

6 Hours ~ Manage Nuclear Quality



Nuclear Energy Executives

‘NMS’ > QA ~ QC

Content From GQM Advisors

‘Nuclear Management Systems’ Course

~ Nuclear ~

Safety-Related

=

Quality-Related

~ Design ~

Your

‘Nuclear Management System’

~ Structure ~

QL | QM

Quality Assurance | Quality Control

Four Disciplines

Quality Leadership ~ QL The Department of the Navy's definition of QL is based on W. Edwards Deming's ideas. "The application of quantitative methods and the knowledge of people to assess and improve a) materials and services supplied to the organization, b) all significant processes within the organization, and c) meeting the needs of the end-user, now and in the future." [U.S. Depart Of The Navy TQL In The Fleet Theory to Practice, J.Wasik, B.Ryan, 1993, AD-A275 444 92pgs.](#)

Quality Management ~ QM That aspect of the overall management function that determines and implements quality policy. Quality management includes strategic planning, allocation of resources, and systematic activities for quality such as quality planning, operations, oversight, and evaluation.

Quality Assurance ~ QA Those planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality.

Quality Control ~ QC Those actions that provide a means of control and measure of the characteristics of an item, process, or facility to established requirements (inspection or source surveillance, or both).

Typical Position Titles

Quality Leadership ~ QL

Chief Quality Officer, Executive Advisor, Sr. VP, Quality Leader (Head of), Sr. Consultant

Quality Management ~ QM

Vice President, Sr. Director, Advisor (System | Program), Sr. Associate, Consultant, Educator | Instructor, Continuous Improvement Lead, QM Professional

Quality Assurance ~ QA

Director, Manager, Engineer (Software, Supplier, Data, Process, etc.), Associate, Representative, Auditor, Assessor, Supervisor, Analyst, Statistician, Black Belt, Coordinator, Records Administrator

Quality Control ~ QC

Manager, Supervisor, Representative, Statistician, Inspector, Test Technician, Clerk

The NMS > QL QM QA QC

U.S. NRC ~ QM QA QC ~ 2008

Definitions and Discussions – Quality Management

Quality Management (QM), Quality Assurance (QA), and Quality Control (QC) each reference a distinct aspect in the focus of the NRC inspection staff.

Quality Management is a *systematic approach* to ensure customer and *performance results* meet their expectations.

QM establishes processes to ensure and measure customer satisfaction.



What is the Baldrige award?

How do its criteria affect present-thinking regarding QM?



Four Quality Disciplines

If you & your executive management do not understand the separate & collective roles & responsibilities of the four quality disciplines, how can your company plan / design / schedule / assign / implement technical & administrative controls to effectively manage nuclear quality?

‘Many companies will not admit they do not understand the separate roles & responsibilities ~ they lump quality under one discipline’

~ Recipe for Failure ~

The NMS > QL QM QA QC



Quality Control | Quality Assurance | Quality Management | Quality Leadership

QC | QA | QM | QL Quality's Path to Leadership

Quality Management Tools

Risk Mitigation, SixSigma, QFD, FEMA, PDCA, C&E
Diagraming, SPC, Control Charts, Remote Audits, Design /
Contract Assurance, Lean, Process Mapping, Software,
Modeling, Self-Assessments, CAPA, Drone Site Monitoring,
Robot Inspections, Cyber Security, Others

Quality Affecting Significant Events

- 1912 RMS Titanic Atlantic Ocean (UK)
- 1941 World War II Mass Production (U.S.)
- 1955 Post-War Aerospace (U.S.)
- 1955 Naval Nuclear Program (U.S.)
- 1955 Atoms for Peace (Global Effort)
- 1960 Global Space Race (NASA, U.S.)
- 1968 Commercial Nuclear Power (U.S.)
- 1979 TMI Unit 2 (Pennsylvania, U.S.)
- 1984 NRC NUREG-1055 Report to Congress
- Nuclear Industry Quality / Safety / Management Failures (U.S.)
- 1986 Challenger Shuttle (U.S.)
- 1986 Chernobyl (Russia)
- 1988 Piper Alpha Oil Spill (North Sea)
- 1989 Exxon Valdez Oil Tanker Spill
- Prince William Sound (Alaska, U.S.)
- 2001 911 (New York City, U.S.)
- 2002 Prestige Oil Spill (Spain)
- 2002 Davis Besse Reactor Head (Ohio, U.S.)
- 2003 Columbia Shuttle (U.S.)
- 2008 Metrolink Train (Southern CA, U.S.)
- 2008 B2 Bomber Crash (U.S.)
- 2010 Deepwater Horizon BP Oil Spill, Gulf of Mexico, 87 Days, (UK)
- 2011 Fukushima Daiichi (Japan)
- 2020 Coronavirus Pandemic Global COVID19

Conformance to Requirements

"Quality is Free concept 1979"

Dr. Philip B. Crosby

U.S. Quality Leaders Emerge

- Dr. Walter A. Shewhart
- Dr. Armand V. Feigenbaum
- Dr. Joseph M. Juran

Dr. W. Edwards Deming's Period of Influence

- 'System of Profound Knowledge'
- Encompassed System, Variation, Knowledge, Psychology
- 4 Lenses of Reference

2000 Work Cultures Emerge as Key Element to QMS Effectiveness

1990 Shift from 'Error Detection' to 'Error Prevention'

1990 U.S. Dept of Navy CNO Enacted Total Quality Leadership Concepts & Practices to Selected Fleet Units. Goal: Process Improvements. ⁽¹⁾

1977 DOE Formed

1971 OSHA Formed

Quality Assurance Emerges

1958 NASA & DARPA Formed

1957 First U.S. Nuclear Power Plant

"Cost of Poor Quality" U.S. Military Suppliers

Increased Emphasis on Quality | Safety

Inspection / Testing

Mass Production

World War II

QRs

QC / SPC
In - Process Inspection

QRs

Quality Control

Complex Software

Quality Assurance

Complex Engineered
Products / Systems / Structures

Challenger Shuttle, U.S.
1986 Accident

Chernobyl, Russia
Nuclear Power Plant
1986 Accident

Three Mile Island, U.S.
Nuclear Power Plant
1979 Accident

Quality Management

Exxon Valdez, Prince William Sound
1989 Oil Tanker Spill, Alaska, U.S.

911, Twin Towers, U.S.
2001

Columbia Shuttle, U.S.
2003 Accident

BP Deepwater Horizon, UK
2010 Oil Spill

Fukushima Daiichi, Japan
Nuclear Power Plant
2011 Accident

Quality 4.0
~ Digital ASQ

COVID-19
Global Pandemic

Management Systems

Industry & Government - Driven

- Environmental / Health / Safety Mgt
- Enterprise / Information Mgt
- Integrated Mgt
- Requirements Mgt
- Risk Mgt
- Emergency Prep Mgt
- Supply Chain Mgt
- Process Hazards Mgt
- Cybersecurity Mgt

QRs
Quality Requirements

1900 1910 1920 1930 1940 1950 1960 1970 1980 1990 2000 2010 2020 2030 2040 2050

2030

Quality Assurance & Quality Control

If You're New to Commercial Nuclear Energy Generation & Waste Management, Please Familiarize Yourself with Two Timelines. You'll See that 'The Management of Quality' BACKED ITS WAY INTO INDUSTRIES & BUSINESS from **Quality Control (circa 1900) to Quality Leadership (2000)** during a 100-year period.

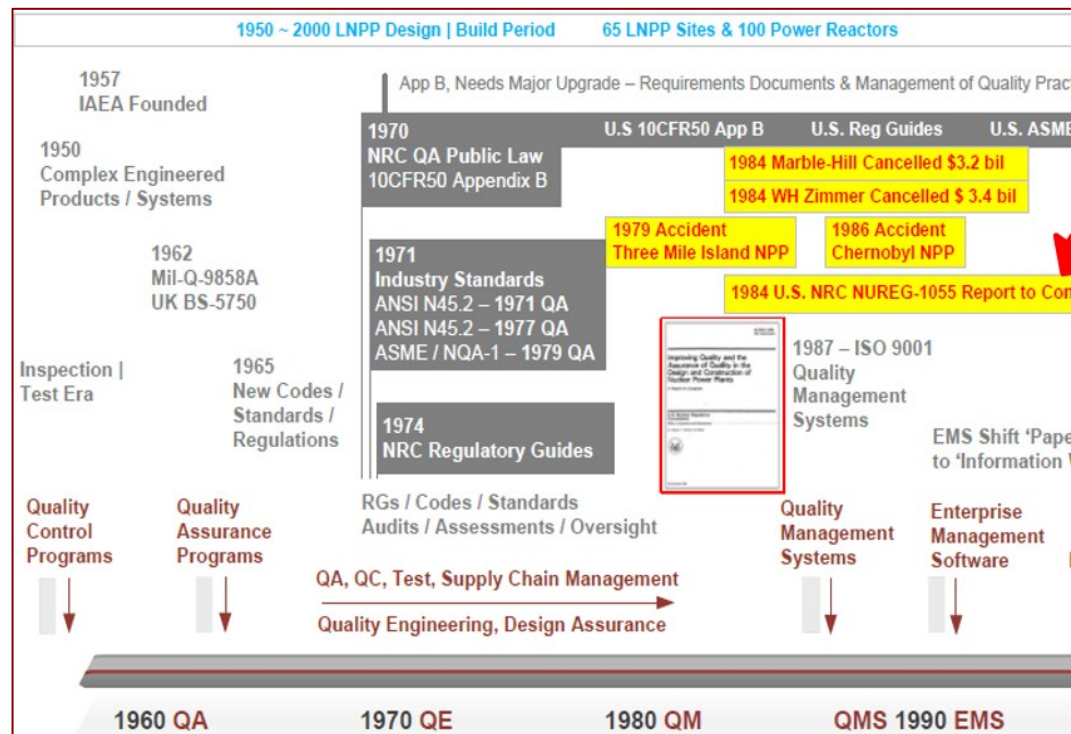
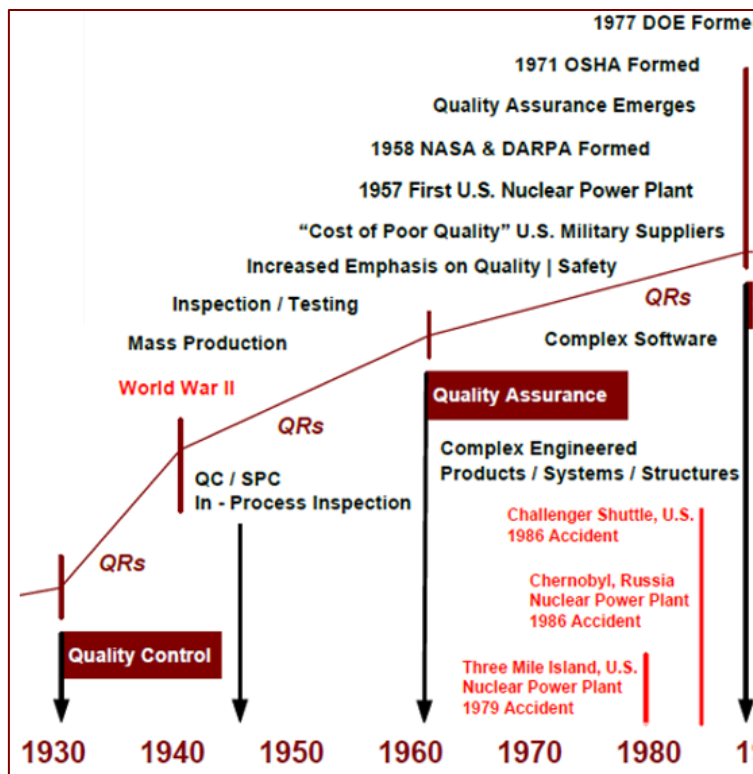
It's Important to Know, that Most Quality Professionals Have Gained Their Body of Knowledge in 'Hands-On' Job Roles in the Quality Disciplines since 1900. Does this Method Foster Consistency Across Business Sectors, Segments, & Applications? Does this Method Foster Workforce Consistency? **Does the nuclear workforce quality culture fully align with the shipbuilding, aviation, healthcare, & aerospace workforce quality cultures?**

Very Few Universities & Colleges Offer BS / MS Degrees or General Studies in Quality Management. Employees are Still Expected to Learn about the Management of Quality in Orientation Sessions which Makes Principles & Practices Company-specific.

The NMS > QL QM QA QC

U.S. QA & QC Evolution 1930 ~ 1990

If You're New to Commercial Nuclear Energy Generation & Waste Management, Please know your company must have a nuclear management system implemented before performing 'safety-related' work. QA & QC functions must be defined & effectively implement. It's expected that all 'quality-related' activities & information are effectively documented & administratively controlled.



~ NMS Design ~

Design Basis ~ Top Level Requirements Documents

Quality Policy ~ Executive Direction

A company quality policy is a core value statement that defines quality-related requirements & commitments by the CEO & executive team for achieving planned goals & objectives. It is expected that every employee & the company's suppliers are commitment to conforming with all applicable requirements.

Executive management team members develop, sign, & implement Quality Policy.

Every person working in the global nuclear industry should be mandated to sign / date an 'Important to Nuclear Safety' (Pledge to Quality Policy Statement) attesting to their efforts to comply with all requirements prior to performing safety-related work?

