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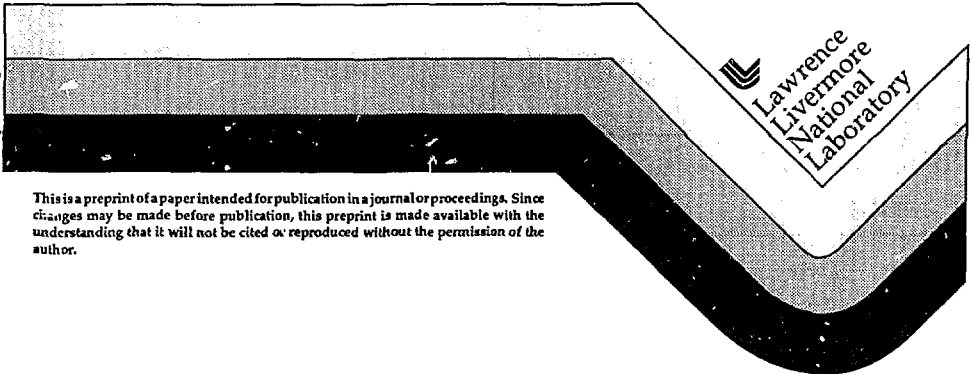
## Making the Transition to ANSI/ASQC E4

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CONF 1113

This paper was prepared for submittal to the  
American Society for Quality Control (ASQC) 19th Annual  
National Energy & Environmental Quality Division Conference  
Orlando, Florida  
September 20-23, 1992

July 1992



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STATUS OF ANSI/ASQC-E4-19XX -  
HARMONIZING QA REQUIREMENTS FOR ENVIRONMENTAL PROGRAMS

MAKING THE TRANSITION TO ANSI/ASQC E4

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ABSTRACT

As ANSI/ASQC E4, *Quality Systems Requirements for Environmental Programs*, nears final form and formal issuance by the American National Standards Institute (ANSI) and the American Society for Quality Control (ASQC), numerous organizations will be developing and implementing quality assurance programs based on the criteria promulgated by ANSI/ASQC E4. The organizations to initially adopt ANSI/ASQC E4 will be those that already have quality assurance programs based either on ASME NQA-1<sup>(1)</sup> or EPA QAMS-005/80<sup>(2)</sup>. This paper presents the changes/enhancements required to transition an ASME NQA-1 or EPA QAMS-005/80 based quality assurance program to a program which meets the requirements of ANSI/ASQC E4.

INTRODUCTION

ANSI/ASQC E4, *Quality Systems Requirements for Environmental Programs*, is the first national consensus standard for quality assurance programmatic requirements prepared specifically for environmental programs. It is also the first standard designed

<sup>1</sup> ASME NQA-1, *Quality Assurance Program Requirements for Nuclear Facilities*, 1989 Edition, American National Standards Institute.

<sup>2</sup> U.S. EPA, *Interim Guidelines and Specifications for Preparing Quality Assurance Project Plans (QAMS-005/80)*, December 29, 1980.

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to satisfy the requirements of the U.S. Department of Energy (DOE) Order 5700.6C<sup>3</sup>. Upon formal issuance of ANSI/ASQC E4 (E4), numerous organizations will develop and implement quality assurance programs based on its requirements. Because of the significant level of support and endorsement the DOE and the Environmental Protection Agency (EPA) have given the development of E4, organizations have already begun developing quality assurance programs based on early draft versions of E4.

There is a large population of potential users of E4. Included are organizations involved in EPA funded and regulated programs, DOE environmental restoration programs, Department of Defense (DoD) environmental programs, State regulated environmental programs, and industry sponsored environmental programs. The kind of activities which may incorporate E4 include environmental restoration, hazardous, radioactive, and mixed waste cleanup, industrial waste treatment, pollution monitoring and control, and environmental monitoring. The most immediate users are organizations involved in DOE environmental programs and EPA sponsored or regulated programs. Both of these groups are currently following the quality assurance programmatic requirements embodied in ASME NQA-1 (NQA-1) or QAMS-005/80 or both. The purpose of this paper is to outline the primary differences between E4 and standards currently being used and to present guidance on the changes and enhancements required to transition an NQA-1 or QAMS-005/80 based quality assurance program to a program which meets the requirements of E4.

