



A Basic Guide to EM's Quality Assurance Program



October 2009

Quality Assurance Program



Overview of the Office of Environmental Management (EM)

The Department of Energy (DOE) Office of Environmental Management (EM) is responsible for the risk reduction and cleanup of the environmental legacy of the Nation's nuclear weapons program, one of the largest, most diverse, and technically complex environmental programs in the world. The EM mission encompasses the entire spectrum of nuclear and non-nuclear facilities and activities such as design, engineering, construction, operation, surveillance and maintenance (S&M), and deactivation and decommissioning (D&D). The EM mission also includes complex operations related to nuclear and hazardous waste management, technology development, packaging, transportation, and large scale environmental restoration.

Fulfilling this mission safely, reliably, and correctly is paramount to maintaining public trust and well-being, protection of workers, safeguarding DOE assets, and advancing the future of the DOE nuclear mission.

An effective quality assurance (QA) program is at the center of EM's strategy to serve the American public in a competent, cost-effective, and accountable manner.

More information about the DOE and EM mission, organization, and resources can be found at:

<http://www.energy.gov>

and

<http://www.em.doe.gov>

What is EM's "Quality Assurance" Program?

The EM Quality Assurance Program (QAP) is based on the requirements of DOE Order O 414.1C, *Quality Assurance*, and 10 CFR 830 Subpart A "Quality Assurance Requirements." Additionally, EM has adopted the American Society of Mechanical Engineers (ASME) NQA-1-2004, **Quality Assurance Requirements for Nuclear Facility Applications**, as the national consensus standard for the implementation of its QAP.

Recognizing the diversity of EM operations, the NQA-1 requirements are applied in a graded approach to meet the needs of specific work conditions, activities, and hazards.

To obtain a copy of the EM QAP please contact the Office of Standards and Quality Assurance at (202) 586-5151.

For illustration purposes, a detailed comparison of 10 CFR 830, DOE O 414.1C, and NQA-1 requirements is presented in the Attachment.

What are EM's Expectations for Its Vendors?

Any organization that works for EM is expected to develop a Quality Assurance Program that meets the requirements of the EM QAP. Furthermore, EM expects that all of its contractors and suppliers have in place an approved Quality Assurance Implementation Plan (QIP). The QIP must describe how the applicable requirements of the QAP are implemented and/or passed down to lower-tier organizations. A sample template for a generic QIP is provided on page 3 of this brochure.

For DOE Prime Contractors, the approving authority for the QIP is generally the immediate manager of the EM organization that sponsors and/or oversees the work performed by the contractor. Lower-tier subcontractors and vendors will have their QIP reviewed and approved by the Prime Contractor.



What does a QA Implementation Plan (QIP) Look Like?

Table 1 below presents a template for the development of an organization-specific QIP. The key to an effective QIP is to ensure that there are robust processes and procedures in place that govern the day-to-day application of QA to how work is performed, services are provided, and products are made.

Table 1. Template for a Quality Assurance Implementation Plan (QIP)

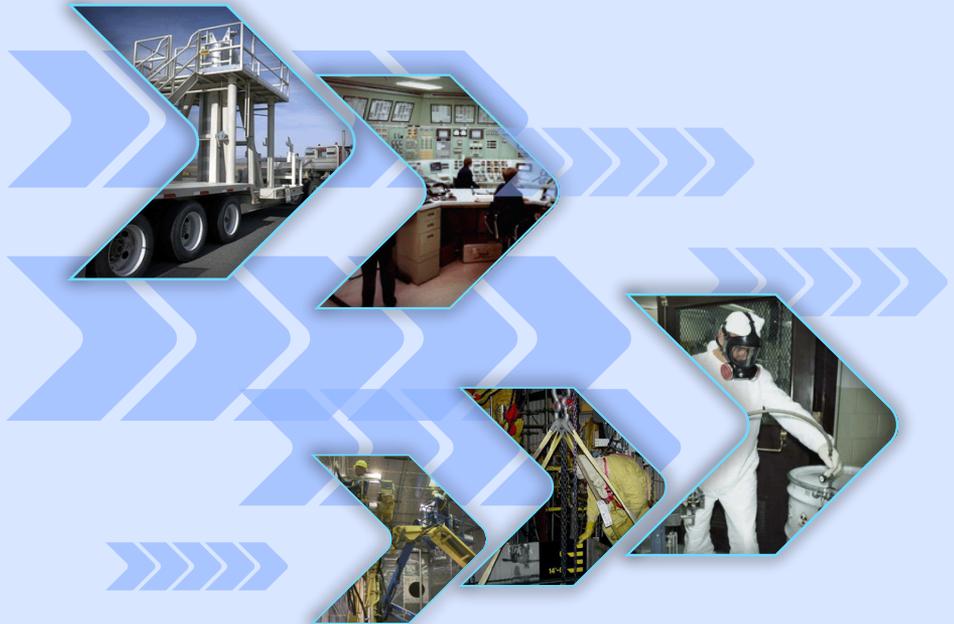
DOE O 414.1C Criteria	Key Processes	Implementing Procedures
Management/Criterion 1 - Program		
1. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing work.		
2. Establish management processes, including planning, scheduling, and providing resources for work.		
Management/Criterion 2—Personnel Training and Qualification		
1. Train and qualify personnel to be capable of performing assigned work.		
2. Provide continuing training to personnel to maintain job proficiency.		
Management/Criterion 3—Quality Improvement		
1. Establish and implement processes to detect and prevent quality problems.		
2. Identify, control, and correct items, services, and processes that do not meet established requirements.		
3. Identify the causes of problems, and include prevention of recurrence as a part of corrective action planning.		
4. Review item characteristics, process implementation, and other quality-related information to identify items, services, and processes needing improvement.		
Management/Criterion 4—Documents and Records		
1. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish design.		
2. Specify, prepare, review, approve, and maintain records.		