Understand Quality Requirements Documents

- U.S. NRC 10CFR50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants & 10CFR52, Licenses, Certifications, and Approvals for Nuclear Power Plants
- U.S. NRC 10CFR Part 21, Reporting of Defects and Noncompliance
- U.S. ASME NQA-1, Quality Assurance Requirements for Nuclear Facility Applications
- U.S. DOE 10CFR830, Nuclear Safety Management & 414.1D, Quality Assurance
- ISO 9001:2015, Quality Management Systems (QMS) – Requirements
- ISO 19443:2018, Quality Management Systems (QMS) – Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)
- Other ~ IAEA Safety Series ~ ~ Leadership & Management Systems Documents

GQM
nuclear advisors

<https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appb.html>



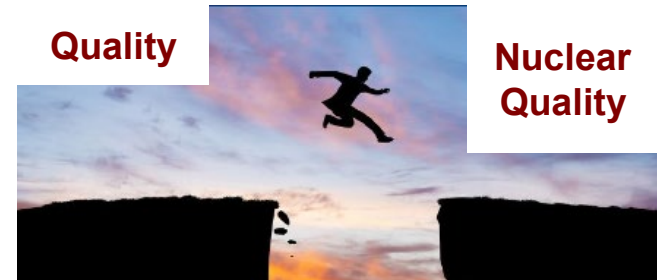
U.S. NRC 10CFR50, Appendix B

<https://www.nrc.gov/reading-rm/doc-collections/cfr/part050/part050-appb.html>

II. Quality Assurance Program

The applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance program which complies with

the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. The applicant shall identify the structures, systems, and components to be covered by the quality assurance program and the major organizations participating in the program, together with the designated functions of these organizations. The quality assurance program shall provide control over **activities affecting the quality of the identified structures, systems, and components, to an extent consistent with their importance to safety. Activities affecting quality shall be accomplished under suitably controlled conditions.**



U.S. NRC 10CFR Part 21 ~ Reporting Defects & Noncompliance



<https://www.nrc.gov/reading-rm/doc-collections/cfr/part021/full-text.html>

§ 21.1 Purpose.

The regulations in this part establish procedures and requirements for implementation of section 206 of the Energy Reorganization Act of 1974. That section requires any individual director or responsible officer of a firm constructing, owning, operating or supplying the components of any facility or activity which is licensed or otherwise regulated pursuant to the Atomic Energy Act of 1954, as amended, or the Energy Reorganization Act of 1974, who obtains information reasonably indicating: (a) That the facility, activity or basic component supplied to such facility or activity fails to comply with the Atomic Energy Act of 1954, as amended, or any applicable rule, regulation, order, or license of the Commission relating to substantial safety hazards or (b) that the facility, activity, or basic component supplied to such facility or activity contains defects, which could create a substantial safety hazard, to immediately notify the Commission of such failure to comply or such defect, unless he has actual knowledge that the Commission has been adequately informed of such defect or failure to comply.

§ 21.2 Scope.

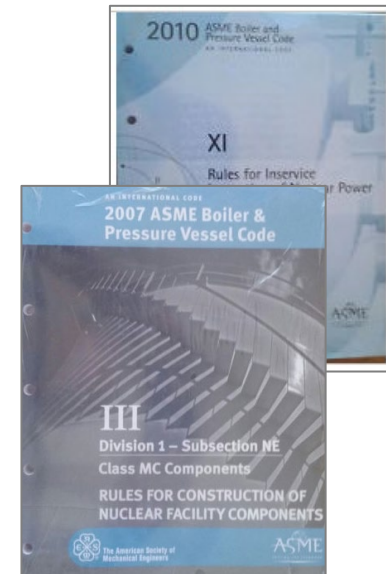
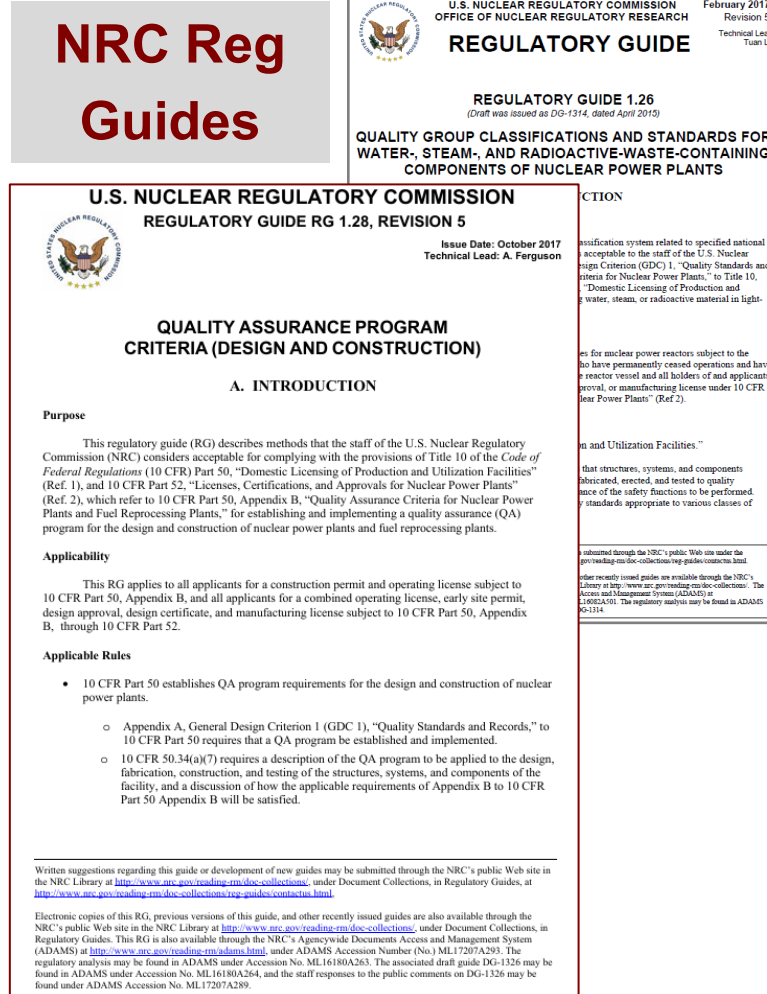
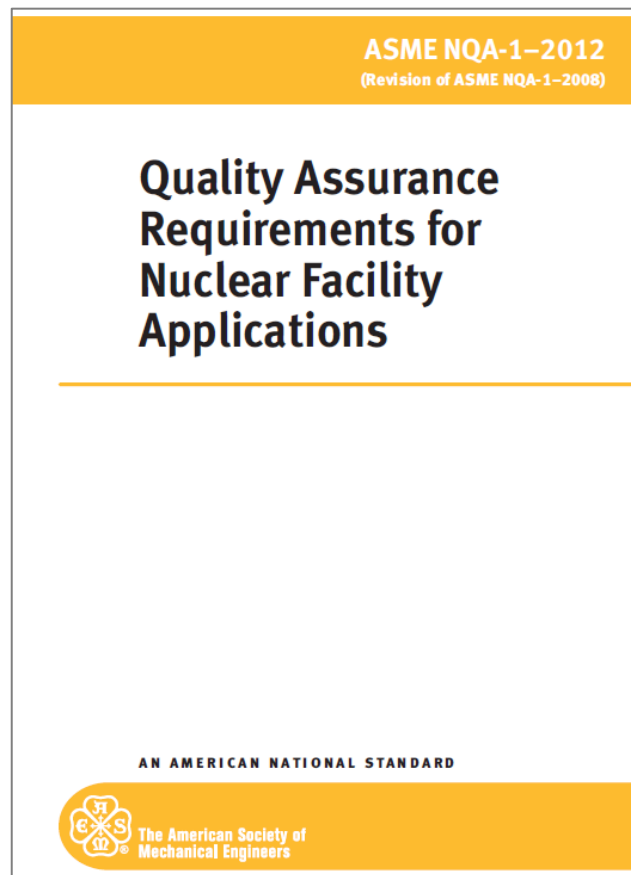
▲ TOP

(a) The regulations in this part apply, except as specifically provided otherwise in parts 31, 34, 35, 39, 40, 60, 61, 63, 70, or part 72 of this chapter, to:

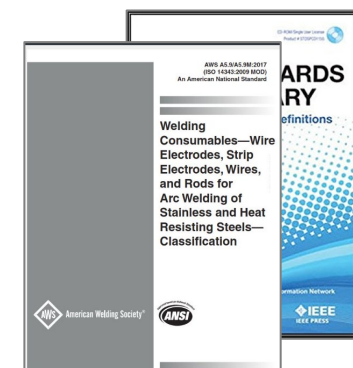
The NMS > QL QM QA QC

U.S. ASME NQA-1, Applicable Edition

<https://www.asme.org/codes-standards/find-codes-standards/quality-assurance-requirements-for-nuclear-facility-applications>

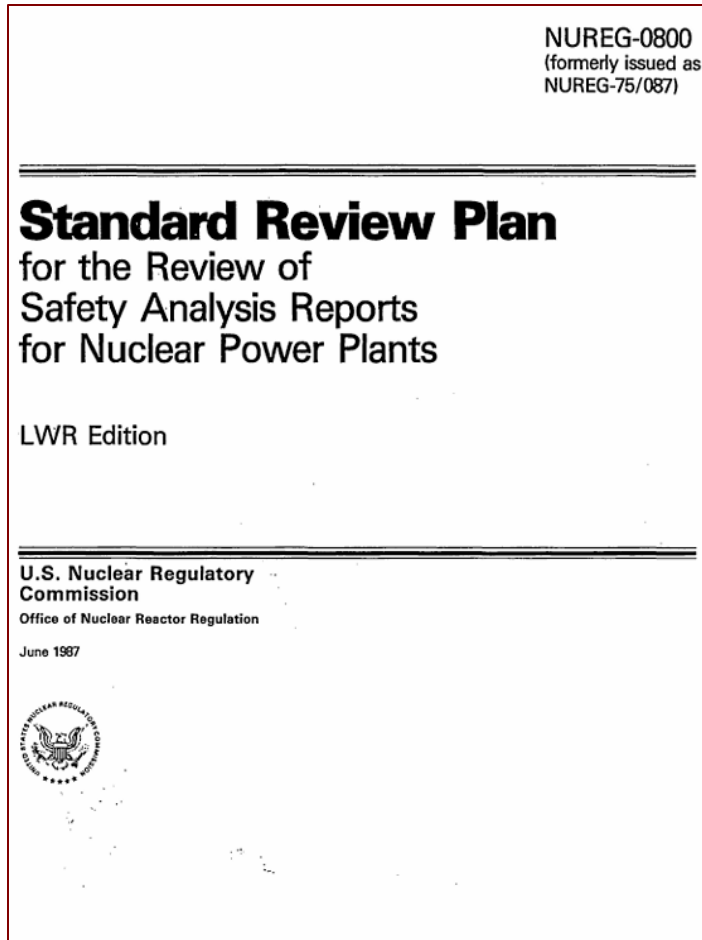


ASME Codes



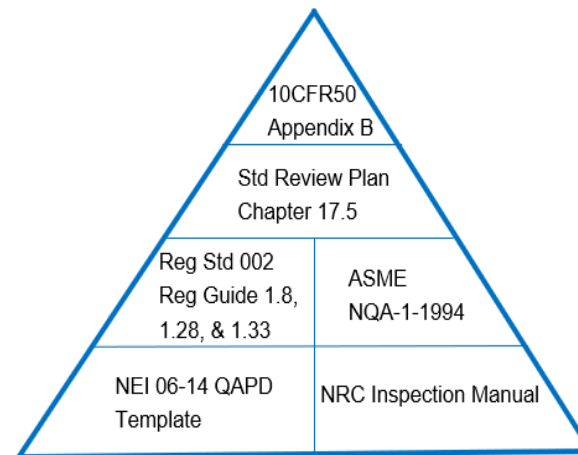
Standards

U.S. NRC NUREG-0800 Standard Review Plan



<https://www.nrc.gov/docs/ML0523/ML052340534.pdf>

CHAPTER 17 QUALITY ASSURANCE			
17.1	Quality Assurance During the Design and Construction Phases	---	75/11
		1	79/2
		2	81/7
17.2	Quality Assurance During the Operations Phase	---	75/11
		1	79/2
		2	81/7



ISO-9001:2015 ~ QMS

<https://www.iso.org/standard/62085.html>



Standards

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INTERNATIONAL
STANDARD

ISO
9001:2015

Edition 5
2015-09

Quality management systems —
Requirements



Reference number
ISO 9001:2015

© ISO 2015

ISO 9001:2015

Quality management systems — Requirements

Published (Edition 5, 2015)

This publication was last reviewed and confirmed in 2021. Therefore this version remains current.

↳ This standard has **1 amendment**.

The NMS > QL QM QA QC



U.S. NRC & ISO-9001:2015 ~ QMS

- U.S. NRC July 9, 2003, SECY-03-0117 ~ ISO 9001 Acceptable Quality Standard
- U.S. NRC May 12, 2020, FSE QMS, Rev 8.0 ~ ISO 9001 Acceptable Quality Standard
- Westinghouse Nuclear, QMS-A, Rev 8.0 (NRC-approved version)

POLICY ISSUE INFORMATION

July 9, 2003

SECY-03-0117

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: APPROACHES FOR ADOPTING MORE WIDELY ACCEPTED
INTERNATIONAL QUALITY STANDARDS

PURPOSE:

To report the results of the staff's effort to review international quality assurance standards against the existing 10 CFR Part 50 Appendix B framework and assess approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework.

SUMMARY:

The staff reviewed ISO 9001:2000, "Quality Management System (QMS) - Requirements," and performed a comparison to Appendix B quality requirements (see attachment). Based on this review, the staff concluded that supplemental quality requirements would need to be applied when implementing ISO 9001 within the existing regulatory framework. The staff developed four potential approaches for licensee implementation of ISO 9001. Two of the approaches were determined to be more suitable for further development. These were licensee-specific controls for ISO 9001 certified suppliers during procurement and using ISO 9001 certified suppliers for procuring commercial-grade items. The staff would expect supplemental quality requirements be applied to ISO 9001 for the areas described in the attachment. The staff also concluded that considerable actions have already been taken or are in progress to reduce regulatory burden associated with Appendix B. The proposed 50.69 risk-informed rulemaking will provide a more efficient and effective regulatory process while continuing to maintain safety.