#### BASIS OF ANSI/ASQC E4

E4 is a modern quality standard which focuses on establishing a quality system that enhances performance for the purpose of satisfying customer expectations. This is a fundamental change of philosophy from those used in NQA-1 and QAMS-005/80. NQA-1 is a requirements based standard and EPA QAMS-005/80 is primarily a set of instructions and does not take the approach of establishing criteria. E4, on the other hand, takes a Total Quality Management (TQM) approach to quality system design. The teachings of Dr. Edwards Deming<sup>4</sup> and the guidance of ANSI/ASQC Q94<sup>5</sup> are used in the tone and presentation throughout E4 and provide the basis for several of its elements. While the approach to E4 is considerably different, the proven concepts of NQA-1 and QAMS-005/80 have been retained and provide the basis for much of E4. Therefore, programs developed from either NQA-1 or QAMS-005/80 will meet a

<sup>3</sup>U.S. DOE Order 5700.6C, *Quality Assurance*, August 21, 1991

<sup>4</sup>W. Edwards Deming, *Out of the Crisis*, Massachusetts Institute of Technology, Cambridge, 7th Printing, April 1989.

<sup>5</sup>ANSI/ASQC Q94, *Quality Management and Quality System Elements - Guidelines*, American Society for Quality Control, June 1987.

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portion of E4's requirements. However, such programs may need revision because of the change in emphasis that E4 places on certain elements and because E4 is a more complete standard for environmental programs than either NQA-1 or QAMS-005/80. Some of the primary changes from NQA-1 and QAMS-005/80 contained in E4 can be summarized as follows:

- Recognition of supplier/customer relationships
- Emphasis on management responsibility
- Emphasis on the importance of planning
- Establishment of both self and independent assessment at the management and technical levels
- Requirements for deliberate quality improvement efforts
- Orientation toward the quality of performance
- Recognition of the importance of resource considerations in the attainment of quality
- Specific criteria for computer hardware and software

The transition to E4 from an existing quality assurance program is discussed below. The changes, additions, and enhancements which may be required for first an NQA-1 based quality assurance program and then for a QAMS-005/80 based quality assurance program are outlined.

#### TRANSITIONING FROM AN ASME NQA-1 BASED PROGRAM

##### General

ASME-NQA-1 is intended as a complete quality assurance programmatic requirements document. However, NQA-1 evolved from the design, procurement, and construction of nuclear power plants and, while it can be easily adapted to manufacturing and operational situations, it is not easily translatable to environmental data operations. It lacks specific verbiage addressing sampling, analysis and other data collection activities. Over time NQA-1 has been updated to provide quality assurance requirements for computer software, however, such requirements are not part of the basic criteria and are addressed fragmentally in a supplement<sup>(6)</sup> and in a sister document, ASME-NQA-2<sup>(7)</sup>.

<sup>6</sup>ASME NQA-1, Supplement 11S-2

<sup>7</sup>ASME NQA-2a-1990 Addenda, Part 2.7, ASME NQA-2, *Quality Assurance Requirements for Nuclear Facility Applications*, 1989 Edition, American National Standards Institute.

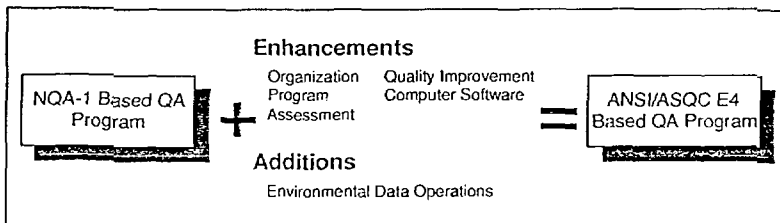
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Several of the criteria of NQA-1 are incorporated with little change other than the use of environmental terminology into E4. However, some criteria have been significantly enhanced by redirection of their emphasis based upon TQM principles and experience in the implementation of NQA-1 in the nuclear industry and within the DOE complex.

Most programs established in accordance with NQA-1 will adapt well to E4. There should be minimal fundamental changes required. As illustrated in Figure 1 and discussed below, some aspects of an NQA-1 based quality program may require evaluation, additions, and possible enhancement to meet E4.

Figure 1  
Considerations Required for an NQA-1 Based Program to Meet E4



### Organization

E4 emphasizes the role and responsibilities of management in the establishment and implementation of quality programs to a much greater extent than NQA-1. It establishes the principle of customer/supplier relationships and places significant responsibilities on management for guidance and definition of customer expectations. Programs should be carefully examined to ensure adequate coverage and tone in the area of organization. Revisions should be made appropriately.

