Quality Management Systems in Environmental Monitoring: Is that report really right?

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15. SUBJECT TERMS

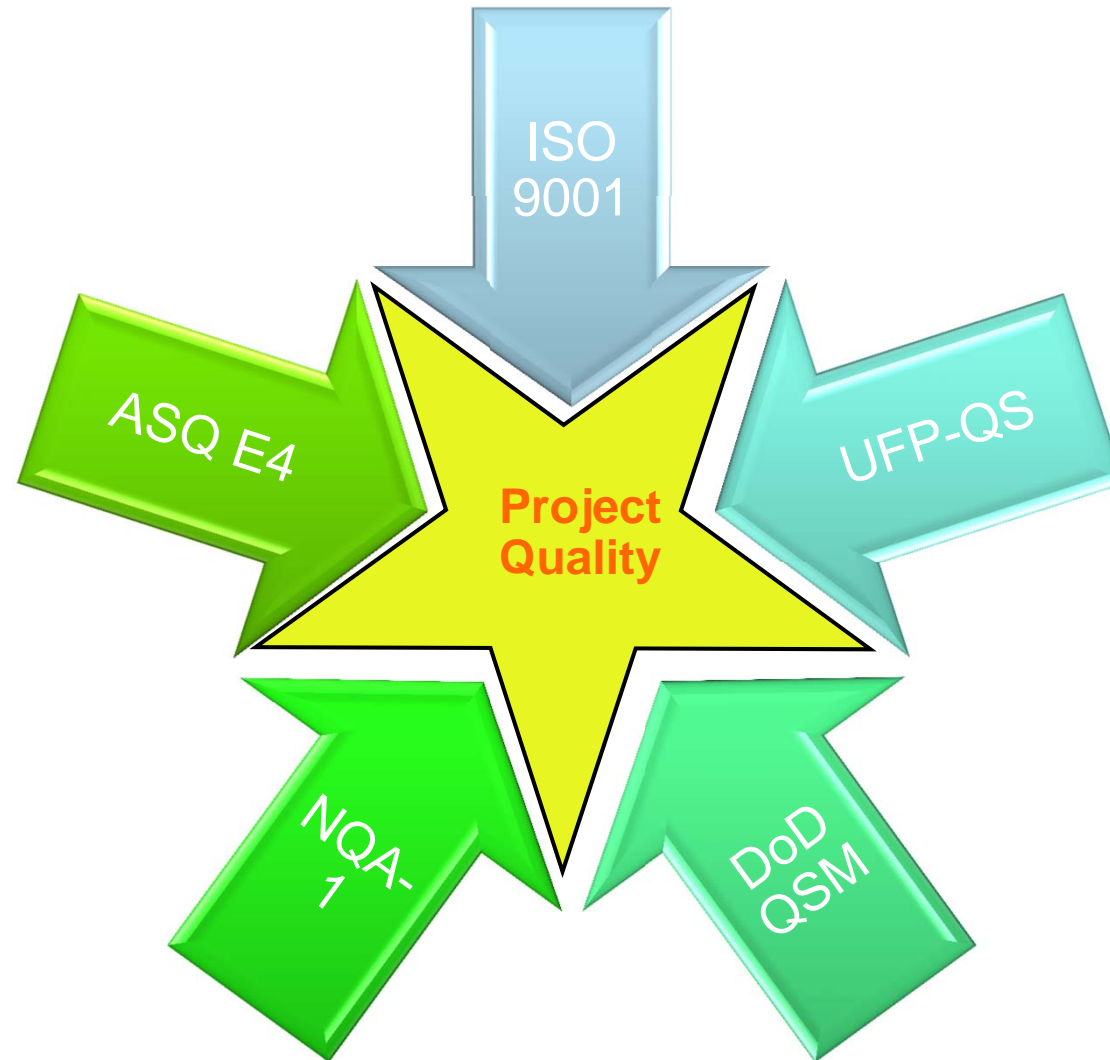| 16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT **Same as Report (SAR)**	18. NUMBER OF PAGES **15**	19a. NAME OF RESPONSIBLE PERSON
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What is a Quality Management System?

