigned work with the level of risk increasing from left to right. In the first column, the activities identified present little public health and safety or project risk therefore only a limited number of management controls were selected.

The work examples in the middle column identify activities that result in risks to the FMDP mission/project objectives. For these examples, the applicable management controls are specified by basic criteria of the DOE regulation or Order. No additional QAP requirements are considered necessary to provide confidence that the work will be performed correctly.

The third column examples include the design and construction of a nuclear facility such as the Pit Disassembly and Conversion Facility (PDCF). The lack of sufficient management controls during the design, construction, and operation of the PDCF, or during HEU blend-down operations at DOE/NNSA facilities could result in a risk to public health and safety or the inability of the facility to meet NNSA mission objectives; therefore, it is considered appropriate that the basic requirements of the DOE Regulation and Order be supplemented with the more prescriptive requirements of NQA-1, similar to the management controls required for the design, licensing, construction and operation of an NRC regulated nuclear facility.

Graded Application of Quality Assurance Requirements for Non-NRC Regulated Facilities & Activities

10 CFR Part 830.122 or DOE O 414.1B QA Criteria	APPLIED TO:		
R & D Activities, including the development of Test Facilities or Test Articles, Scoping Investigations or EIS and CDR preparation.	Development Testing Activities or Environmental Monitoring.	Facility, activity, or item that could adversely affect public health and safety, or significantly affect FMDP mission objectives, e.g. design and construction of the PDCF or HEU blend-down operations at DOE/NNSA facilities.	
Criterion 1: Program	DOE O 414.1B, para. 4.a & b or 10 CFR § 830.121 & 122, para.(a) to include the following criteria :	DOE O 414.1B, para. 4.a & b or 10 CFR § 830.121 & 122, para. (a) and NQA-1 Requirement 1 & Requirement 2, para. 100(1) to include the following criteria:	
Criterion 2: Personnel Training and Qualification	N/A	DOE O 414.1B, para. 4.b(2) or 10 CFR § 830.122, para. (b)	DOE O 414.1B, para. 4.b(2) or 10 CFR § 830.122, para. (b) and NQA-1, Requirement 2, para.100(b) & 200 - 500
Criterion 3: Quality Improvement	N/A	DOE O 414.1B, para. 4.b(3) or 10 CFR § 830.122, para. (c)	DOE O 414.1B, para. 4.b(3) or 10 CFR § 830.122, para. (c) and NQA-1, Requirement 15 and 16
Criterion 4: Documents and Records	DOE O 414.1B, para. 4.b(4)	DOE O 414.1B, para. 4.b(4) or 10 CFR § 830.122, para. (d)	DOE O 414.1B, para. 4.b(4) or 10 CFR § 830.122, para. (d) and NQA-1, Requirements 5, 6, and 17
Criterion 5: Work Processes	DOE O 414.1B, para. 4.b(5)(d)	DOE O 414.1B, para. 4.b(5) or 10 CFR § 830.122, para. (e)	DOE O 414.1B, para. 4.b(4) or 10 CFR § 830.122, para. (e) and NQA-1, Requirements 8, 9,12, 13 and 14
Criterion 6: Design	DOE O 414.1B, para. 4.b(6)(d)	DOE O 414.1B, para. 4.b(6) or 10 CFR § 830.122, para. (f)	DOE O 414.1B, para.4.b(6) or 10 CFR § 830.122, para. (f) and NQA-1, Requirement 3
Criterion 7: Procurement	N/A	DOE O 414.1B, para. 4.b(7) or 10 CFR § 830.122, para. (g)	DOE O 414.1B, para. 4.b(7) or 10 CFR § 830.122, para. (g) and NQA-1, Requirements 4 and 7
Criterion 8: Inspection and Acceptance Testing	N/A	DOE O 414.1B, para. 4.b(8) or 10 CFR § 830.122, para. (h)	DOE O 414.1B, para. 4.b(8) or 10 CFR § 830.122, para. (h) and NQA-1, Requirements 10, 11, and 12

Graded Application of Quality Assurance Requirements for Non-NRC Regulated Facilities & Activities

APPLIED TO:			
10 CFR Part 830.122 or DOE O 414.1B QA Criteria	R & D Activities, including the development of Test Facilities or Test Articles, Scoping Investigations or EIS and CDR preparation.	Development Testing Activities or Environmental Monitoring.	Facility, activity, or item that could adversely affect public health and safety, or significantly affect FMDP mission objectives, e.g. design and construction of the PDCF or HEU blend-down operations at DOE/NNSA facilities.
Criterion 9: Management Assessments	N/A	N/A	DOE O 414.1B, para.4.b(9) or 10 CFR § 830.122, para. (i) and NQA-1, Requirement 2, para. 100(c)
Criterion 10: Independent Assessments	N/A	DOE O 414.1B, para. 4.b(10) or 10 CFR § 830.122, para. (j)	DOE O 414.1B, para. 4.b(10) or 10 CFR 830.122, para. (j) and NQA-1, Requirement 18
Scientific, Technical, and Process Computer Software	N/A	NQA-1, Requirement 3, para. 802	NQA-1 Requirement 3, para.800 and Requirement 11 para.400 or NQA-1, Subpart 2.7 or similar consensus standard