60 Minutes ~ Lessons Learned



Content From GQM Advisors 'Nuclear Management Systems' Course



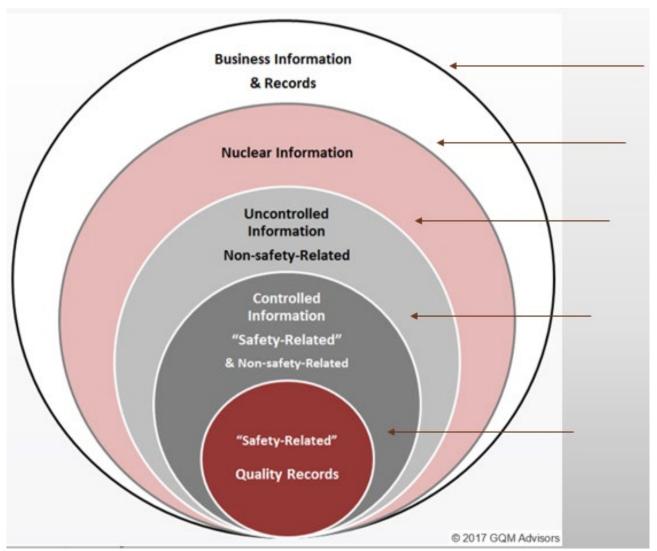
Nuclear Information

Safety-Related =

Quality-Related



Controlled Information ~ 'Safety-Related'





- Can Your Nuclear Information Management System ID Safety-Related Documents, Data, Records?
- Do You Understand The NIM Concept, Processes, Procedures, & Requirements?
- Is NIM In Your NEO Training Portfolio?
- Is Proficiency Maintenance Training Provided?

WHY NOT?



Is 'The Management of Nuclear Information' Owned by Your C-Suite Members?





In The C-Suite, Is There a Consensus on The <u>'Critical Legal Aspects'</u> Of Managing Nuclear Information'?





In The C-Suite, Is There a Consensus on 'Why Proper Resources are Critical for Acceptable Licensing Information & Overall Operations'?





Is The C-Suite Message 'NIM is A Critical Core Discipline For All to Embrace & Manage'?





10CFR50, Appendix B Regulatory

- Criterion 6 'Document Control'
- Criterion 17 'Quality Assurance Records'

ASME/NQA-1 Industry

- Requirement 6 'Document Control'
- Requirement 17 'Quality Assurance Records'

Regulatory - Other

- RG 1.88 Rev 2 Collection, Storage, & Maintenance of NPP Quality Assurance Records
- U.S. NRC Generic Letter 88-18 & RIS 2000-18



- NIRMA Industry's Nuclear Information & Records Management Association - 1979
 - Now Managed by ANSI
 https://webstore.ansi.org/sdo/nirma?srsltid=AfmBOooDuja8eMaEyHVSjy294rLq7X5pOndMHw
 WB-okn754AuRt8NKrS

Technical Guidelines

- NIRMA TG 11-2011, Authentication of Records & Media
- NIRMA TG 15-2011, Management of Electronic Records
- NIRMA TG 16-2011, Software Quality Assurance Documentation & Records Electronic Media
- NIRMA TG 21-2011, Required Records Protection, Disaster Recovery & Business
 Continuation



Critical Information Control

Phases

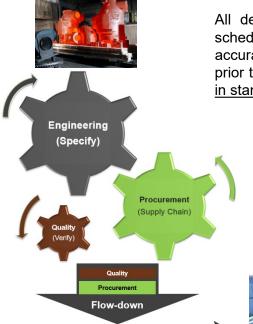
Design - Conceptual, Preliminary, Final

Procurement, Build, Test

Licensing, Operations



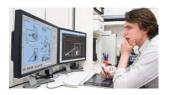
Purdue School of Nuclear Engineering. Purdue University Reactor Number One. or PUR-1.



All deliverable information must be accepted / approved at scheduled "Points-of-Use" (Time). Licensee must demonstrate accurate & complete information "What is Actually There" prior to startup. Loss of information control and/or errors results in stand-down(s) or cancellation.