From ANSI/ASQ E-4

"A structured and **documented** management **system** describing the policies, objectives, principles, organizational authority, responsibilities, accountability, and implementation plan of an organization **for ensuring quality** in its work processes, products (items), and services. The Quality System provides **the framework** for **planning, implementing, and assessing the work** performed by an organization and for carrying out required quality assurance (QA) and quality control (QC) activities."

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Pop Quiz

- How many work within a <u>defined</u> quality system?
  - *If you work for a laboratory, put your hand down.*

- How many work within a system that conforms to:
  - ISO9001 but is not certified?
  - ANSI/ASQ E-4
  - Uniform Federal Policy for Quality Systems (UFP-QS)

- How many people work within a quality system certified to ISO9001?

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Quality Systems
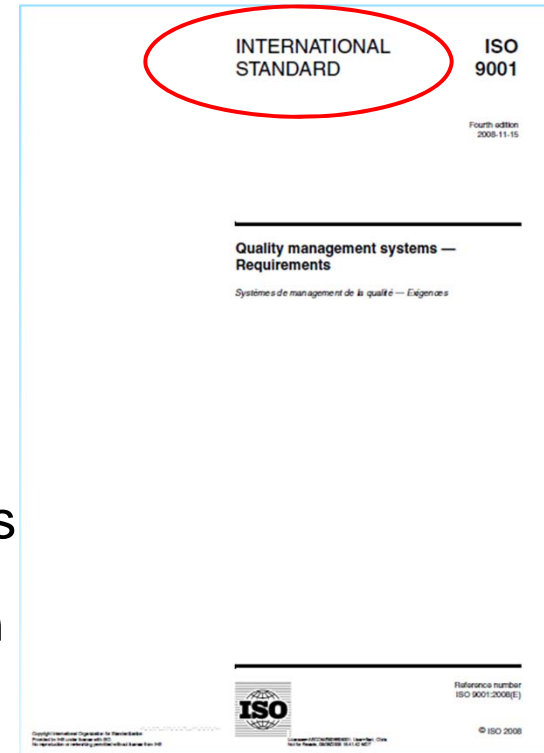
Define "Quality"

Meeting Requirements

ISO 9001

The ISO standard is a framework

8 Principles

– Client focus, leadership of top management, involvement of people, process approach, system approach to management, continual improvement, factual approach to decision making, mutually beneficial supplier relationships

Certification Bodies are Accredited by (in the US) ANSI/ASQ National Accreditation Board

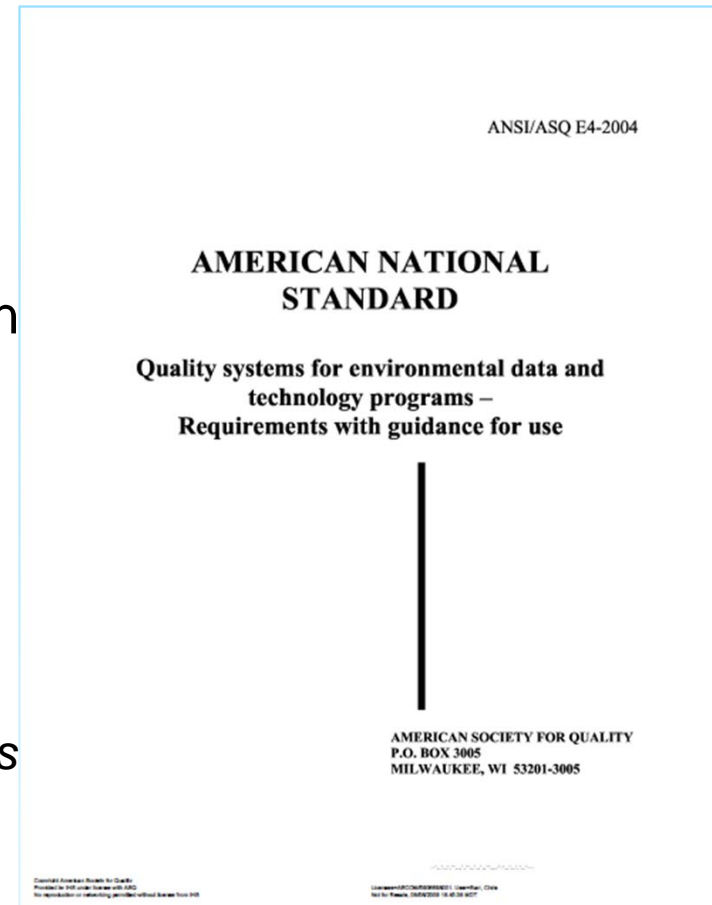**"Say what you do, do what you say, show your work"**

