60 Minutes ~ Nuclear Quality

Nuclear Professionals **ISO 19443 ITNS**

Content From GQM Advisors 'Nuclear Management Systems' Course



ITNS Important To **Nuclear Safety**



Our Intent Raise Awareness 8 **Prevent Problems**



Nuclear **Safety-Related Quality-Related**



Nuclear Don't Ignore ITNS for Your **Quality Management System**



Nuclear **QMS** Alignment with **Global Market**



Don't Let 'Show Stoppers' Disrupt Your Reactor & Site Design | Build | Startup Plans & Upset Your Investors!

Please ~ Do Not Ignore Global ISO / IAEA Requirements Documents for 'The Management of Nuclear Quality'

1st Fleet Nuclear Quality Management Professionals Know How to 'Prevent Your Show from Stopping'



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





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Foreword

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This document was prepared by Technical Committee ISO/TC 85, Nuclear energy, nuclear technologies, and radiological protection.



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1 Scope

ISO 9001:2015, Quality management systems — Requirements
1 Scope
This International Standard specifies requirements for a quality management system when an organization:
a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and
b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.
NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.
NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

This International Standard applies to organizations supplying ITNS products or services.

Application of this standard to organizations performing activities on a licensed nuclear site is subject to prior agreement by the Licensee.

Requirements specified in this International Standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

QMS ~ ISO 19443:2018 - ITNS



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Bibliography



7 ~ Primary Management Elements





Example Process Flow Model





Management Team ~ Design Your Nuclear QMS

- U.S. NRC 10CFR50, App. B '18 Criteria' & ASME NQA-1, Applicable Edition
- ISO 9001 & 19443 QMS '7 Management System Elements' ~ Process-based
- Understand Your Commitments | Processes ~ Requirements Matrix



'18' Functional Requirements



'7' Management System Elements



Management Team ~ Manage Your Requirements Matrix

Appendix A				
	QMQA Requirement Matrix			
10CFR830 / DOEO414.1D / DOE EM-QA-001 ASME / NQA-1 ISO9001				
No.	Criterion	Requirement	F' ment	Section
1	Program	1, 2	5.4.2, 5.5.2	1, 2, 4, 6, 7
2	Personnel Training and Qualification	2	6.2.2	4
3	Quality Improvement	15 *	8.5.1	2, 4, 6, 10
4	Document GQM and Records		+.2.3, 4.2.4	8, 9
5	Work Processes			3, 4
6	Design	x hu	7.3.1, 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.6	2, 3, 4
7	Procurement		7.4.1, 7.4.2, 7.4.3	3
8	Inspection and Acce	،, 10, 11, 12, 14	7,.6, 8.1, 8.2.3, 8.2.4, 8.3, 8.5.2, 8.5.3	4
9	Management Assessn	2, 18	5.6.1, 5.6.2, 5.6.3, 8.2.1, 8.2.2, 8.4, 8.5.1, 8.5.2, 8.5.3	2, 10
10	Independent Assessment	NA	8.2.1, 8.2.3, 8.2.4, 8.4, 8.5.2, 8.5.3	2, 10



The Show Stopper?

During the U.S. 1st Fleet Design & Build Era 1970 ~ 1990 The 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, 2008

U.S. Study ~ Public Law 97-415



NRC Study at the Request of 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

- <u>To Conduct a Study of Existing & Alternative Programs for Improving Quality & the Assurance</u> 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)









U.S. NPP Events Leading to The Study

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Brown's Ferry Incident in 1975

Three Mile Island Accident in 1979

Construction Contractors Issued SWOs & SCOs

Investigations – Policy, Procedure, Specification Non-conformances

Construction Problems in '70s such as Marble-Hill & W. H. Zimmer

Licensees Unable to Demonstrate Plant Built to All Requirements Marble-Hill & W. H. Zimmer Cancelled

Reports of Schedule Precedence Over Quality

Reports Lowered Trust that Plants were being Built per Regulations, Codes, Standards to ensure Safety & Quality