Critical Information Large Step in Volume

What Needs to be There

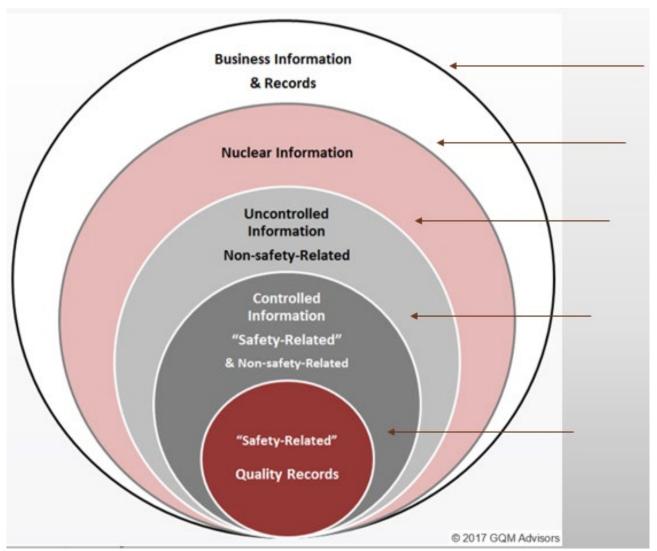
What we Say is There

What is Actually There

Requirements & Configuration Management



Controlled Information ~ 'Safety-Related'





OperationsPolicy Statement

Nuclear Information Policy Statement

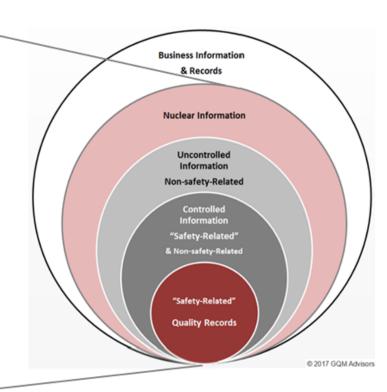
The identification and overall management of Nuclear Information is a critical business element for ensuring compliance and effective daily operations. Guidance and oversight is the responsibility of the Chief Operations Officer.

The overall Nuclear Information Management administrative controls are delineated in two primary documents:

- AA BB CC Document Management
- XX YY ZZ Records Management

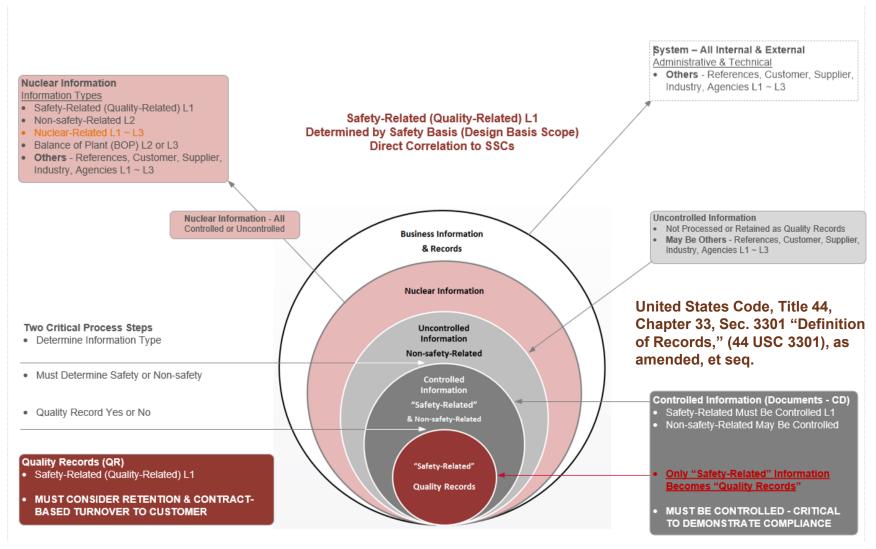
These are complimenting processes that encompass corporate, regulatory, industry, operational, and program level requirements and how work activities are performed to deliver high quality information to our customers.

Compliance with this policy is mandatory.