### Program

Quality assurance programs established under NQA-1 are of two primary formats: 1) Those established organization wide when the organization performs only one technical activity. 2) Those established organization wide but are adapted to



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specific projects on a case by case basis using QA project plans. Due to the nature of environmental programs, there can be considerable quality assurance differences between data collection efforts, cleanup efforts, etc. Organizations that handle multiple environmental efforts should examine the format and structure of their quality assurance program to ensure that it provides for clear definition of different individual environmental program quality requirements. Those organizations that perform only a single environmental activity, such as pollution monitoring of a specific process, should not be impacted by this aspect of E4.

E4 contains extensive provisions for activity planning. This is because of the recognition that there is significant experience with environmental programs that have not reached their goals due to poor or inadequate planning. To meet the requirements of E4, a quality program should contain provisions for planning that provide for definition and accomplishment of each environmental program's technical and quality goals. NQA-1 specifically addresses planning only in a non mandatory appendix<sup>8)</sup> and not in its basic or supplementary requirements. Quality assurance programs established under NQA-1 should be carefully examined and updated to ensure that planning of both technical and quality aspects of work is adequately addressed.

There is a recognition in E4 of the importance of resources (e.g., funding, materials, personnel) in achieving and ensuring quality. This recognition is not present in NQA-1. Quality assurance programs established under NQA-1 should be examined to ensure that there are provisions to plan and provide adequate resources to achieve and ensure quality. Programs should recognize that there are resource limitations and other constraints that must be considered in establishing quality programs. Programs should provide for the grading of quality requirements to individual activities commensurate with their relative importance to the goals of individual environmental programs. Such grading should incorporate a cost/benefit analysis to assure that the appropriate level of quality is achieved at a cost commensurate with the relative risk presented by the environmental program.

There is a fundamental difference in purpose between NQA-1 and E4. NQA-1 is designed to provide quality assurance for nuclear safety reasons for facilities not yet designed or constructed. E4 is designed to provide quality assurance for activities dealing primarily with existing environmental conditions. The cost of an NQA-1 quality assurance program can be designed into the overall facility construction costs and included in decisions relative to the merit of the project. However, if a quality assurance program for an environmental project is so extensive and costly that the

<sup>8</sup>ASME NQA-1, Appendix 2A-2

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project is delayed or can not proceed, there may be a greater risk to human and environmental health and safety than if a less ambitious quality program is adopted.

#### Audits and Surveillance

In the area of audits NQA-1 and E4 differ considerable in their approach. NQA-1 addresses audits and auditing personnel extensively. Regardless of the original intent of the audit requirements of NQA-1, their implementation has historically involved very little attention to how effective a QA program is in support of the accomplishment of the technical goals of an organization. Audits have been performed by personnel who are independent of activities for compliance to QA program and procedural requirements. Evaluations of QA program effectiveness have focused on how effective the QA program is in meeting QA requirements. E4 takes a different approach to and emphasis in over sight of activities. E4 focuses on evaluation or assessment of the effectiveness of the QA program in achieving quality performance of activities not is not confined to procedural or QA program compliance. E4 also recognizes the importance of involving those personnel who are responsible for the performance of activities in the assessment of those activities. Quality assurance programs established under NQA-1 should be carefully examined and updated to ensure that they provide for both self and independent assessment, to ensure that they focus on the performance of activities by technically qualified individuals as well as procedural compliance, and to ensure that all levels of management are appropriately involved.

#### Environmental Data Operations

NQA-1 does not provide any guidance for the collection, evaluation and documentation of environmental data. Many QA programs have been recently modified to address such requirements. Quality assurance programs established under NQA-1 should be updated to address all of the environmental data collection quality assurance requirements presented in E4.

#### Corrective Action

NQA-1 requirements for corrective action are regressive and emphasize the identification and correction of quality problems in work accomplished (after the fact) and only mentions prevention in the context of preventing the recurrence of those identified problems. Experience indicates that the interpretation of this requirement has been a negative incentive during work performance (problems are bad, more problems



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are even worse). E4 takes a progressive approach and emphasizes quality improvement. Problems are treated as only one indication of the need for improvement. It is the purpose of E4 to promote continuous improvement regardless if problems are being encountered (the more improvement the better). Quality assurance programs established under NQA-1 should be carefully examined and updated to ensure that they provide for quality improvement and that the tone is progressive and positive.