Contacts: Richard P. McIntyre, NRR/DIPM
301-415-3215

Paul Prescott, NRR/DIPM
301-415-3026



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 12, 2020

QMS-A
Revision 8.0
22 May 2020

Ms. Camille Zozula, Manager
Infrastructure & Facilities Licensing
Westinghouse Electric Company
1000 Westinghouse Drive
Building 1, Suite 165
Cranberry Township PA 16066

SUBJECT: FINAL SAFETY EVALUATION FOR WESTINGHOUSE ELECTRIC COMPANY
TOPICAL REPORT "QUALITY MANAGEMENT SYSTEM (QMS),"
REVISION 8.0 (EPID L-2020-TOP-0022)

Dear Ms. Zozula:

By letter dated April 27, 2020 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML20118C994), Westinghouse Electric Company (Westinghouse) submitted to U.S. Nuclear Regulatory Commission (NRC) Topical Report (TR) "Quality Management System (QMS)," Revision 8.0. By letter dated April 30, 2020 (ADAMS Accession No. ML20120A538), the NRC issued its request for additional information questions. By letter dated May 5, 2020, the NRC issued its draft safety evaluation (SE) for the TR "Quality Management System (QMS)," Revision 8.0. By letter dated May 7, 2020 (ADAMS Accession No. ML20129K029) Westinghouse provided comments on the draft SE.

The enclosed final SE addresses the applicability of the TR "Quality Management System (QMS)," Revision 8.0.

The NRC staff has found that "Quality Management System (QMS)," Revision 8.0, is acceptable for referencing in licensing applications to the extent specified and under the limitations delineated in the TR and the enclosed SE.

According to the guidance provided on the NRC website, we request that Westinghouse publish accepted proprietary and non-proprietary versions of these TRs within three months timeframe after non-proprietary version of this final SE is issued by NRC.

The accepted versions shall incorporate this letter and the enclosed final SE after the title page. Also, they must contain historical review information, including NRC RAI questions and your responses. The accepted versions shall include an "-A" (designating accepted) following the TRs identification symbol.



<https://westinghousenuclear.com/media/jo4fxm3n/qms-a.pdf>

ISO-19443:2018 ~ QMS ITNS

<https://www.iso.org/obp/ui/en/#iso:std:iso:19443:ed-1:v1:en>



Standards

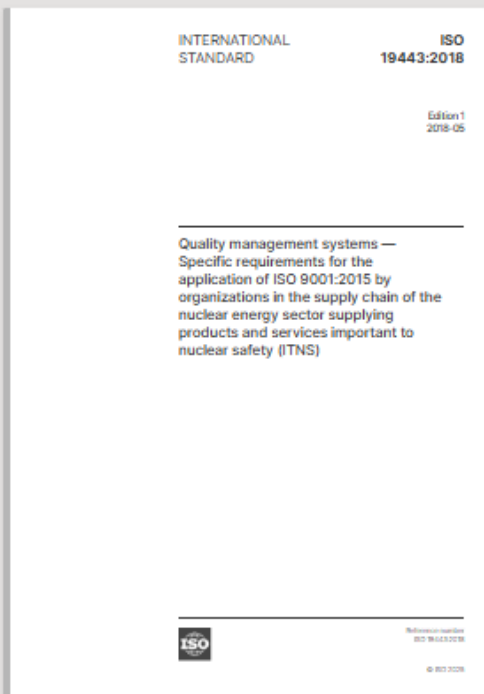
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[Read sample](#)

ISO 19443:2018

Quality management systems — Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)

Published (Edition 1, 2018)

↳ This standard has **1 amendment**.

The NMS > QL QM QA QC

U.S. NRC & ISO-19443:2018 ~ QMS - ITNS

- Westinghouse Nuclear QMS-A, ISO 19443 Certified, June 4, 2024 (Multi-site)
- Registrar LRQA QMS-A, Rev 8.1 (NRC-approved version)
- ISO 19443 Executive Commitment Statement, April 12, 2024, Page 3 of 72

LRQA	Current issue date: 4 June 2024 Expiry date: 14 June 2025 Certificate identity number: 10010500	Original approval(s): ISO 19443 - 15 June 2022
Certificate of Approval		
This is to certify that the Management System of: Westinghouse Electric Company		
1000 Westinghouse Drive, Cranberry Township, PA, 16066, United States		
has been approved by LRQA to the following standards: ISO 19443:2018		
Approval number(s): ISO 19443 – 00036672		
This certificate is valid only in association with the certificate schedule bearing the same number on which the locations applicable to this approval are listed.		
The scope of this approval is applicable to: Design of Nuclear Power Plants, Design and Manufacture of Nuclear Fuel, Design, Engineering, Manufacture and / or Procurement, Installation, Modification, Inspection, Testing, Repair, Refurbishment, Maintenance, Dismantling, and Decommissioning of Nuclear Power Related Systems, Structures, Equipment, and Components. Project Management of Projects Associated with the Above Scope Activities.		

<https://westinghousenuclear.com/media/l13emxny/00036672-19443-engus-ukas-3.pdf>

WESTINGHOUSE NON-PROPRIETARY CLASS 3

QMS-A
Revision 8.1
12 April 2024



Management System-A
(Approved Version)

3

12-01-24, (This statement was added by the PRIME system upon its validation)

1.0 QUALITY MANAGEMENT SYSTEM

The QMS incorporates quality planning, provides a framework for managing the activities that enable the company to create items and services which consistently satisfy the customer and regulatory requirements, and is a tool for achieving enhanced customer satisfaction. The QMS also provides for continual improvement by monitoring processes based on their significance, measuring their effectiveness against objectives, and managing processes for improvement.

The QMS aligns with the requirements of ISO 9001 and ISO 19443. Westinghouse will comply with the most recent editions of the ISO 9001 and ISO 19443 standards prior to the required compliance date. Requirements for sites having and maintaining external certifications to ISO 9001 and ISO 19443 will be documented within our management system.

~ Structure ~

ISOs

WESTINGHOUSE NON-PROPRIETARY CLASS 3

QMS-A
Revision 8.1
12 April 2024

The QMS includes commitments to address quality standards and regulatory requirements as indicated in the Applicability section. The QMS provides for, and organizations comply with, applicable QA requirements imposed by the governing regulatory agency and/or customer contract.

The QMS and changes thereto are reviewed and approved by Westinghouse management. The control of the QMS is the responsibility of the Management Representative, or designee.

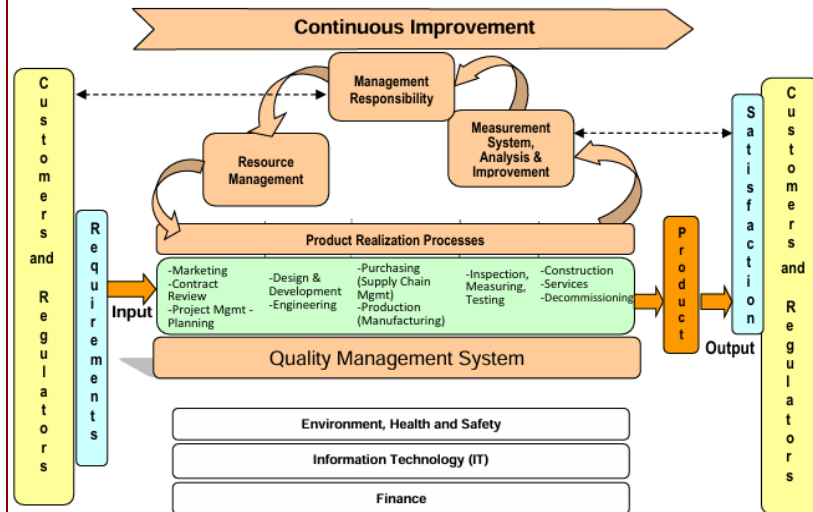
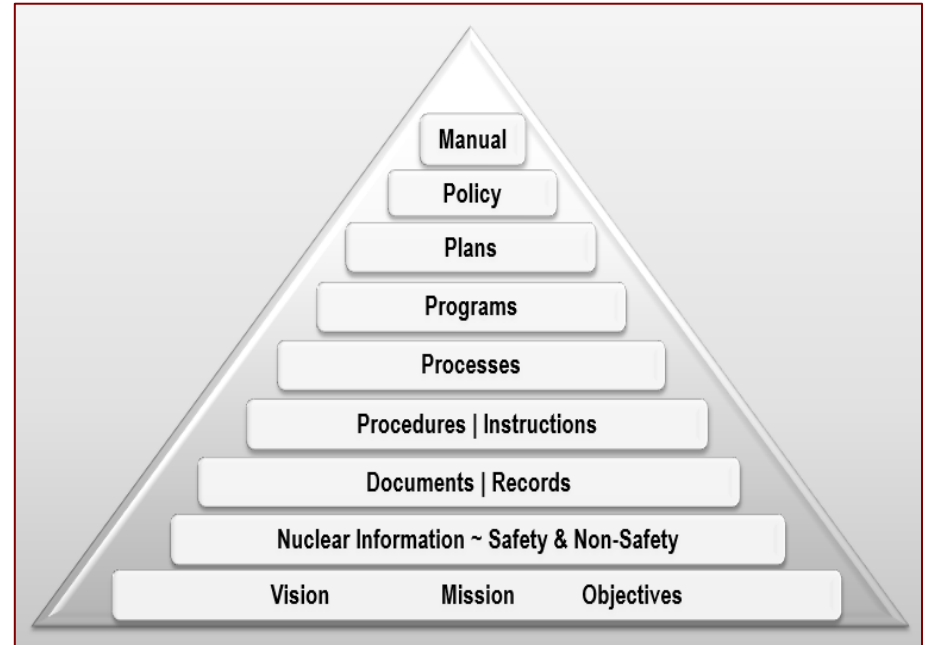


FIGURE 1
QUALITY MANAGEMENT SYSTEM
PROCESS INTERACTION



10CFR50, App B
ASME NQA-1

U.S. NEI ~ QAPD Structure - Standard Template

NEI 06-14 is structured as a template for use in developing the applicant-specific QAPD required as part of ESP and COL applications. The template consists of two documents: (1) a Policy Statement, and (2) a Quality Assurance Program Description that consists of five Parts.

NEI 06-14, Revision 9, "Quality Assurance Program Description."

NEI 06-14 [Revision 9]

Nuclear Energy Institute

Quality Assurance Program Description

May 2010

EXECUTIVE SUMMARY

NEI 06-14, "Quality Assurance Program Description (QAPD)" provides a generic template for use by early site permit (ESP) and combined license (COL) applicants to implement applicable requirements related to the Quality Assurance Program. The QAPD template includes the QA methods and administrative control requirements that meet 10 CFR 50, Appendix B, and 10 CFR Part 52. The template is based on the requirements of ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Parts I, II, and III, as specified in this document. ASME NQA-1-1994 is the latest NRC approved standard for a Quality Assurance Program as referenced in the Standard Review Plan (NUREG-0800).

NEI 06-14 is structured as a template for use in developing the applicant-specific QAPD required as part of ESP and COL applications. The template consists of two documents: (1) a Policy Statement, and (2) a Quality Assurance Program Description that consists of five Parts. The applicant will format their specific QAPD in accordance with their process for developing such documents. The QAPD template contains bracketed text that the applicants will modify with specific information as necessary for the ESP or COL application. Owing to the NRC Safety Evaluation (SE) accepting the generic QAPD, NRC staff review of applicant-specific QAPDs based on NEI 06-14 is expected to focus on the specific information provided to replace the bracketed text in the generic template.

This revision of NEI 06-14, addresses issues identified in the NRC's SE dated November 3, 2009 (ML092650695) and subsequent comments on Revision 8. In particular, a new Part V has been added to describe the QA and administrative controls for the operational phase. Upon NRC acceptance of Revision 9 in a new or revised SE, NEI will incorporate the SE and reissue the document as NEI 06-14-A, Revision 1.

The NMS > QL QM QA QC

U.S. DOE ~ Integrated Safety Management System



Quality – Addressed as QA-related to Safety. No explicit definition except by reference to ASME NQA-1.