INTERNATIONAL STANDARD

ISO 9001

Fourth edition 2008-11-15

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

Reference number ISO 9001:2008(E)

© ISO 2008

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ANSI/ASQ E-4

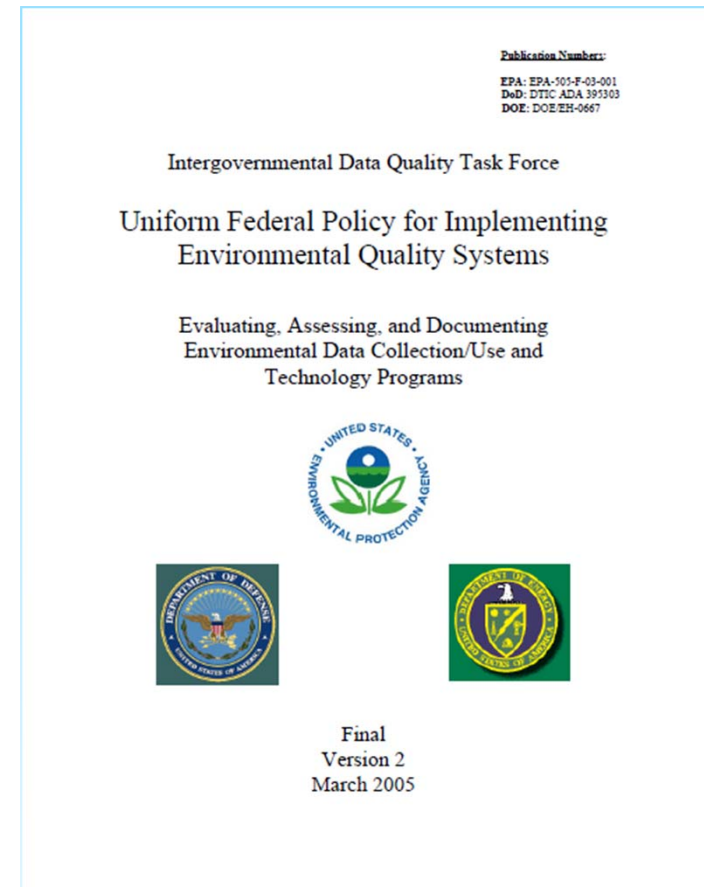**ANSI is the US Standards setting organization**

- Original issued in 1994, updated in 2004

- Adapted principles of manufacturing quality management to environmental data and technology