Brown's Ferry







Scope ~ Licensee Design | Build Programs

Build Program	Case Study	Major Quality Problems	Utility	Online Dates
Marble Hill Cancelled	A	Yes	Public Service of Indiana	Proposed 1973. \$2.2 billion failed design/build program closed 1984
St. Lucie 2	В	Νο	Florida Power & Light	R1 03/01/76 R2 06/10/83
Diablo Canyon	С	Yes	Pacific Gas & Electric	R1 05/07/85 R2 03/13/86
South Texas	D	Yes	Houston Lighting & Power	R1 08/25/88 R2 06/19/89
Vogtle 1 & 2	E	Νο	Georgia Power	R1 06/01/87 R2 05/20/89
Palo Verde	F	Νο	Arizona Public Service	R1 01/28/86 R2 10/19/86 R3 01/08/88
W. H. Zimmer Cancelled	G	Yes	Cincinnati Gas & Electric	Proposed 1969. \$3.4 billion failed design/build program converted to coal 1984



NRC Report to Congress

	NUREG-1055 For Comment
Improving Quality and the Assurance of Quality in the Design and Construction of Nuclear Power Plants	
A Report to Congress	
U.S. Nuclear Regulatory Commission Office of Inspection and Enforcement	
W. Altman, T. Ankrum, W. Brach	
Reprinted March 1987	



https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1055/index.html

"Those Who Cannot Remember the Past are Condemned to Repeat It"

Glenn M. Tracy, NRC, 2008

https://www.nrc.gov/docs/ML0930/ML093020509.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



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What Are The Deficiencies?

What is being observed in current construction efforts:

- Inadequate QC
 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



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https://www.nrc.gov/docs/ML0930/ML093020509.pdf

What Are The Deficiencies?

What is being observed in current construction efforts:

- Vendors inexperienced in nuclear environments
- Construction craft and contractors inexperienced in nuclear environments
- Difficulty managing multiple design control processes
- Difficulty managing multiple problem identification and resolution (PI&R) programs
- Procurement specification issues beyond code but not enforcing
- Vendor oversight challenges
- Insufficient QA personnel for oversight activities
- Lack of Commercial Grade Dedication understanding
- Lack of 10 CFR Part 21 understanding



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NUREG-1055

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Most Critical Deficiency

.S. Nuclear Regulatory ommission "Early training to Appendix B of 10CFR50 was through on-the-job-training fice of Inspection and Enforce Altanan T. Anknum W. Brack (Sel) with experienced personnel. In 1975, training in App B consisted of **self-reading.** In 1976, one hour of a fragmented course whose schedule was diverted by the class, was allocated to App B. A longer formalized course was not developed until 1983. During the study, it was stated there is a great need for more training in Quality Assurance, Standards, & App B of 10CFR50. It was also stated that there was practically no training in how to apply modules or how to do inspections. These skills come mainly from on-the-job-training. More training is needed to improve the caliber & qualifications of inspectors."



Study Conclusion

A primary focus of the study was to determine the underlying causes of **major guality**-(H) **Related problems** in the design & construction of some nuclear power plants & the untimely detection & correction of these problems. The study concluded that the root cause for major quality-related problems 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. These management shortcoming arose in part from inexperience on the part of some project teams in the construction of nuclear power plants. In addition, NRC's past licensing and inspection practices did not adequately screen construction permit applicants for overall capability to manage or provide effective management oversight over the construction project.



Study Recommendations

The study recommends self-imposed rising standards of excellence, treatment of (U#) quality assurance as a management tool, not a substitute for management, improved trend analysis & identification of root causes of quality problems, & a program of comprehensive third-party audits of present & future construction projects. To improve NRC programs, the study recommends a heavier emphasis on team inspections & resident inspectors, an enhanced review of new applicant's capabilities to construct commercial nuclear power plants, more attention to management issues, improved diagnostic & trending capabilities, improved guality & guality assurance for operating reactors, & development of guidance to facilitate the prioritization of guality assurance measures commensurate with the importance of plant structures, systems, & components to the achievement of safety.