DOE 414.1D/10 CFR 830 Criteria

- | | |
|--|---------------------------------------|
| I. Program | VI. Design |
| II. Personnel Training & Qualification | VII. Procurement |
| III. Quality Improvement | VIII. Inspection & Acceptance Testing |
| IV. Documents & Records | IX. Management Assessment |
| V. Work Process | X. Independent Assessment |
| | CRD - S/C/I/SQA |

Author: R.A. Carter, WCH E0807023_1
(Updated to use DOE O-414.1D)

ASME NQA-1-2004 Part I

- | | |
|--|--|
| BR-1 Organization | BR-10 Inspection |
| BR-2 QA Program | BR-11 Test control |
| BR-3 Design Control | BR-12 Control of M&TE |
| BR-4 Procurement Document Control | BR-13 Handling, storage & shipping |
| BR-5 Instructions, Procedures & drawings | BR-14 Inspection test & operating status |
| BR-6 Document Control | BR-15 Control of nonconforming material |
| BR-7 Control of purchased items & services | BR-16 Corrective Action |
| BR-8 ID & Control of items | BR-17 QA Records |
| BR-9 Control of special processes | BR-18 Audits |
| | Part II - Subpart 2.7 - SQA |

BR = Basic Requirement & Supplemental Requirements as applicable

QA Rule/DOE Order 414.1D/10 CFR 830, Subpart A & NQA-1 Alignment with ISMS

Competence Commensurate with Responsibilities RULE-II,IV,IX,X NQA-BR-1,2,3,4,6,10,11,15,16,17,18	Provide Feedback & Continuous Improvement RULE-III,IV,V,VIII,IX,X NQA-BR-3,4,6,8,9,12,13,14,17,18	Balanced Priorities RULE-II,IV,IX,X NQA-BR-2,3,4,6,10,11,12,15,16,18
Define Scope of Work RULE-IV,V,VI,VII,VIII,IX,X NQA-BR-1,2,3,4,5,6,7,8,10,11,12,14,17,18	Establish ESH&Q Policy RULE-I,IV,V,VIII,IX NQA-BR-1,2,3,4,6,8,9,12,13,14,17	Identification of Safety Standards & Requirements RULE-IV,V,VI,VII,VIII,IX,X NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18
Analyze Hazards RULE-IV,V,VI,VII,VIII,IX,X NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18	Management Review RULE-I,III,IV,IX NQA-BR-1,2,3,4,6,15,16,17	Hazard Controls Tailored to Work being Performed RULE-IV,V,VI,VII,VIII,IX,X NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18
Develop & Implement Hazard Controls RULE-IV,V,VI,VII,VIII,IX,X NQA-BR-1,2,3,4,5,6,7,8,9,10,11,12,14,15,16,17,18	Line Mgmt Responsible for Safety RULE-I,IV,IX NQA-BR-1,2,3,4,6,17	Suspect/Counterfeit Items (S/C/I) QA Order - Att. 3 Safety Software Quality Assurance (SQA) - Att. 4
Perform Work with Controls RULE-II,V,VI,VIII NQA-BR-2,3,6,8,9,10,11,12,13,14,18	Clear Roles & Responsibilities RULE-I,IV,IX,X NQA-BR-1,2,3,4,6,10,11,15,16,17,18	

U.S. DOE ~ 10CFR830 Safety Management System Specific

Quality means the condition achieved when an item, service, or process meets or exceeds the user's requirements and expectations.

Quality Assurance means all those actions that provide confidence that quality is achieved.

Quality Assurance Program (QAP) means the overall program or management system established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Safety basis means the documented safety analysis and hazard controls that provide reasonable assurance that a DOE nuclear facility can be operated safely in a manner that adequately protects workers, the public, and the environment.

Safety class structures, systems, and components means the structures, systems, or components, including portions of process systems, whose preventive or mitigative function is necessary to limit radioactive hazardous material exposure to the public, as determined from safety analyses.

Safety evaluation report means the report prepared by DOE to document:

- (1) The sufficiency of the documented safety analysis for a Hazard Category 1, 2, or 3 DOE nuclear facility;
- (2) The extent to which a contractor has satisfied the requirements of Subpart B of this part; and
- (3) The basis for approval by DOE of the safety basis for the facility, including any conditions for approval.

U.S. DOE ~ 10CFR830 Safety Management System Specific

Safety limits means the limits on process variables associated with those safety class physical barriers, generally passive, that are necessary for the intended facility function and that are required to guard against the uncontrolled release of radioactive materials.

Safety management program means a program designed to ensure a facility is operated in a manner that adequately protects workers, the public, and the environment by covering a topic such as: Quality assurance; maintenance of safety systems; personnel training; conduct of operations; inadvertent criticality protection; emergency preparedness; fire protection; waste management; or radiological protection of workers, the public, and the environment.

Safety management system means an integrated safety management system established consistent with [48 CFR 970.5223-1](#), *Integration of environment, safety, and health into work planning and execution*.

Safety significant structures, systems, and components means the structures, systems, and components which are not designated as safety class structures, systems, and components, but whose preventive or mitigative function is a major contributor to defense in depth and/or worker safety as determined from safety analyses.

Safety structures, systems, and components means both safety class structures, systems, and components and safety significant structures, systems, and components.

U.S. DOE ~ 10CFR830 Safety Management System Specific

Service means the performance of work, such as design, manufacturing, construction, fabrication, assembly, decontamination, environmental restoration, waste management, laboratory sample analyses, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like.

Surveillance requirements means requirements relating to test, calibration, or inspection to ensure that the necessary operability and quality of safety structures, systems, and components and their support systems required for safe operations are maintained, that facility operation is within safety limits, and that limiting control settings and limiting conditions for operation are met.

Technical safety requirements (TSRs) means the limits, controls, and related actions that establish the specific parameters and requisite actions for the safe operation of a nuclear facility and include, as appropriate for the work and the hazards identified in the documented safety analysis for the facility: Safety limits, operating limits, surveillance requirements, administrative and management controls, use and application provisions, and design features, as well as a bases appendix.

Quality ~ Consistency | Effectiveness

In 2025, there is an unprecedented number of entities globally & domestically developing new nuclear reactor, system, & fuel designs for commercial, industrial, military, space flight, & transportation energy supply demands. Advanced concept descriptions & predicted applications are reaching & shaping the news each day. The U.S. DOE & industry advocates are now using **‘Nuclear Renaissance’** during press briefings & in energy-related publications. The future use of nuclear fuels & related engineered containment systems is taking potential applications to a complete new level.

As advanced fuel & system design variations take shape & gain approvals, there is one constant that must prevail throughout the entire lifecycle of all safety-related products & services ~

**‘The Management of Quality Must Remain Constant
with the Highest Standards, Efficiencies, & Effectiveness’**

~ NMS ~

Design | Structure Support Documents

The NMS > QL QM QA QC

Quality & The NMS

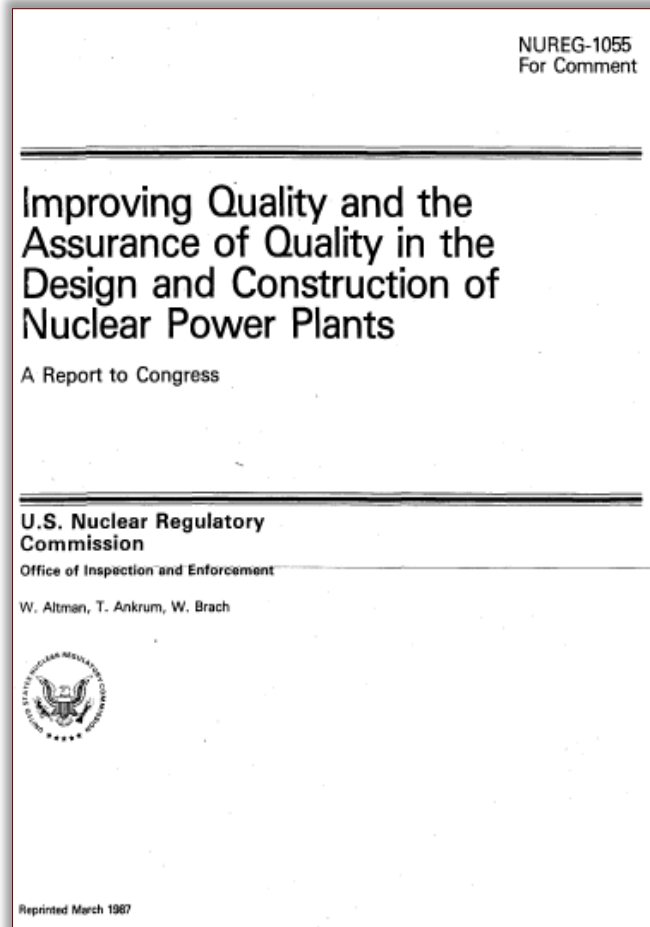
If you're new to commercial nuclear energy generation & waste management, please know you don't have to Reinvent the Wheel. Since the 1970s, there's been standards, codes, regulations, domestic & international committees, & numerous publications on the Management of Nuclear Quality | Quality Assurance | Quality Control.

GQM Nuclear Advisors strongly recommend you read & leverage from the available support documents. We can assist you.



U.S. NRC NUREG-1055-1984 ~ Congressional Report

<https://www.nrc.gov/docs/ML0630/ML063000293.pdf>



What Were The Deficiencies?

Per NUREG-1055, quality of structures, systems, and components was indeterminate due to:

- Inadequate quality inspection documentation
- Inadequate reporting of nonconformances
- Drawing deficiencies
- Inadequate specifications
- Materials control deficiencies
- Inadequate procedures and instructions
- Procedure violations
- Inadequate licensee audits
- Inadequate corrective action program



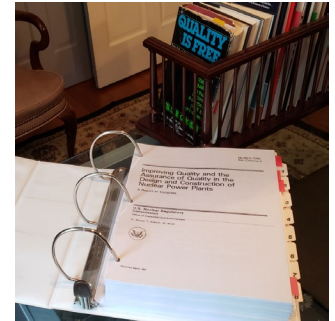
564 Pages

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The NMS > QL QM QA QC

1970 ~ 1990 Design & Build Era of 1st Fleet

Show Stopper



“Was the Failure or Inability of Some Utility Management to Effectively Implement a Management System that Ensured Adequate Control Over All Aspects of the Project”

~ Poor Management of Nuclear Quality ~

“Those Who Cannot Remember the Past are Condemned to Repeat It”

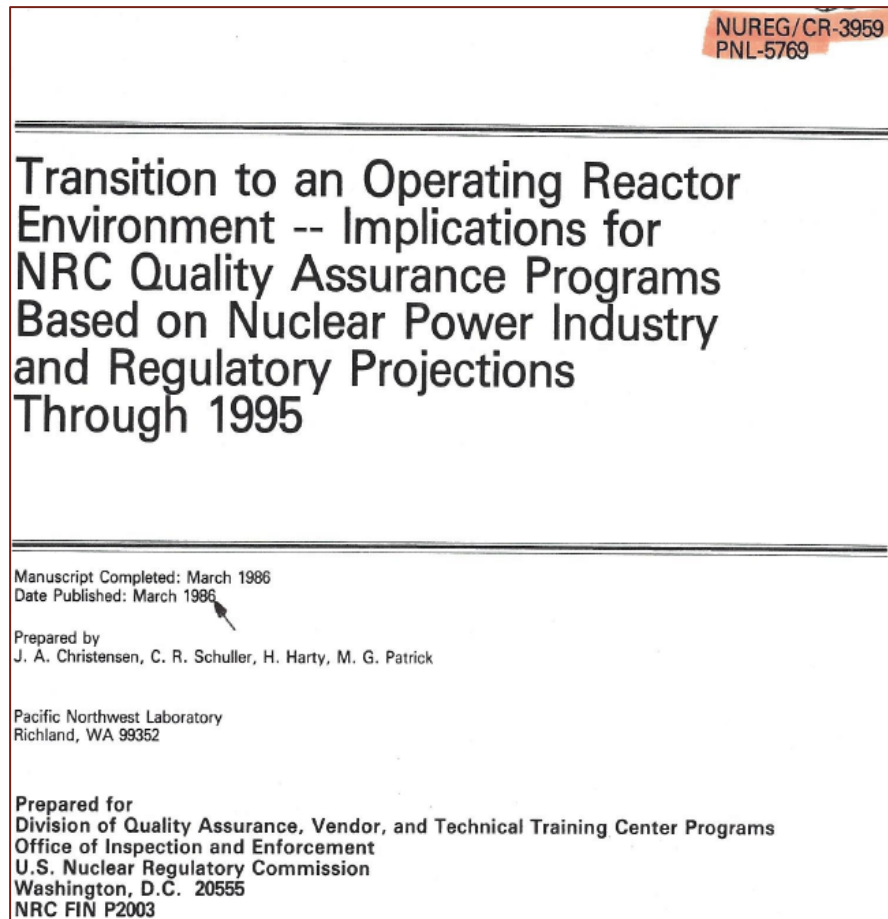
Glenn M. Tracy, NRC

1984 ~ Study Request to Congress, NUREG-1055

- H.R. 2330 Bill authorizing appropriations to the NRC in accordance with Section 261 of the Atomic Energy Act of 1954
- H.R. 2330 became Public Law 97-415 also known as the NRC Authorization Act for fiscal years 1982-'83
 - To Conduct a Study of Existing & Alternative Programs for Improving Quality & the Assurance of Quality in the Design & Construction of NPPs
- Ford Amendment adding Section 13(b) outlining the specifics of the study
 - Introduced by Senator Wendell Ford of Kentucky
 - Cosponsored by Senators Simpson, Mitchell, Levin, Hart
 - Outlined five alternatives referred to as alternatives b(1) - b(5)



1986 U.S. NRC ~ Implications for NRC QA Programs > 1995



Document not found in NRC online Library.

Prepared by Pacific Northwest Laboratory.

1987 ~ U.S. Commissioners ~ Assurance of Quality

August 31, 1987

POLICY ISSUE

SECY-87-220

For- The Commissioners (information)

From- Victor Stello, Jr. Executive Director for Operations

Subject: ASSURANCE OF QUALITY

Purpose: To inform the Commission of the staff's shift in emphasis from 'compliance-based' inspections of licensee's quality verification organizations to "performance-oriented" inspections of these organizations.

Background: In May 1984, the staff issued NUREG-1055, 'Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants.' NUREG-1055 identified poor management as a major contributor to quality breakdowns. The report also addressed issues that went beyond traditional quality assurance (QA) issues and focused on (1) steps that could be taken in licensees' QA programs and (2) changes in the NRC oversight of such programs to improve the performance of the line organizations ("quality achievers") and the licensees' QA organizations ("quality verifiers"). Traditionally, a licensee established a QA program that was reviewed and accepted by the NRC; the NRC then "inspected" the implementation of the licensee's programs. These inspections were heavily oriented towards programmatic reviews rather than reviews of actual day-to-day work in progress or actual plant hardware.