- *Not the same as ISO14001*

  *Environmental **Management** Systems*

ANSI/ASQ E4-2004

AMERICAN NATIONAL STANDARD

**Quality systems for environmental data and technology programs –
Requirements with guidance for use**

AMERICAN SOCIETY FOR QUALITY
P.O. BOX 3005
MILWAUKEE, WI 53201-3005

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UFP-QS

– Based on Part A of E4

– Related to **but different** from EPA QA/R2 – <u>Requirements for Quality Management Plans</u>
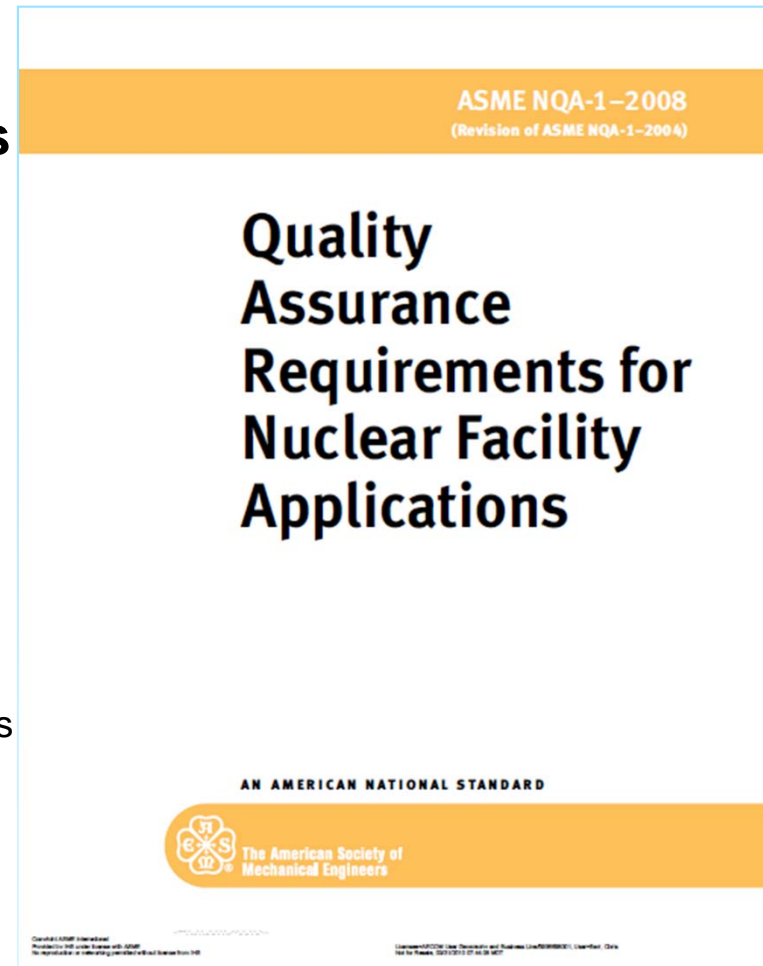

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ASME NQA-1

Specifically developed to address

10 CFR 50 Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing

Two of the important differences:

- ISO-9001 does not require independence in the design review process. Also, the ISO-9001 inspection requirement does not require the inspectors to be independent from the individuals who performed the work.

- ISO-9001 audit program does not require independent auditors. ISO-9001 programs are audited by auditors under a commercial contract to the supplier, hence, a possible conflict of interest.

ASME NQA-1–2008
(Revision of ASME NQA-1–2004)

Quality Assurance Requirements for Nuclear Facility Applications

AN AMERICAN NATIONAL STANDARD

The American Society of Mechanical Engineers

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Quality Systems Manual for Laboratories