Report to Congre

.S. Nuclear Regulatory ommission frice of Inspection and Enforcement



Potential Show Stoppers

- C-Suite Executives Not Establishing Nuclear-Related Policies | Processes for Flowdown
- C-Suite Executives Not Knowing Impacts of Global Requirements Documents
- C-Suite Executives No Requirements & Configuration Management Strategies
- Clear Evidence of Cost & Schedule Priorities over Quality
- Major Inconsistencies in Knowing Quality Principles, Practices, Processes, Procedures
- Lack of Effective Enterprise-wide Training & Certifications, as Required
- Lack of Strong Engineering Control | Oversight for All Safety | Quality-Related Aspects
 - Engineering is The Specifying Organization ~ Sets & Controls the Design Safety Basis
 - Weak Contract Review Process Controls
 - Weak Engineering | Procurement | Supplier Quality Engineering Interface Controls
- Lack of a High-Performing Nuclear Information Program (Doc, Data, Rec Adm. Controls)
- Poor Communications & Requirements Flowdown Among the Supply Chain



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GQMadvisors NMS-MNQ TmLn 04-09-25, R1 Fig 2



Questions

- 1. In your opinion, are your senior management, program management, workforce, & suppliers committed to unconditionally executing your Nuclear Quality Management Policy?
- 2. Are all employees committed to Company Policies, Processes, & Procedures?
- 3. Do you have access to the Nuclear Management System (aka, QA Program)?
- 4. Have you attended training on Nuclear Quality Management, Four Disciplines QL/QM/QA/QC, 10CFR50 App A & B, 10CFR Part 21, ASME/NQA-1, ISO9001, ISO19443, ASME Codes, NPP Licensing, Nuclear Safety Culture, Employee Concern & Corrective Action Programs, others?
- 5. Do you feel confident in understanding the requirements as they apply to your daily programs / projects / activities / tasks & flowdown requirements to suppliers?
- 6. Does your management unconditionally endorse the Employee Concern Program or are you working in a "chilled" work environment?
- 7. Do you feel confident in submitting a formal Employee Concern to your management?

You're welcome to share answers with Professionals at GQM Advisors. Simply state yes or no in a message using our Web Contact page https://gqmadvisors.com/contact/ or Email to paul@gqmadvisors.com/contact/ or Email to paul@gqmadvisors.com/contact/ or Email to paul@gqmadvisors.com/contact- or paul@gqmadvisors.com/contact- or paul@gqmadvisors.com/contact- or paul@gqmadvisors.com/contact- or paul@gqmadvisors.com/contact- or <a href="mailt



Is Your C-Suite Aware of <u>ISO 19443</u> <u>Nuclear Energy-Specific Requirements</u>?

If NOT Contact



Lynn Williams, PhD – More than 30 Years Experience Founder & Managing Director Nuclear cc, Advisor | Consultant

Nuclear CC - Consultancy in the nuclear and manufacturing industry

List of ISO 19443 Certified Companies (nqsa.org)



Is Your C-Suite Aware of 10CFR50, App. B & <u>ASME/NQA-1 Audit / Assessment Processes</u>?

If NOT Contact



John H. Johnson – More than 40 Years, Nuclear Professional President, J-E-T-S Quality Consultants, Inc.

Nuclear Training Company | J-E-T-S Quality Consultants (jetsquality.com)

Free Audit & Assessment Help | Jets Quality Consultants



Is Your C-Suite Aware of Their Roles in U.S. NRC 10CFR50, App B & 10CFR Part 21?

If NOT Contact

Beri Associates (USA) Inc.

About Beri Associates

Beri Associates was founded in 1994. We are a small, highly specialized company that provides training, auditing and consulting located in the great Pacific Northwest, USA. We are excited that you are interested in our high quality trainings based on Sham Beri's experience of nearly 850 audits all over the globe.

Shamsher (Sham) Beri – More than 35 Years President, Beri Associates, Inc.

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GQM Nuclear Advisors ~ Mastery



Does Your C-Suite <u>Operate from</u> <u>A Risk Mitigation Standpoint</u>?

If NOT Contact



Greg Hutchins, PE, CERM – More Than 45 Years Principal Engineer & Founder, Quality Plus Engineering (Q+E)

Quality + Engineering (qualityplusengineering.com)



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We Have Extensive Mastery of The Four Quality Disciplines

Quality Leadership (QL) The Department of the Navy's definition of QL is based on Dr. 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>U.S. Depart Of The Navy</u> <u>TQL In The Fleet Theory to Practice, J.Wasik, B.Ryan, 1993, AD-A275 444 92pgs.</u>

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).



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 <u>Four</u> <u>Quality Disciplines > QL, QM, QA, & QC.</u> 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).



Advisors collective expertise exceeds 1,000 years encompassing more than <u>50 Business Sectors</u> | <u>Segments | Applications</u>. 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.

Nuclear Quality Management Advisors

Nuclear Management Systems

~ Focused on Quality

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