The Commission, in a December 12, 1985 response to Congress involving the Issues raised in NUREG-1055, made it clear that it is the responsibility of licensees—not the NRC—to achieve and assure quality. The Commission indicated that improvements in quality must come from the industry itself, and that the-key to achieving quality and assuring quality lies in line management. Therefore, the Commission concluded that the NRC programs for improving quality should focus on the ability of licensee management to ensure that significant safety problems are either prevented or detected early and adequately resolved.

NRC SECY-87-220
Referenced in ~ 231

NRC SECY-97-231

October 8, 1997

SECY-97-231

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: PERFORMANCE-BASED INSPECTION GUIDANCE AND THE DISTINCTION BETWEEN INSPECTING FOR PERFORMANCE AND INSPECTING AGAINST A PERFORMANCE-BASED RULE - STAFF RESPONSE TO STAFF REQUIREMENTS MEMORANDUM DATED MARCH 17, 1997 (REF. M970213A, PARAGRAPH 4)

PERFORMANCE-BASED INSPECTION GUIDANCE AND THE DISTINCTION BETWEEN INSPECTING FOR PERFORMANCE AND INSPECTING AGAINST A PERFORMANCE-BASED RULE - STAFF RESPONSE TO STAFF REQUIREMENTS MEMORANDUM DATED MARCH 17, 1997 (REF. M970213A, PARAGRAPH 4)

1987 ~ U.S. Commissioners ~ Assurance of Quality

Discussion: In the three years since the completion of NUREG-1055, many of the NRC programs it generated to focus on the performance of line management have been completed or are ongoing. Because the majority of the NRC's regulatory oversight and inspection activity is aimed at monitoring the performance of the licensee's line organization in achieving quality, most of these programs were initiated in NRC organizations outside of the NRC Quality Assurance Regulatory Programs. These include, for example, the development of performance indicators and improved diagnostic inspection techniques. Therefore, with most of the agency's focus on the line organization, it is now appropriate for the NRC Quality Assurance Regulatory Programs to focus principally on initiatives aimed at evaluating the effectiveness of the quality verification organizations in identifying, reporting, and ensuring the correction of significant safety problems.

NRC SECY-87-220

Partials ~

Quality verification is synonymous with systems of checks, audits, inspections, and other forms of verification performed by a licensee's Quality Assurance organization, the Quality Control organization, the Quality Engineering organization, and/or other independent review organizations such as a Plant Operations Review Committee and Safety Operation Review Committee. These organizations monitor the overall performance of the line organization and are responsible for ensuring that quality is achieved and that significant problems are avoided.

IAEA GSR-2 ~ Leadership & Management

<https://gnssn.iaea.org/CSN/Relevant%20Documents/Safety%20Requirements/English/GSR%20Part%202.pdf>

IAEA Safety Standards

for protecting people and the environment

Leadership and Management for Safety

General Safety Requirements No. GSR Part 2



IAEA

International Atomic Energy Agency

THE MANAGEMENT SYSTEM

Requirement 6: Integration of the management system

The management system shall integrate its elements, including safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements, so that safety is not compromised.

4.8. The management system shall be developed, applied and continuously improved. It shall be aligned with the safety goals of the organization.

4.9. The management system shall be applied to achieve goals safely, to enhance safety and to foster a strong safety culture by:

- (a) Bringing together in a coherent manner all the necessary elements for safely managing the organization and its activities;
- (b) Describing the arrangements made for management of the organization and its activities;
- (c) Describing the planned and systematic actions necessary to provide confidence that all requirements are met;
- (d) Ensuring that safety is taken into account in decision making and is not compromised by any decisions taken.

4.10. Arrangements shall be made in the management system for the resolution of conflicts arising in decision making processes. Potential impacts of security measures on safety and potential impacts of safety measures on security shall be identified and shall be resolved without compromising safety or security [20–23].

4.11. The organizational structures, processes, responsibilities, accountabilities, levels of authority and interfaces within the organization and with external organizations shall be clearly specified in the management system.

4.12. Regulatory requirements shall be reflected in the management system.

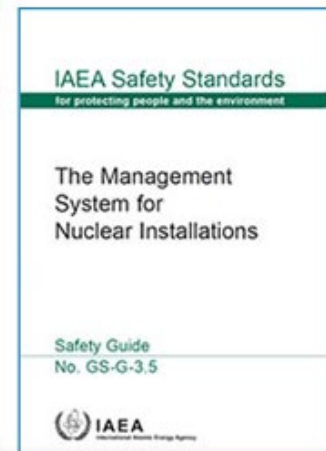
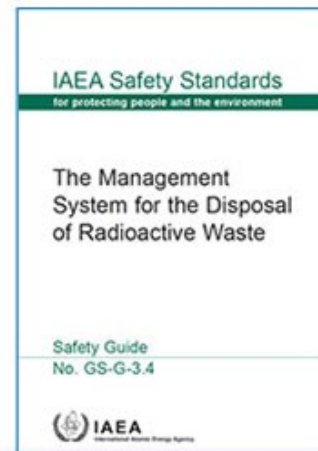
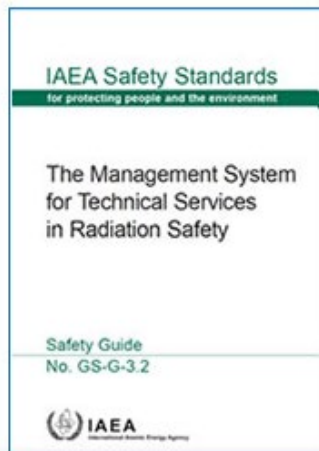
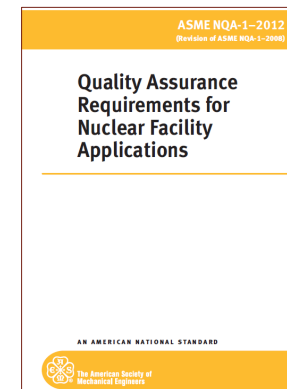
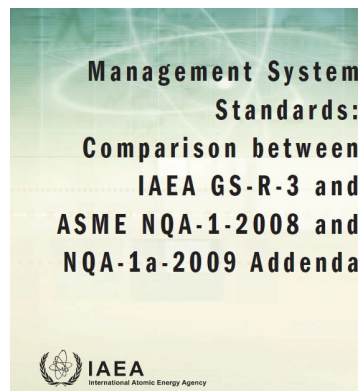
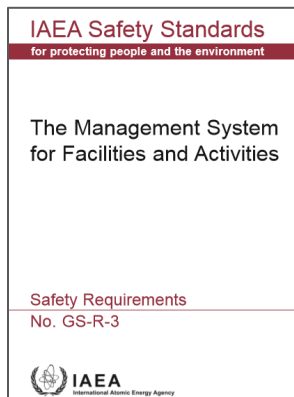
4.13. Provision shall be made in the management system to identify any changes (including organizational changes and the cumulative effects of minor changes) that could have significant implications for safety and to ensure that they are appropriately analysed.

4.14. Arrangements shall be established in the management system for an independent review to be made before decisions significant for safety are made.

The NMS > QL QM QA QC

IAEA GS-R-3 v. U.S. ASME NQA-1 ~ A Comparison Matrix

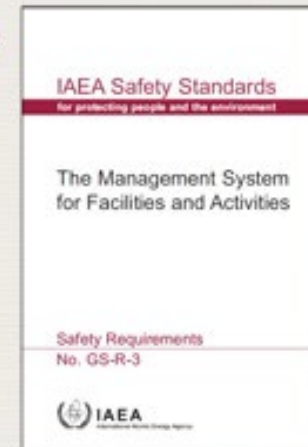
http://www-pub.iaea.org/MTCD/publications/PDF/Pub1253_web.pdf



IAEA GS-R-3 ~ Structure

The Structure of GS-R-3

- Section 1: Introduction
- Section 2: **Management System** general requirements including safety culture, grading, documentation and records.
- Section 3: Requirements for and **responsibilities of senior management** for the development and implementation of the management system
- Section 4: Requirements for **resource management** including human resources, infrastructure and work environment.
- Section 5: Requirements for the **processes** of the organisation – their specification, development and management including generic processes.
- Section 6: Requirements for **measuring, assessing and improving** the management system.



IAEA GS-R-3 ~ Management | Leadership

'management' is a formal, authorized function for ensuring that an organization operates efficiently and that work is completed in accordance with requirements, plans and resources

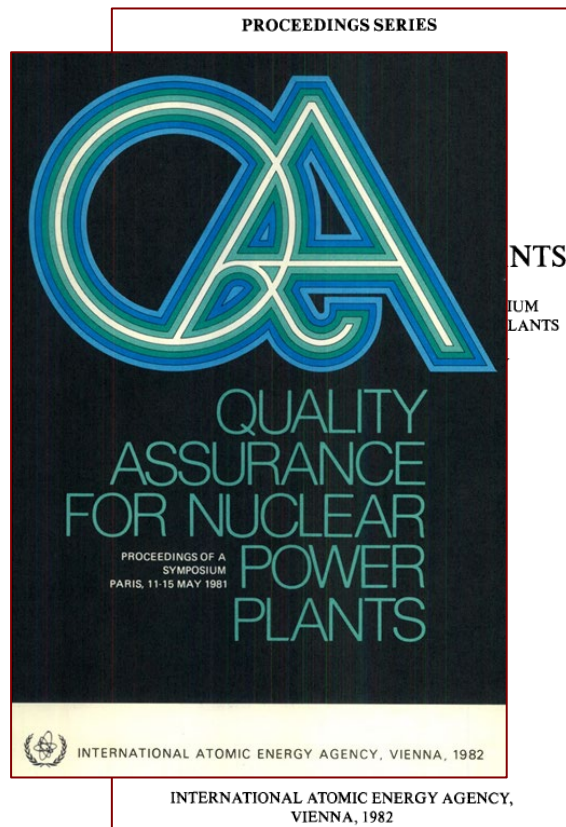
While

'leadership' is the use of capabilities/skills to influence others and communicate with others with the aim of achieving the commitment of all individuals to appropriate goals, shared values and behaviours.



IAEA SM-253-1982 ~ QA NPPs

[34060723.pdf](#)



IAEA-SM-253/100

5

CONCEPT OF QUALITY ASSURANCE

In the IAEA Member States there is a spectrum of practices which might be identified as formal quality assurance. It is customary to distinguish between two different concepts that may be considered as two extremes of existing approaches:

FOREWORD

The International Symposium on Quality Assurance for Nuclear Power Plants, organized by the International Atomic Energy Agency, was held in Paris from 11 to 15 May 1981. The meeting was opened at the Palais des Congrès, Centre International de Paris, by Mr. B.A. Semenov, Deputy Director General of Technical Operations of the IAEA, after addresses given by Mr. M.B. Saitcevsy, Deputy Manager of the Direction d'équipement of Electricité de France, and Mr. F. Perrot of the Commissariat d'énergie atomique. The main objectives of the symposium were the following:

- (1) To review the present requirements and practices in implementing quality assurance (QA) in nuclear power projects in Member States.
- (2) To identify the existing similarities and differences and to highlight those aspects of QA in Member States which are controversial and in need of harmonization.
- (3) To assess the practical use of the established requirements and recommendations of the IAEA Code of Practice on Quality Assurance for Safety in Nuclear Power Plants and the relevant Safety Guides.

Because of the interdisciplinary nature of QA and the rather broad scope of its activities, only seven topics of QA were selected for review and discussion. They included, besides a general comparison of QA requirements and practices in IAEA Member States, methodologies for the selection of appropriate QA programme levels for specific items and services; the role of independent inspection in verification activities; economic aspects of QA; manpower requirements for QA in nuclear power projects; training, qualification and certification of QA personnel; and specific aspects of the implementation of QA in countries embarking on nuclear power projects.

Each of these topics was treated in a separate session and each session was opened by one or two invited papers intended to review the respective QA topic and to highlight the existing problems. Then followed the oral presentation of contributed papers selected from those submitted by the participants. Each group of papers presented was followed by free discussion. A working group was assigned to each session to summarize the findings.

These Proceedings include the full text of all invited papers and of a large part of the contributed papers. The contributed papers that are not published in full are represented by abstracts in the session summaries. The summaries of the sessions as prepared by the working groups appear at the end of the appropriate sessions.

The holding of an international symposium on quality assurance appeared well timed. The importance of QA in the nuclear industry is constantly growing

with the increasing requirements for safety and availability of nuclear power plants. The Agency's programme for the preparation and issue of nuclear safety standards including those for QA has reached a point where the practical implementation of the Agency's requirements and recommendations in nuclear power projects of Member States has a priority over the development of new standards. This has been demonstrated at the symposium by the large number of participants (over 250), the submission of about 80 papers, out of which 33 were selected for presentation, and the lively discussions following each presentation. The Agency's Codes of Practice and Safety Guides on QA were a subject of review and discussion, leading to the general conclusion that they represent a good and consistent basis for establishing regulatory QA requirements and also for setting up and implementing an effective QA programme for activities associated with nuclear power projects.