ISO Guide 25
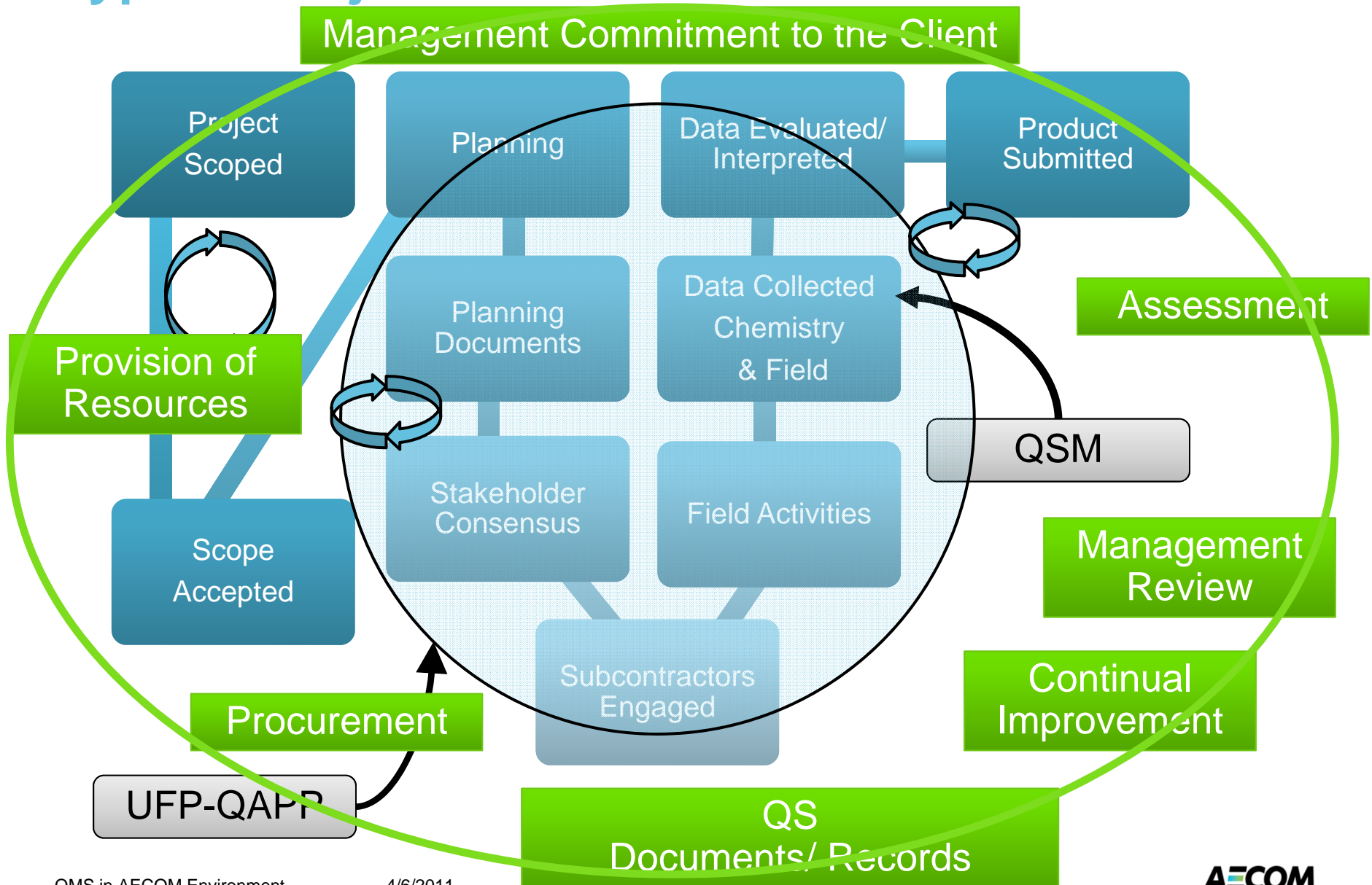
ISO 17025

State Certification Programs

DoD Quality Systems Manual for Environmental Laboratories

Version 4.2

Based on NELAC Voted Revision
5 June 2003

10/25/2010

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Typical Project Work Flow

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Elements of Quality Systems

Elements as they relate to the Project

- Processes to understand and communicate the Customer (Client) Requirements
- Plan the Work
- Control of Project Input
- Qualification of those performing the work
- Checking and Verification of Work Product
- Management of Subs and Suppliers
- Records of the Quality Activities (QC & QA)

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Elements of Quality Systems

Common Features
- Commitment of the Organization
- Organization of the System
- Processes for Product Realization
- Management Review
- Continual Improvement
- Assess Client Satisfaction

Required Procedures of an ISO 9001 QMS
- Control of Quality System Documents
- Control of Quality Records
- Internal Audit
- Control of Non-conforming Product
- Corrective Action
- Preventive Action

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Closing

- Benefits of a Quality System
  - Written processes
  - Transparency – for the client, for the organization
  - Commitment to improvement
  - Focus on the Client and requirements

- As a Client – what am I looking for?
  - Documented System
  - Management Commitment and Support
  - Assessment
  - Review

- Certification?

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