Table 1. Template for a Quality Assurance Implementation Plan (QIP)
(Continued)

DOE O 414.1C Criteria	Key Processes	Implementing Procedures
Performance/Criterion 5—Work Processes		
1. Perform work consistent with technical standards, administrative controls, and hazard controls adopted to meet regulatory or contract requirements using approved instructions, procedures, etc.		
2. Identify and control items to ensure their proper use.		
3. Maintain items to prevent their damage, loss, or deterioration.		
4. Calibrate and maintain equipment used for process monitoring or data collection.		
Performance/Criterion 6—Design		
1. Design items and processes using sound engineering/scientific principles and appropriate standards.		
2. Incorporate applicable requirements and design bases in design work and design changes.		
3. Identify and control design interfaces.		
4. Verify/validate the adequacy of design products using individuals or groups other than those who performed the work.		
5. Verify/validate work before approval and implementation of the design.		
Performance/Criterion 7—Procurement		
1. Procure items and services that meet established requirements and perform as specified.		
2. Evaluate and select prospective suppliers on the basis of specified criteria.		
3. Establish and implement processes to ensure that approved suppliers continue to provide acceptable items and services.		
Performance/Criterion 8—Inspection and Acceptance Testing		
1. Inspect and test specified items, services, and processes using established acceptance and performance criteria.		
2. Calibrate and maintain equipment used for inspections and tests.		

Table 1. Template for a Quality Assurance Implementation Plan (QIP)
(Continued)

DOE O 414.1C Criteria	Key Processes	Implementing Procedures
Assessment/Criterion 9—Management Assessment		
1. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.		
Assessment/Criterion 10—Independent Assessment		
1. Plan and conduct independent assessments to measure item and service quality and the adequacy of work performance and to promote improvement.		
2. Establish sufficient authority and freedom from line management for independent assessment teams.		
3. Ensure that persons conducting independent assessments are technically qualified and knowledgeable in the areas to be assessed.		
Appendix A – Suspect/Counterfeit Items Prevention		
Appendix B – Corrective Action Management Program		
Appendix C – Safety Software Quality Requirements		



Background Information about Select Voluntary Consensus Standards

Office of Management and Budget (OMB) Circular A-119 directs Federal agencies, such as the Department of Energy, to use voluntary consensus standards. Voluntary consensus standards are *voluntary*, in that users select the one standard or combination of standards that best serves their purpose. Once selected and incorporated into licensing documents or contracts, the standard or standards become *mandatory* for the work the user designates. Voluntary *consensus* standards are consensus because they are developed by “standards bodies” (e.g., American National Standards Institute (ANSI) and American Society of Mechanical Engineers (ASME) and International Organization for Standardization (ISO)) consisting of private sector and Federal representatives.

Voluntary consensus standards provide detailed information and guidance on “how to” meet requirements. There are a number of nuclear-related voluntary consensus standards, each with a different focus and constituency. The most widely accepted and used consensus standards in the United States are ANSI/ASME NQA-1 and ISO 9000 series¹.

As mentioned earlier, EM has adopted the American Society of Mechanical Engineers (ASME) NQA-1-2004, **Quality Assurance Requirements for Nuclear Facility Applications**, as the national consensus standard for the implementation of its QAP.



¹ NQA-1 and ISO-9001 provide strong foundations on which an organization can build a QA Program that meets the requirements of 10 CFR 830.120 and Order 414.C.