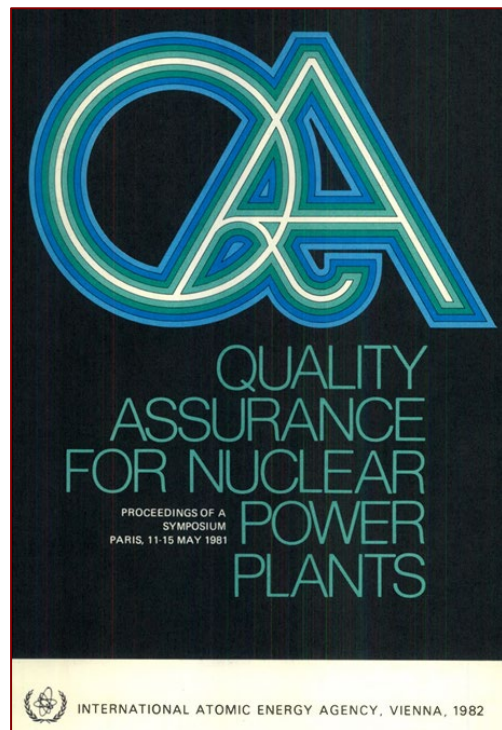
The success of the symposium was greatly enhanced by the efficient support of the host country. Gratitude is expressed in particular to Electricité de France, Service contrôle des fabrications, who provided substantial support to the Agency's Secretariat before and during the symposium in connection with the organization and the programme.

The Agency greatly appreciates the support of the members of its Technical Review Committee on Quality Assurance in the preparation of the symposium, particularly in the review of submitted papers and the selection of work for oral presentation, and their active contributions to the working groups and drafting committees during the symposium.

519 Pages

IAEA SM-253-1982 ~ QA NPPs

[34060723.pdf](#)



IAEA-SM-253/33

UPGRADING OF QUALITY ASSURANCE PROGRAMMATIC REQUIREMENTS FOR OPERATING NUCLEAR POWER PLANTS

W.P. HAASS

United States Nuclear Regulatory Commission,
Washington, DC,
United States of America

Presented by W.M. Morrison

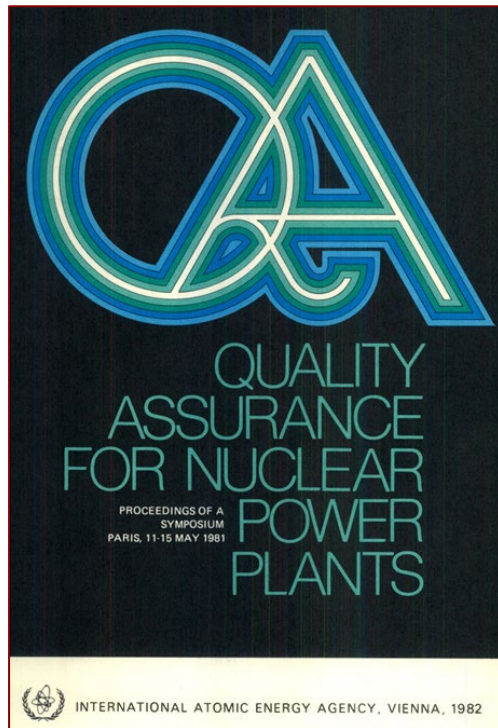
Abstract

UPGRADING OF QUALITY ASSURANCE PROGRAMMATIC REQUIREMENTS FOR OPERATING NUCLEAR POWER PLANTS.

As a result of the analysis of the TMI-2 accident and experience at several construction sites for nuclear power plants, the staff of the United States Nuclear Regulatory Commission (NRC) has concluded that certain quality assurance (QA) programmatic modifications relative to currently existing requirements should be made. These modifications are directed toward upgrading and strengthening the QA function at operating nuclear power plants to improve its effectiveness in identifying and correcting operational deficiencies in order to protect the public health and safety. Specific areas of QA programmatic upgrading include: 1. Improving management attitudes toward QA; 2. expanding the category of structures, systems and components to which the QA programme applies, to include all items that affect safety; 3. improving the organizational independence of the QA function from the performing functions; 4. increasing QA staffing levels and qualification requirements for QA personnel; 5. increasing the involvement of the QA organization in the inspection and verification of operational activities; and 6. increasing the involvement of the QA organization in the review and approval of quality-affecting documents. The NRC has developed new requirements in the above areas and has initiated their implementation on TMI-1 (re-start) and several other operational units at sites located near areas of high population density. It is ultimately planned to demand the implementation of these new requirements for all nuclear power plants under design and construction as well as in operation. These and other new requirements are also contemplated for implementation in new plants under design and construction.

IAEA SM-253-1982 ~ QA NPPs

[34060723.pdf](#)



50

HAASS

the need for management to recognize the value of, to create and to maintain an effective QA programme. Because of the rather general nature of the criteria of Appendix B to 10 CFR, Part 50, none of the upgradings require revision to the Regulations other than a clarification of certain language regarding the structures, systems and components to which the QA programme applies.

The specific areas of upgrading the QA programmes have been identified in the TMI Action Plan (NUREG-0660) for nuclear power plants under design and construction as well as in operation. Several of the more significant areas have been selected for earlier application to specific facilities than is otherwise called for by the Action Plan schedule.

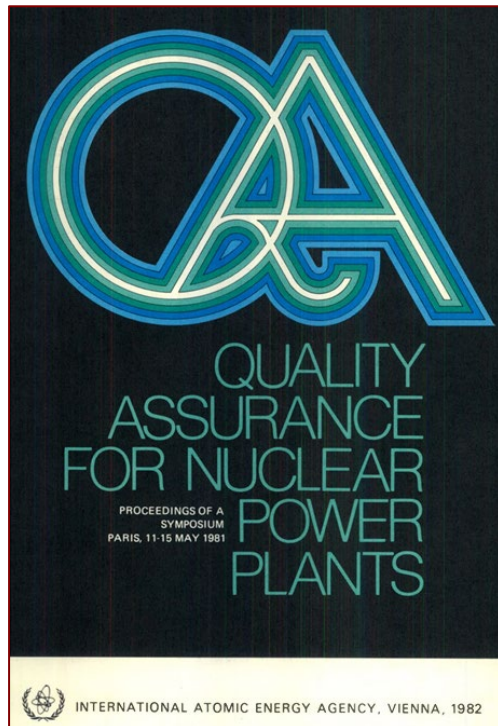
MANAGEMENT ATTITUDE TOWARD QA

The attitude of the licensee's management toward QA is of utmost importance to the success or failure of the QA programme. Only with a clearly positive attitude toward QA transmitted from top management can an effective QA programme be created and implemented. Too many utilities still view QA as a costly and overdone 'paper-mill' rather than a necessary and cost-effective management tool. QA should permeate all levels of management and should enjoy a strong commitment to provide the maximum potential for full effectiveness. The key activity areas where top management should be involved are:

- (a) Formulating the company's basic QA policies, goals and objectives
- (b) Establishing a highly qualified QA organization with the necessary authority, organizational freedom, staffing levels and management backing
- (c) Periodically assessing the scope and implementation of the QA programme to ensure that it satisfies the objectives of the company.

IAEA SM-253-1982 ~ QA NPPs

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INVOLVEMENT OF QA ORGANIZATION IN OPERATIONAL ACTIVITIES

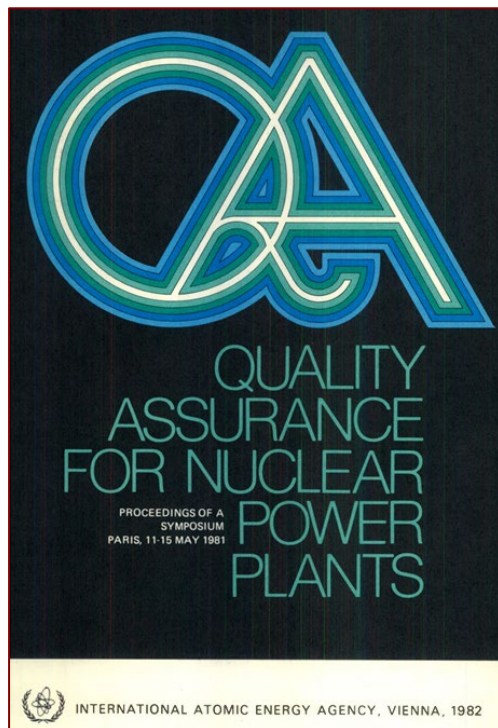
Both on-site and off-site elements of the QA organization should be actively involved in all the operational aspects of a nuclear power plant affecting safety. Up to now, the QA involvement has been at best inconsistent and minimal in certain areas, with the result that the effectiveness of the QA programme has not attained the desired results. The responsibilities of the QA organization should include:

- (a) Surveillance and verification of pre-operational, start-up and operational tests and inspections; maintenance; and modifications
- (b) Review of procurement documents to ensure that the necessary QA requirements are specified, and inspection of received items
- (c) Verification of accomplishment of training and indoctrination of plant personnel in order to ensure demonstrated proficiency and capability to perform assigned tasks
- (d) Active involvement of the off-site QA manager to monitor the implementation of the QA programme and to assist in the resolution of quality-related problems
- (e) Performance of an overall assessment of the effectiveness of the QA programme, which involves developing and evaluating a trend analysis, and promulgating and modifying QA policies and procedures as necessary.

Involvement of the QA organization to accomplish the above functions is fundamental and essential to gain confidence and credibility in ensuring plant safety through proper implementation of operational activities.

IAEA SM-253-1982 ~ QA NPPs

[34060723.pdf](#)



QA FOR DESIGN AND CONSTRUCTION

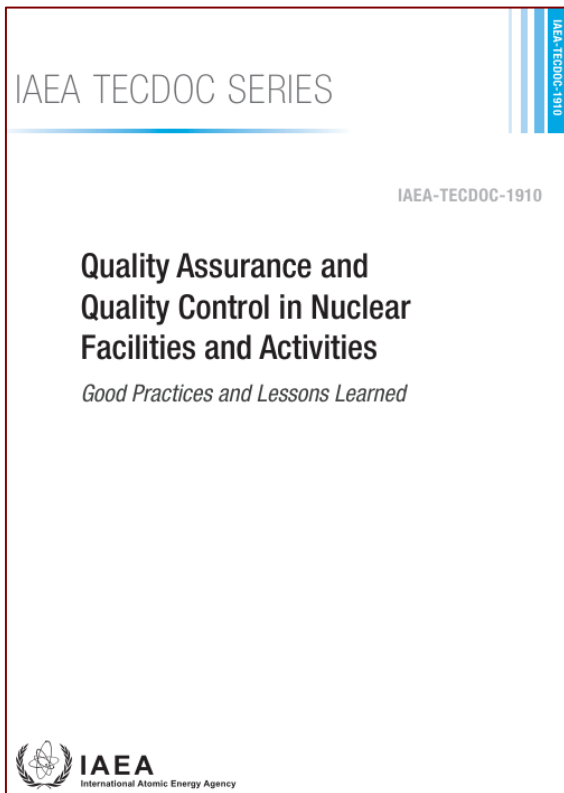
With regard to nuclear plants under design and construction, the NRC staff is also engaged in upgrading the application of QA requirements in a similar way to that discussed above. Many of these improved requirements stem from detailed analysis of programmatic and implementation deficiencies recently identified at construction sites. Areas that will receive particular attention include:

- (a) Expanding the category of structures, systems and components to which the QA programme applies, to include all items affecting safety
- (b) Ensuring improved independence of the organization performing QA functions from the work-performing organization
- (c) Improving management control of the QA function at construction sites by requiring appropriate management levels to be constantly present at the site
- (d) Participation of QA personnel in the review and approval of quality-related procedures for design and construction
- (e) Establishing criteria for assigning QA requirements to specific classes of equipment
- (f) Establishing minimum qualification requirements for QA personnel
- (g) Ensuring the availability of sufficient staffing levels commensurate with duties and responsibilities
- (h) Establishing procedures for preparation and maintenance of 'as-built' documentation in a timely manner
- (i) Defining in a clearer manner the role of QA in design activities.

The NMS > QL QM QA QC

IAEA TE-1910-2020 ~ NMS > QA & QC

https://www-pub.iaea.org/MTCD/Publications/PDF/TE-1910_web.pdf



FOREWORD

The management of quality has long been recognized as important to achieving safety and other objectives of nuclear facilities and activities. Quality assurance and quality control activities generally take place as part of a nuclear facility's management system or quality assurance programme. However, requirements for quality assurance and quality control have become less explicit in more recent editions of some management system standards. Participants in the Technical Meeting on Quality Control and Quality Assurance and on Their Relationship with Management Systems, held in 2016, highlighted the potential value of a publication on these topics.

The IAEA has developed this publication, describing relevant practices and lessons, to provide information on the implementation of quality assurance and quality control as a part of the management system of nuclear facilities and activities. It is to be used in conjunction with the IAEA Safety Standards Series, IAEA Nuclear Energy Series and other appropriate publications. The expected audience of the publication is broad, ranging from managers to experts dealing with the quality of products and services on a day-to-day basis. Newcomers to the nuclear management and quality management fields will benefit the most from this material.

The IAEA wishes to acknowledge the contribution of D. Brown (United States of America), G. Watson (United Kingdom) and J. Kickhofel (United States of America) for their role in producing the final version. The IAEA officers responsible for this publication were P. Pyy and D. Jeon of the Division of Nuclear Power.