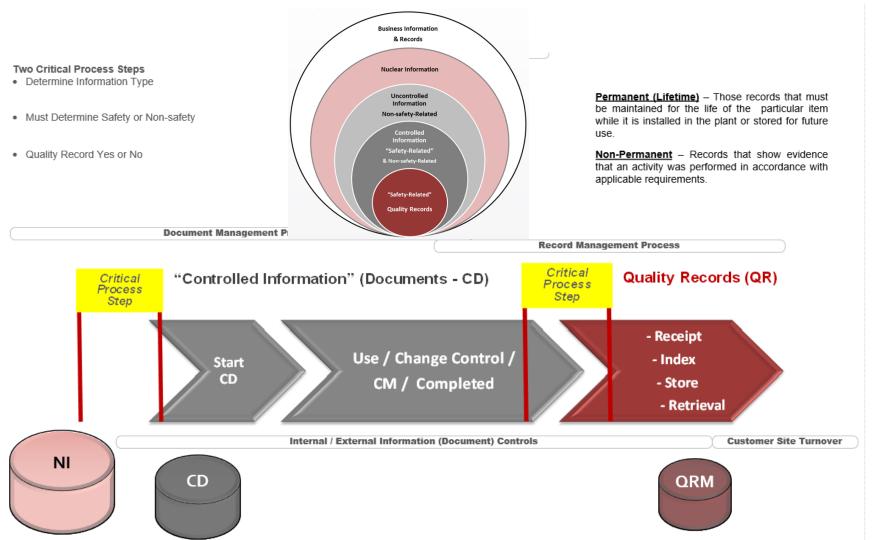


Critical Information ~ Elements





Critical Information ~ Process





Critical Information ~ Terms & Definitions

Concept & Commitment Development

Document Management QAPD Section 6 Record Management QAPD Section 17

Linked Core Processes

Identification, Preparation, Review, Approval, Issue, and Change of "Controlled Documents" Containing "Nuclear Information" Relating to the Quality of Items and Services.

"Document" vs. "Controlled Document"

- Electronic / Hard Copy
- Everyone's Responsibility
- Data / Document Same
- Traceability Who & Point of Use
- Completed Document > Record
- Safety-related > "Quality Record"

Identification, Preparation, Collection, Index, Retention, Storage, Retrieval, and Disposition of "Quality Records."

"Record" vs. "Quality Record"

- Electronic / Hard Copy
- · Everyone's Responsibility
- Data / Document Same
- Statutes of Limitation
- Traceability Variable
- Completed Document > Record
- Quality Record vs. Record
- Permanent / Non / Turnover

Primary Requirements

Controlled Document

- 10CFR50 Appendix B Criterion 6
- · Regulatory Guide 1.28, R3, August 1985
- ASME/NQA-1-1994, Parts I, II, III
- U.S. NIRMA Technical Guides
- Customer Contract

"It is the responsibility of the owner to assure itself, in accordance with Criterion 17 of Appendix B to 10 CFR Part 50, that sufficient records are maintained to furnish evidence of activities affecting quality."

Appendix B & NRC RG 1.28

Quality Record

- 10CFR50 Appendix B Criterion 17
- Regulatory Guide 1.28, R3, August 1985
- ASME/NQA-1-1994, Parts I, II, III
- U.S. NIRMA Technical Guides (1998) TG-11, -15, -16, -21
- NRC Generic Letter 88-18
- NRC RIS 2000-18

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Customer Contract



Applicable Accurate Information (Records)

Must be at the NPP in the "Controlled Access Environment"

Phases

Design - Conceptual, Preliminary, Final

Procurement, Build, Test

Licensing, Operations

All deliverable information must be accepted / approved at scheduled "Points-of-Use" (Time). Licensee must demonstrate accurate & complete information "What is Actually There" prior to startup. Loss of information control and/or errors results in stand-down(s) or cancellation.