ANSI/ASME NQA-1

NQA-1 is a management system organized into 18 requirements. It is based on the Nuclear Regulatory Commission (NRC) 10 CFR 50, Appendix B for regulation of the commercial nuclear industry. Appendix B is primarily focused on inspection, documentation, and program development.² NQA-1 is a multi-part Standard which includes 18 Requirements and Non-mandatory Guidance to establish and implement QA requirements for any nuclear-related application. These include:

- **Part I**
Contains QA program requirements for nuclear facilities.
Part I is mandatory.
- **Part II**
Contains QA requirements for nuclear facility applications.
Part II is mandatory.
- **Part III**
Contains non-mandatory guidance and application appendices
- **Part IV**
Contains NQA position papers, application matrices for users, cross-reference comparisons to NQA-1, and other quality program information.

More information about NQA-1 can be found at:

<http://catalog.asme.org/Codes/>



² NRC NUREG-1055, Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants

ISO 9001

ISO 9001 is a *management system* organized into five quality management topics. It is part of a family of standards collectively known as the “ISO 9000 series.” Some of the requirements in ISO 9001 (which is one of the standards in the ISO 9000 family) include:

- Procedures that govern all key processes in the business;
- Monitoring processes to ensure they are effective;
- Maintaining adequate records;
- Checking output for defects, with appropriate and corrective action where necessary;
- Regularly reviewing individual processes and the quality system itself for effectiveness; and
- Facilitating continuous improvement.

More information about ISO 9001 can be found at:

<http://www.iso.org>

What are the differences between ISO-9001 and NQA-1?

Although there are fundamental similarities between ISO-9001 and NQA-1, there are significant gaps. For example, NQA-1 is primarily focused on assuring quality of the design, construction, and operation of a nuclear facility or operation. The ISO standard seeks to achieve quality by a process that “promotes the adoption of a process approach when developing, implementing, and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.” Additionally, within the ISO 9001-2000 Standard there exist terms and usage that are unique and, therefore, differences exist with the terms used within the NQA-1 Standard.

For a detailed and comprehensive analysis of the differences between ISO 9001-2000 and NQA-1, please refer to ASME NQA-1, Subpart 4.3, *Guide to Modification of an ISO 9001-2000 Quality Program to Meet NQA-1 Requirements*.

How Do I Establish a QA Program?

The following provides the basic steps involved in the development and implementation of a QA program.

- **Establish a Baseline - Where are you Today**
 - This could range from “Nothing” to “Full Management System with QA Integrated into the way you do your Business”
 - Determine if you have internal resources who can develop and apply QA Requirements
 - If internal resources are not available, acquire outside assistance
- **Identify the Base QA Standard for your Program³**
 - For EM, this is NQA -1
- **Review your Existing Systems, Processes, Procedures, etc., against the Criteria in Selected NQA-1 Standard**
 - Determine which Criteria apply to your Products and Services
 - Complete a Gap Analysis to identify changes needed in your current system/way of doing business
- **Develop a Quality Assurance Implementation Plan (QIP) that describes how the applicable requirements of the QAP are implemented and/or passed down to lower-tier organizations.**
 - Improve quality of products and services
- **Monitor and Assess Effectiveness**
 - Implement the needed changes

³ EM QA Program is based on American Society of Mechanical Engineers (ASME) NQA-1-2004, Quality Assurance Requirements for Nuclear Facility Applications, and Addenda Through 2007.

Attachment

10 CFR 830 (DOE Order 414.1C) and NQA-1 Crosswalk⁴

	ASME NQA-1						
	1. Organization	2. Quality Assurance Program	3. Design Control	4. Procurement Document Control	5. Instructions, Procedures and Drawings	6. Document Control	7. Control of Purchased Items and Services
10 CFR 830 (DOE O 414.1C) Criteria							
QA Requirements							
1. Program	●	●					
2. Personnel Training and Qualification		●					
3. Quality Improvement		●					
4. Documents and Records					●	●	
5. Work Processes					●		
6. Design			●				
7. Procurement				●			●
8. Inspection and Acceptance Testing							
9. Management Assessment							
10. Independent Assessment	●	●					
Other Requirements							
a. Software QA							
b. Suspect/Counterfeit Items							
c. Grading							

8. Identification and Control of Items	9. Control of Special Processes	10. Inspection	11. Test Control	12. Control of Measuring and Test Equipment	13. Handling, Storage, and Shipping	14. Inspection Test, and Operating Status	15. Control of Non-conforming Items	16. Corrective Action	17. Quality Assurance Records	18. Audits	Subpart 2.7
●	●			●	●	●	●	●	●		
●		●	●	●							
		●	●				●	●		●	
											●

⁴ This comparison is for illustrative purposes only. The details of individual programs using these basic requirements will vary according to licensing conditions, contract requirements, and regulatory specifics.

Points of Contact

For additional information or assistance, please contact:

■ **Bob Murray**

Acting Director, Standards and Quality Assurance (EM-64)

Office of Environmental Management

Phone: (202) 586-7267

robert.murray@em.doe.gov