136 Pages

The NMS > QL QM QA QC

IAEA TE-1910-2020 ~ NMS > QA & QC

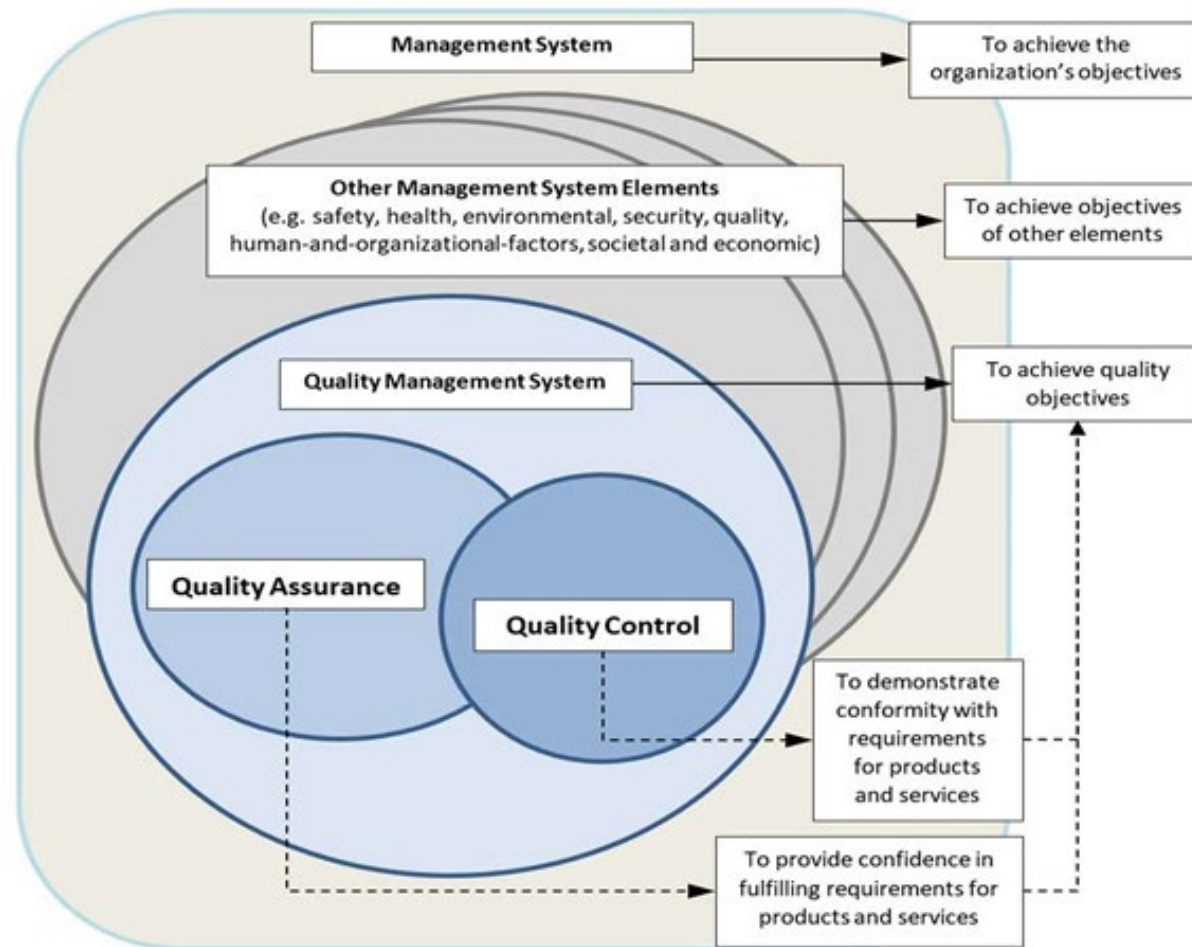


FIG. 3. A high-level illustration of connections between quality assurance, quality control and the management system of nuclear facilities.

The NMS > QL QM QA QC

IAEA TE-1910-2020 ~ Regulations | Standards

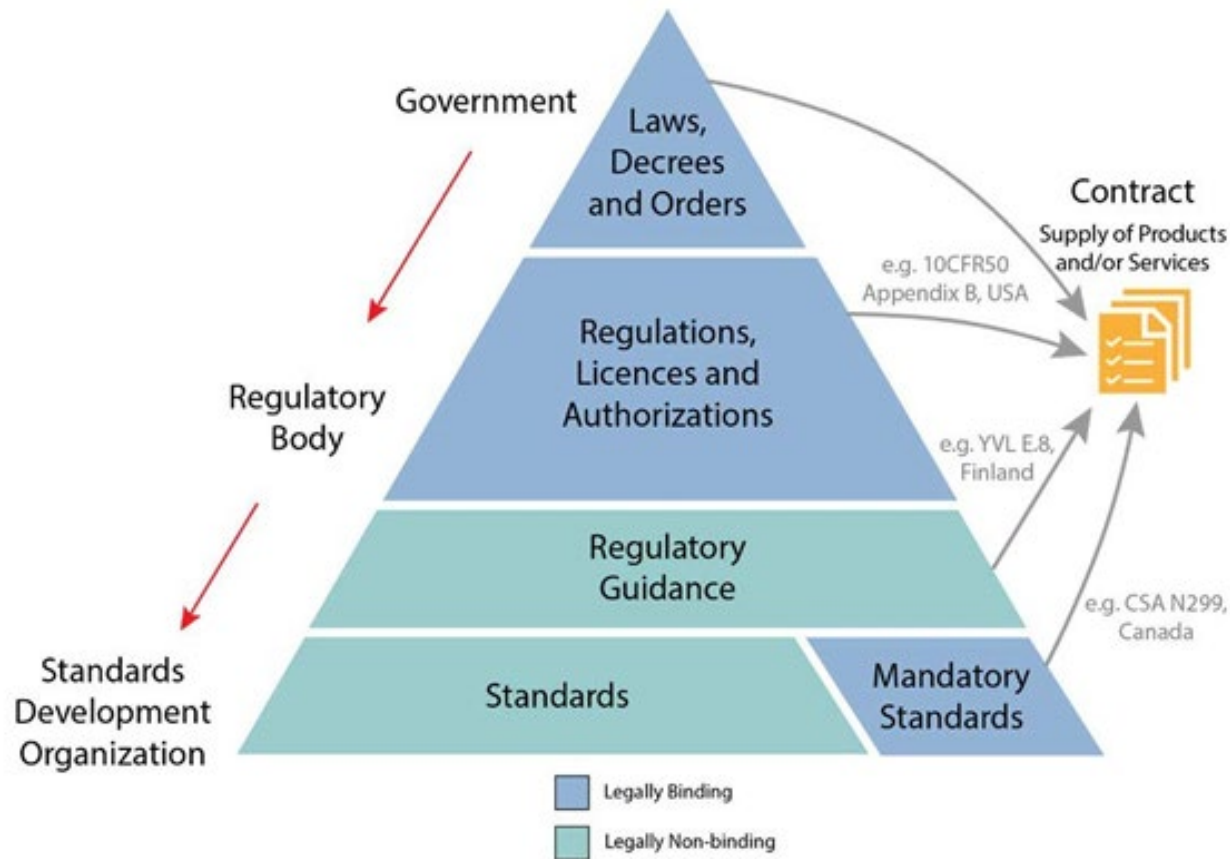
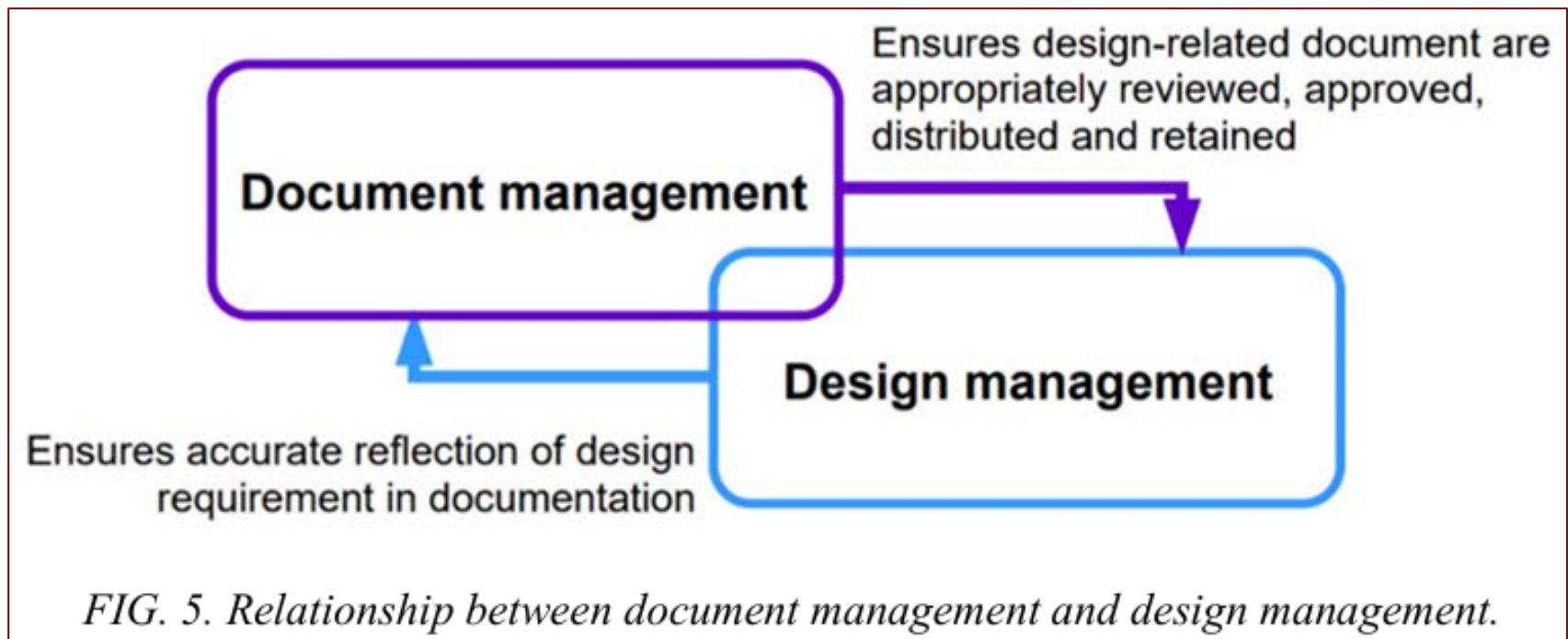


FIG. 4. Hierarchy of legal requirements, regulations and standards and the bodies issuing them.

IAEA TE-1910-2020 ~ Nuclear Information

Safety | Quality-related Information Controls



Most Nuclear Energy Companies ~ NMS

As nuclear energy-related companies (mainly startups) work to establish & implement a 'Nuclear Quality Program,' most of them recognize the 'Program' is actually the making of a full-scope 'Nuclear Management System.'

This understanding happens over time as management realizes they didn't have well defined business processes & procedures before entering the commercial nuclear energy sector (segment). Most recognize their product & service quality levels move toward higher performance & effectiveness. Most increase the 'Scope of Quality' throughout the company because of the increased ROI.

Isn't it time to clarify that a 'System' (NMS) is all encompassing while the 'QA Program' is a 'limited-scope Program' for safety-related Structures, Systems, & Components?

Some Nuclear Energy Companies ~ NMS

As nuclear energy-related companies (mainly startups) work to establish & implement all safety & quality-related requirements, some companies tend to focus most or all efforts towards the 'Technical' aspects for logical reasons ~ the goal is to effectively operate a nuclear power reactor & complex systems. A heavy focus & effort towards the goal can cause 'Administrative' aspects to take the back seat.

Caution ~ This can cause 'Show Stoppers' since the Owner, NSSS Designer, Suppliers are required to demonstrate all aspects of meeting requirements. The lack of highly effective & accurate Administrative results can end (or stand down) a developmental program when the party(ies) CAN NOT properly demonstrate compliance or reconstruct the chain of events, as necessary.

Balance Technical & Administrative Controls

<https://gqmadvisors.com/concept/>

Concept

Approach

Are Quality Performance Goals and Objectives Defined and Achievable?

Requirements

Is the QMS “Technically Complex” and “Administratively Complex”?

Disciplines

Are Operation and Program Discipline Roles and Responsibilities Defined?

Resource Integration

Is the QMS Able to Demonstrate Effective Resource Allocations?

QMS Structure

How Does the QMS Look Inside the Company?

Infrastructure

Does the QMS Scope Encompass All Company Operating Requirements?

GQM Advisors understand that some companies may struggle with the complex nature of *defining, designing, implementing, maintaining, and improving* a formal Quality Management System (QMS), especially when committing to annual quality performance goals and objectives.

A properly *defined* QMS ensures clear discipline roles and responsibilities, correct identification of technical and administrative requirements, shared ownership at interfaces, allocation and integration of needed resources, and alignment with contract and operational requirements. A properly *designed* QMS provides a simple framework that depicts process flows of products and information supported by accurate work steps, data, and data points.