Critical Step in Information Volume for Build, Licensing, Operations, & Maintenance







What Needs to be There

What we Say is There

What is Actually There

Requirements & Configuration Management



1987 Nuclear Information Control Center

Entergy Nuclear Operations ~ Services Group (NOLA)

1st Fleet ~ '70s & '80s'

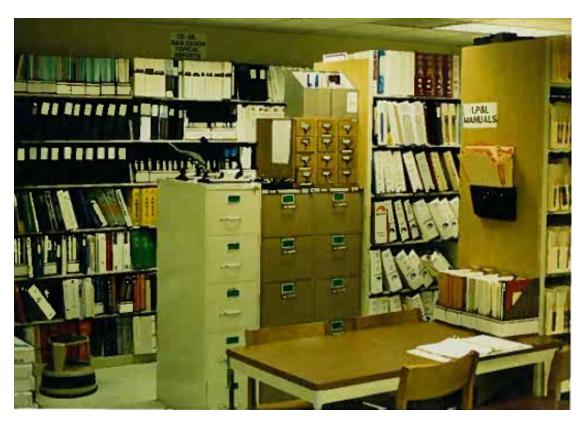
Scope

ANO 1 & 2 ~ Operations (APL)

Grand Gulf ~ Operations (MPL)

Waterford 3 ~ Operations (LPL)

Partial Photo
8K Project File Folders
9K Operations Procedures
10 Contract Fire Proof Cabinets
(Not in View)





Which Method Satisfies 10CFR50 App B?







Electronic Information Management Systems?

- Can Your Nuclear Information Management System ID Safety-Related Documents, Data, Records?
- Design Your System to Fully Comply w/ Baseline Requirements Stated on Slides 9 / 10 & Licensees (Owners) Commitments.
- Challenge your supply chain's Methods & Procedures.
- Ensure Disaster Recovery Capabilities.



U.S. Commercial Nuclear ~ Quality Management

1990 2000 2005 2010

Renaissance ~ AP1000 ~ U.S. NuStart Consortium 9 Utilities - Build 30 AP1000 Reactors

ISO 9001 ISO 14001 ISO 45001 ISO 27001 other ISO Management System Certs, ISO 19443 N

U.S. Quality Leaders Emerging

Dr. Walter A. Shewhart

Dr. W. Edwards Deming 'Conformance to Requirements' Philip B. Crosby-

Dr. Armand V. Feigenbaum

1979 Concept Emerged

1970

· Dr. Joseph M. Juran

1960

Articles & Books on Quality

1960 QA

Major Emphasis on Quality | Safety

'Cost of Poor Quality' U.S. Military Supply Chain

1946 ISO Formed

OSHA Regulations

1970 QE

'79 1980

SHALITY

IS FREE

Quality Management Systems (QMS)

1987 ISO 9001 QMS Standards Released

Accident Impacted - Design | Fabrication | Build | Startup | Operations

1987

1987

(PMI) Formed

U.S. Reagan | Baldrige

Performance Excellence

Project Management Institute

1980 QM

Quality Management Tools SixSigma, QFD, FEMA, PDCA, C&E Diagraming, Mapping, Software, Assessments

1995 ISO QMS Certified 75K

Enterprise Software

- Intra- & Internet
- e-QMS
- CMM Site Wide

Integrated Management Systems (IMS)

<<< Knowledge Transfer Gap >>>>

- IMS, QMS, EMS, RM, SCM, Others
- Requirements Matrix (Advanced)
- Process Hazards Mgt
- Enterprise Software (Advanced)
- Cyber Security
- Supply Chain Mgt (Advanced)
- Post 911 Safety / Security

2006 ISO 9001 QMS Certified .6 million, among 155 Countries

> 2012 ISO 9001 QMS Certified 1.1 mil, among 178 Countries

> > 2010 Culture

Renaissance ~ TBD

SMRs > 80 Reactor Designers

2030

MMRs ~ TBD

LNPPs > 25 Reactor Designs

Fusion ~ TBD

CS & AI ~ TBD 1960 ~ 2025

2025

2020

65 Years ~ Will The Gap Close?

Numerous global non-nuclear industry sectors have been implementing ISO 9001 Quality Management Systems & quality tools since 1987. QMS certifications now exceed 1.5 million. Many nations require QMS certification as a part of product / service / system safety-basis certifications.