#### Computer Hardware and Software

E4's quality assurance requirements for computer software are different than those of NQA-1 and NQA-2. While NQA-1 Supplement 11S-2 and E4 require software testing, E4 provides additional requirements for configuration management. At the same time, E4 is not as rigorous as the requirements of NQA-2 part 2.7. Quality assurance programs established under NQA-1 should be carefully examined and updated to ensure that the requirements of E4 are incorporated.

#### TRANSITIONING FROM AN EPA QAMS-005/80 BASED PROGRAM

##### General

QAMS-005/80 was not intended as a standard when it was issued in 1980. However, over the last 10 years with the emergence of the significant hazardous waste cleanup in the public sector and the hazardous, radioactive, and mixed waste cleanup and environmental restoration in the government sector, it has become a de facto standard. QAMS-005/80 is primarily a set of instructions and takes a cook book approach for the preparation of quality assurance project plans which specify an environmental project's specific data quality requirements. It is not a complete quality standard in the same sense as NQA-1. However, where as NQA-1 has no guidance on the subject of sampling and analysis and collection of environmental data. QAMS-005/80 and other related EPA guidance documents provide quality assurance principles for environmental data operations which have been proven over many years of application on EPA regulated and sponsored projects. The concepts of data quality objectives, quality control samples, sample custody, and assessment of data quality are well established in EPA guidance and not addressed in any comparable national standard.

While NQA-1 and QAMS-005/80 are different in both their approach and content they have several aspects in common. The concepts of organization and responsibilities, procedural controls, calibration, audits, and corrective action are shared

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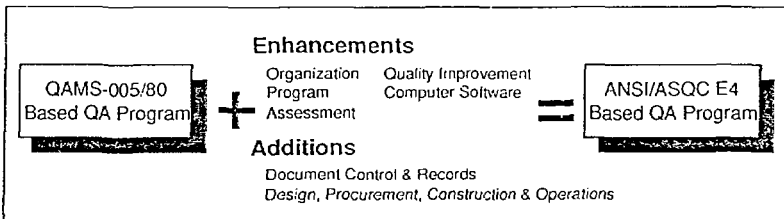


by both. QAMS-005/80 also introduces the quality concept of preventative maintenance. Preventative maintenance as a quality concept, could be applied to the operation of any facility.

Several of the requirements of QAMS-005/80 are incorporated with little change into E4. Changes of QAMS-005/80 requirements which are evident are the introduction of some TQM concepts and some enhancements to the more than 12 year old QAMS-005/80 requirements.

Quality assurance programs established in accordance with QAMS-005/80 will not adapt well the more programmatic requirements of E4. As illustrated in Figure 2 and discussed below, considerable additions, modifications and enhancements may be required for a QAMS-005/80 based quality assurance program to meet E4. For those areas that NQA-1 and QAMS-005/80 share in common, the same kinds of enhancements are required for a QAMS-005/80 based quality program as are for an NQA-1 based program. These areas are discussed above and include organization, program, audit (or assessment), and computer software. Considerations unique to a QAMS-005/80 program are discussed below.

Figure 2  
Considerations Required for a QAMS-005/80 Based Program to  
Meet E4



Program

There are no provisions for the establishment of an organization wide quality assurance program in QAMS-005/80. While QAMS-005/80 defines project or activity requirements for quality assurance it does not define institutional requirements. Quality programs designed to meet QAMS-005/80 should be reviewed and may require revision to define institutional quality assurance programmatic requirements.



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QAMS-005/80 contains no discussion of these topics and provides no quality assurance program requirements for their implementation. Quality assurance programs based solely on QAMS-005/80 will require both institutional and project level provisions for these subject areas.

CONCLUSIONS

This paper has presented guidance based on two scenarios for transitioning of existing quality assurance programs to E4. However, most quality assurance programs today have been rarely prepared in response to a single set of requirements. Therefore, it is highly likely that an existing quality system established for environmental programs will meet the majority of the requirements of E4. Since E4 is a modern quality standard, it embraces the concepts of TQM and incorporates lessons learned from both the nuclear and environmental quality assurance arenas. Existing quality programs should be examined closely and revised to incorporate the modern concepts of *Total Quality Management* and enhancements based on lessons learned from the nuclear and environmental industries that are presented in ANSI/ASQC E4.

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Work performed under the auspices of the U.S. Department of Energy by the Lawrence Livermore National Laboratory under contract number W-7405-ENG-48.