~ RM ~

Requirements Management

Embrace the Matrix

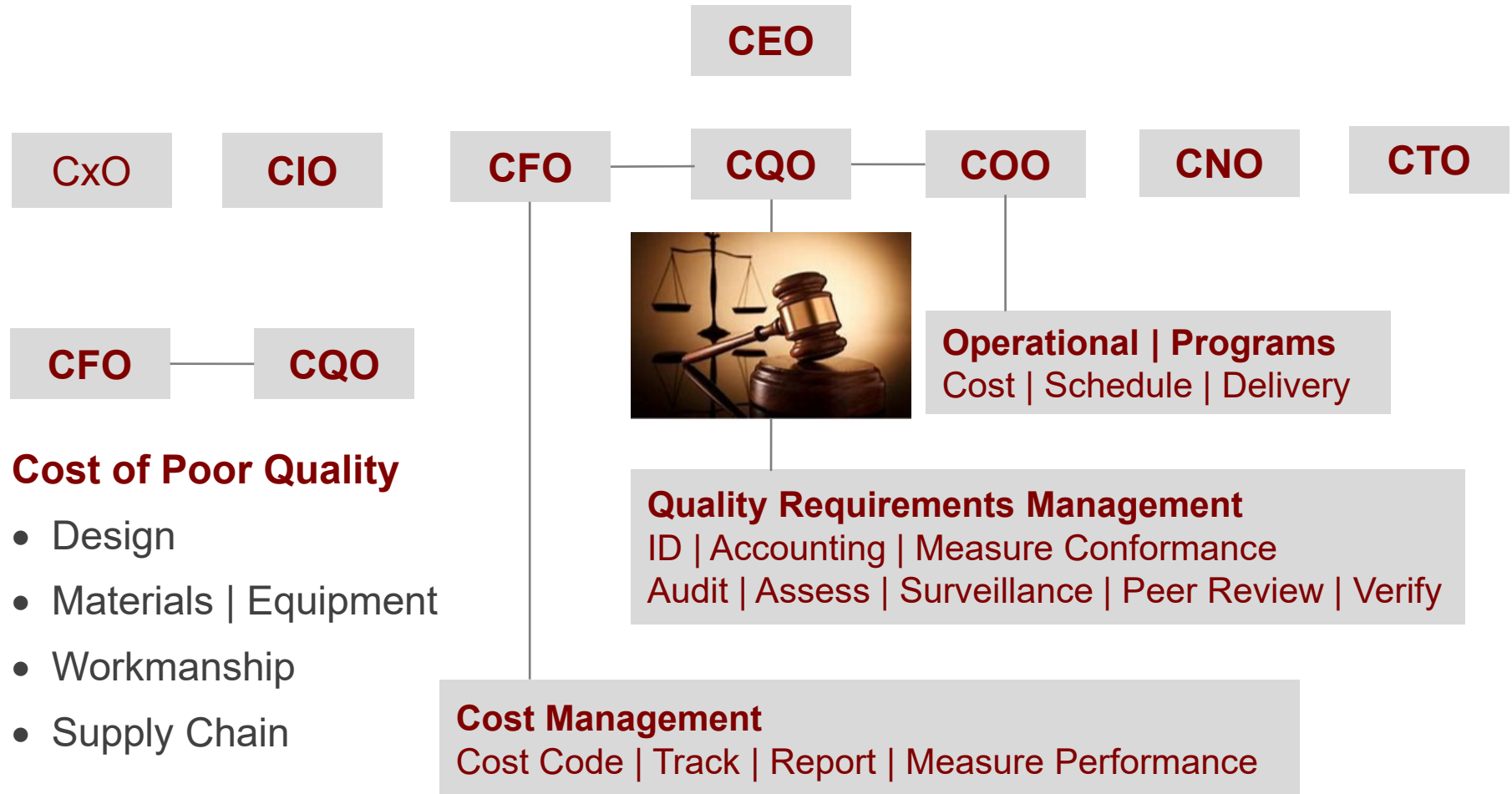
The NMS > QL QM QA QC

Requirements Management Matrix ~ NMS

Overview					Updated: 10.22.08 Revision A		Prepared / Maintained by: Paul W. Gladieux, CQO							
1) Describes the commitments in each Section of the Quality Management System 2) Shows the correlation between Commitments in the Nuclear Quality Manual derived from 10CFR50, App. A, 10CFR50, App. B, ASME-NQA-1, Others 3) Lists the applicable NuScale Power Quality-related documents 4) Shows the correlation between ABC Power quality documents and applicable customer / partner quality documents 5) Depicts Quality Activity Dates / Notes for Master Schedule and Quality Implementation Schedule Integration 6) Assists with Audit Program planning / performance 7) Provides references for training materials 8) It's a reference document to demonstrate compliance when NuScale Power is requested to demonstrate the level of compliance 9) It demonstrates the alignment of ABC's QMS across multiple requirements source documents.					Revision History		Support by: ABC Management Team							
							DOCUMENT CONTROL - This document is under the control of the Quality							
Proprietary Information					Latest Revisions Blue Text - TBD		REFERENCES							
NOTICE: This document contains information that is proprietary to ABC Power Inc. It is submitted in confidence and is to be used solely for the purpose for which it is furnished and returned upon request. This document and such informaton is not to be reproduced, transmitted, disclosed or used otherwise in whole or in part without the authorization of the Chief Executive Officer & Chief Quality Officer of ABC Power.					NOTE: Six Mandatory Procedures Stated in		1. Quality Management Plan, Latest 2. QMP Implementation Schedule, Latest							
					Procedures Applicable to Implement the Quality Documents that Correlate to the Quality Plan		Customer Procedures - Align w/ Quality Mama Partner Procedures							
Item	ISO Element	10CFR50, Appendix A	10CFR50, Appendix B	ASME NQA-1 1b-2007	QM Sect	Commitments	Requirements Definition for Implementation	ABC Power QMS Documents	Customer / Partner Documents	Number Date	Evaluation Accept / Date			
1	5.1				A	Introduction								
					A.1	Purpose	To implement Quality Management Commitments.							
2	5.1				A.2	Scope								
					3	5.3 8.2.4 8.2.3 8.2.3, 8.4 8.2.3, 8.4 8.2.3, 8.4	A.3	Corporate Quality Policy and Statement of Authority						
4	4.2.2, 5.4.2				A.4	Objectives								
					5	5.4.2 5.1, 8.5	A.5	Quality Management						
6	5.4.2						A.6	Management of Quality Plan	Prepared by: Chief Quality Officer Endorsed (Approved) by: CEO, CTO					
					1	Oranization								
1	4.2.2 5.4.2													
2	6, 6.1, 6.2 6, 6.1, 6.2													
1	4.2.2							2	Quality Assurance Program (QMS)					
2	4.2.1													
3	4.2.1 4.2.1													
								3	Design Control					
1	6.1, 6.2 6.1, 6.2							4.1	Demonstration of Competency Assessment	Process used for personnel selection w/ Roles & Responsibilities tabulation included in the Alignment Plan in the PEP. Performance is recorded & linked to annual appraisals.	P Annual Performance Review Procedure			
2	6.2							4.2	Orientation and Training	Program Director & Program Discipline Leads ensure orientation & training for all applicable Team Members.				
								5	Document and Records Management					
1	4.2.3							5.1	Document Management	Program Director & Program Discipline Leads w/ overall	ISO Mandatory Data Management Procedure			

The NMS > QL QM QA QC

Organize for Quality ~ ID Cost of Poor Quality



Nuclear CQO in the C-Suite

- Is Westinghouse Nuclear Still the Only Nuclear Company with a CQO? Why?
- Without a CQO, which C-Suite Executive 'Automatically Wears the Quality Leadership Hat'? Isn't This a High-Risk Situation?
- Without a CQO, How are KPIs & Corrective Actions Understood, Addressed, Improved?
- Without a CQO, Are Employee Concerns Communicated to C-Suite Members?
- Shouldn't Your Quality Director / Manager Report at the Correct Level ~ CQO?
- Perhaps Revisit the Timelines & 'Quality's Path to Leadership.'



Quality ~ 'Important to Nuclear Safety' (ITNS)

- Should there be one nuclear industry-specific definition & use of the term Quality?
- Should there be specific & consistent use / application of the four quality disciplines?
- Should there be specific pre-requisites & qualifications for nuclear quality professionals in each of the four disciplines?
- Should the U.S. DOE & NRC require a person in the role of CQO in organizations engaged in safety-related product & services? Is the CQO a partner with the CNO?
- Should the U.S. take the Leadership Role in eliminating confusion about The Management of Quality?
- Should every person in the U.S. nuclear industry be mandated to sign / date an 'Important to Nuclear Safety' (Pledge to Quality Policy Statement) attesting to their efforts to comply with all requirements prior to performing safety-related work?

In Modern Times ~ Definitions Emerged

There are several quality definitions, some industry-specific, that have emerged over the past 10 decades. The most important aspect is that each person understands the applicable definition used by their employer or customer and continually pursues improvements and excellence in what work they perform. The world has improved in endless ways because of the pursuit of quality improvement. Definitions have emerged over time. There are probably others.

- For starters, quality can be represented by how time and energy is being used to accomplish tasks
- A degree of excellence
- fitness for intended use
- Conformance to requirements
- Superiority in kind
- Customer satisfaction
- Fitness for use
- Doing things right the first time
- Zero defects
- It can represent how many ISO9001 requirements are met
- The degree to which an item or process meets or exceeds the user's requirements and expectations

What's Your Definition of Quality?



Does it Align With Your Workplace Products & Services?

Is Quality Clear in Your Vision, Mission, Value, Policy Statements?

True Operational & Program Effectiveness ~ Excellence

Requires A Consensus & Consistent Use Of Your Definition & Application

Requires Deliberate Focus On The Management of Quality



Who Defines Quality in Your Organization?

Why is it Critical to Have a Clear & Consistent Definition of Quality?

High-Risk & High-Consequence Safety-Related Products & Services Must be Designed, Produced, & Supplied in the Best Form & Function as Possible for End Users.

Engineers & Designers are ‘The Specifiers’ of Quality-Level Requirements & Performance Expectations for Safety-Related Products & Services for Protecting Life, Safety, Health, Security, & Environments.

Image Being in a Plane at 40K Feet NOT DESIGNED for the Highest Quality & Safety?

~ Specifying Engineers Define Quality in the U.S. Nuclear Industry ~

The NMS > QL QM QA QC

Nuclear High-Quality ~ A Global Imperative w/ Direct Impact on
Safety, Health, Environments, Cost, Schedule, Security, Profit,
Consistency, Contract | Regulatory Compliance, Competition,
Customer Satisfaction, Effectiveness, & Humanity



Quality ~ Quality ~ Qualite' ~ Qualità ~ Hinshitsu

The NMS > QL QM QA QC

Quality



Quality



Global Quality Management Advisors



~ Quality ~

What Is It ~ What It Is

~ What's The Problem ~

White Paper

December 2024

Paul W. Gladieux ~ CEO | CQO | Founder

Management Systems Focused on Quality
Since 1991

White Paper ~ December 2024

It's my goal to provide readers and researchers what I've learned the past 50 years working in and learning about The Management of Quality. What a fascinating career in a number of business sectors making efforts to ensure basic quality principles, practices, and policies where appropriate for each application. My efforts included using the art of patience, kindness, and active listening as I helped define quality management commitments then make efforts to implement.

<https://gqmadvisors.com/wp-content/uploads/2025/03/GQMadvisors-Quality-12-15-24-13pgs.pdf>

What is Quality ? ~ The Never-Ending Question

Isn't quality a simple understanding of what you like and dislike or what works and doesn't work? Isn't it shopping and finding a sweater that fits perfectly, compliments your wardrobe, and helps you feel good? Isn't it having your favorite food on a Saturday evening with your favorite friends? If your friends pick up the tab, perhaps you've experienced 'total satisfaction.' Perhaps it's having your favorite cake with family members on your birthday. We know what it is when it comes to our personal quality of life.

Come Monday morning, we're on our way to work to make a living and contribute to the goals and objectives of a business enterprise. Isn't it true you enter an environment of requirements that must be met to achieve specified results? Are you showing up for what will be a great week or, will your week start with numerous unknowns: nagging unsolved supplier problems, needing to wear three hats because of an operational RIF two weeks ago, trying to influence the lead design engineer on your proposed solutions, or overly concerned about the procurement group always being behind schedule with a compliance audit beginning in two days. Every week, we face another week of meeting quality requirements in our work life.

Paul W. Gladieux ~ Professional Goal

My goal is to assist anyone making efforts to properly define ‘The Management of Nuclear Quality.’ Please contact me if you have questions, comments, or need for assistance.

paul@gqmadvisors.com

<https://www.linkedin.com/in/paul-w-gladieux-3b53a582/>

<https://gqmadvisors.com/professional-resources/advisors/#teamMember8>

Paul W. Gladieux, CEO | CQO | Founder – More than 45 Years
GQM Advisors, Management Systems Professional

Expertise

Expertise encompasses all aspects of defining, designing, requirements baselining, structuring, writing, deploying, and upgrading effective management systems in multiple sectors. Systems range from simple commercial to complex high-hazard safety-related requiring: requirements management matrix development, large-scope information management systems (data/documents/records/reports), complex multi-site assessments and sustaining analysis. Mastery in baselining management system startups, upgrades, turnarounds. Working knowledge of national/international codes, standards, regulations, and stipulations encompassing U.S. ASME, U.S. DOE Orders, ISO Standards, U.S. NRC Regulations/NUREGs/CFRs, IAEA Standards, U.S. Baldrige Performance Criteria, and others. Over 10K hours engaged in management system assessments (1983 ASME/NQA-1 Nuclear Lead Assessor certified, and 1994 U.S. and UK ISO QMS Lead Assessor certified - six sectors). Service marked 'GQM Advisors Management Systems Focused on Quality Since 1991.'

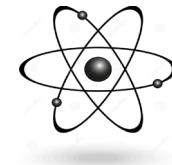
GQM ADVISORS WAS FOUNDED IN 1991 on the belief the “Management of Quality is a fundamental responsibility of everyone engaged in the delivery of products & services.” We are a group of leading Independent Quality-focused Professionals with a reputation of mastery & excellence in deploying the Four Quality Disciplines > QL, QM, QA, & QC. The Group understands that all business disciplines must be quality-focused for an organization to achieve annual goals & objectives delineated in its Quality Management System (QMS).



Since 1991

<https://gqmadvisors.com/professional-resources/advisors/>

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	Canada	
	Netherlands	
	United Kingdom	



Since 1974

Advisors collective expertise exceeds 1,000 years encompassing more than 50 Business Sectors | Segments | Applications. Our established relationships in various industries, societies, agencies, business peer groups, & supply chains enables us to align the never-ending mix of management systems baseline requirements in virtually any operation and program environment. Our experiences vary & span a 50-year period beginning in the early 1970s.

Global Quality Management Advisors

Nuclear Management Systems ~ Focused on Quality ~

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34 Years ~ Serving Clients

Since 1991

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