The U.S. NRC recognized ISO9001:2000 in 2003. This model also suggests the industry may require provisions for implementing "Integrated Management

2018 ~ New ISO 19443 Nuclear QMS

Will U.S. Nuclear Industry Executives Recognize & Integrate Advanced Quality Management Tools to Enhance Overall

The U.S. chemical, oil, and gas industries have a history of QC. Inspection, & Testing as the methods for ensuring safety & specification compliance. In the mid-'60s, the nuclear industry initiated QA with

- · Is the new generation of professionals well trained in U.S. NRC 10CFR50, App. B & ASME NQA-1 Quality Management Requirements?
- · Does the nuclear industry recognize the 'Management of Quality' & its focus is driven by company executives & safety-related items?
- Do executives recognize & embrace advanced 'Quality Management Tools' available to enhance, safety, effectiveness, & compliance?
- unconditional Quality Management support?

Paul W. Gladieux ~ CEO | CQO | Founder

2030

2020 CS | AI

Systems."

1950 ~ 2000 LNPP Design | Build Period 65 LNPP Sites & 100 Power Reactors 2000 Renaissance ~ LNPP & SMR NPPs 2005 China AP1000 2 NPP Sites w/ 4 Reactors Operational Effectiveness? 1957 App B. Needs Major Upgrade – Requirements Documents & Management of Quality Practices 2008 NuScalePower SMR -TBD IAFA Founded U.S 10CFR50 App B U.S. Reg Guides U.S. ASME/NQA-1 **U.S ANS 3.2** CSA Z299 IAEA-GS-R3 1950 NRC QA Public Law 1984 Marble-Hill Cancelled \$3.2 bil Operational ~ Vogtle 3 & 4 AP1K Complex Engineered 10CFR50 Appendix B 1984 WH Zimmer Cancelled \$ 3.4 bil 2017 VC Summer AP1K Cancelled \$9 bil Products / Systems the goal of "error prevention." 2016 mPower SMR Cancelled \$400 mil 1979 Accident 1986 Accident 1962 1971 Three Mile Island NPP Chernobyl NPP 2011 Accident Mil-Q-9858A **Industry Standards** 1984 U.S. NRC NUREG-1055 Report to Congress Fukushima NPP UK BS-5750 ANSI N45.2 - 1971 QA ANSI N45.2 - 1977 QA 2010 BP 1987 - ISO 9001 ASME / NQA-1 - 1979 QA Deepwater Horizon 2001 1965 Inspection | Quality 911 Twin Towers New Codes / Test Era Management Standards / Systems 1974 Culture EMS Shift 'Paper Work' Regulations **NRC Regulatory Guides** Safety to 'Information Work' Quality RGs / Codes / Standards Will industry members realize the benefits by Quality Quality Quality Enterprise Integrated - Risk Audits / Assessments / Oversight Control Assurance Management Management Management Programs Programs Systems Software Robotics System - Security Cyber Security | Al QA, QC, Test, Supply Chain Management Quality Engineering, Design Assurance

GQMadvisors NMS-MNQ TmLn 04-09-25, R1 Fig 2 @ 2017 GQM Advisors

2000 IMS

QMS 1990 EMS

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https://gqmadvisors.com/disciplines/

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 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 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).



Arizona	Nevada	Tennessee
California	New Jersey	Texas
Colorado	North Carolina	Utah
Florida	Ohio	Virginia
Georgia	Oregon	Washington
Michigan	South Carolina	Washington, DC



Canada

Netherlands

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

United Kingdom

<u>Advisors</u> 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.



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

If NOT Contact



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



https://beriassociates.thinkific.com/pages/about-beri-associates

https://beriassociates.thinkific.com/collections



Is Your C-Suite Aware of <u>ISO19443</u> Nuclear Energy-Specific Requirements?

If NOT Contact



Nuclear CC - Consultancy in the nuclear and manufacturing industry

<u>List of ISO 19443 Certified Companies (nqsa.org)</u>



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

If NOT Contact



Quality + Engineering (qualityplusengineering.com)

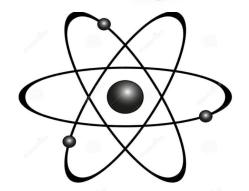
Nuclear Quality Management Advisors

Nuclear Management Systems

~ Focused on Quality

Paul W. Gladieux CEO | CQO | Founder Lynchburg, VA USA 503-939-4498 C

34 Years ~ Serving Clients



Since 1974

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