

60 Minutes ~ Lessons Learned



Nuclear Information Safety-Related

Content From GQM Advisors
'Nuclear Management Systems' Course

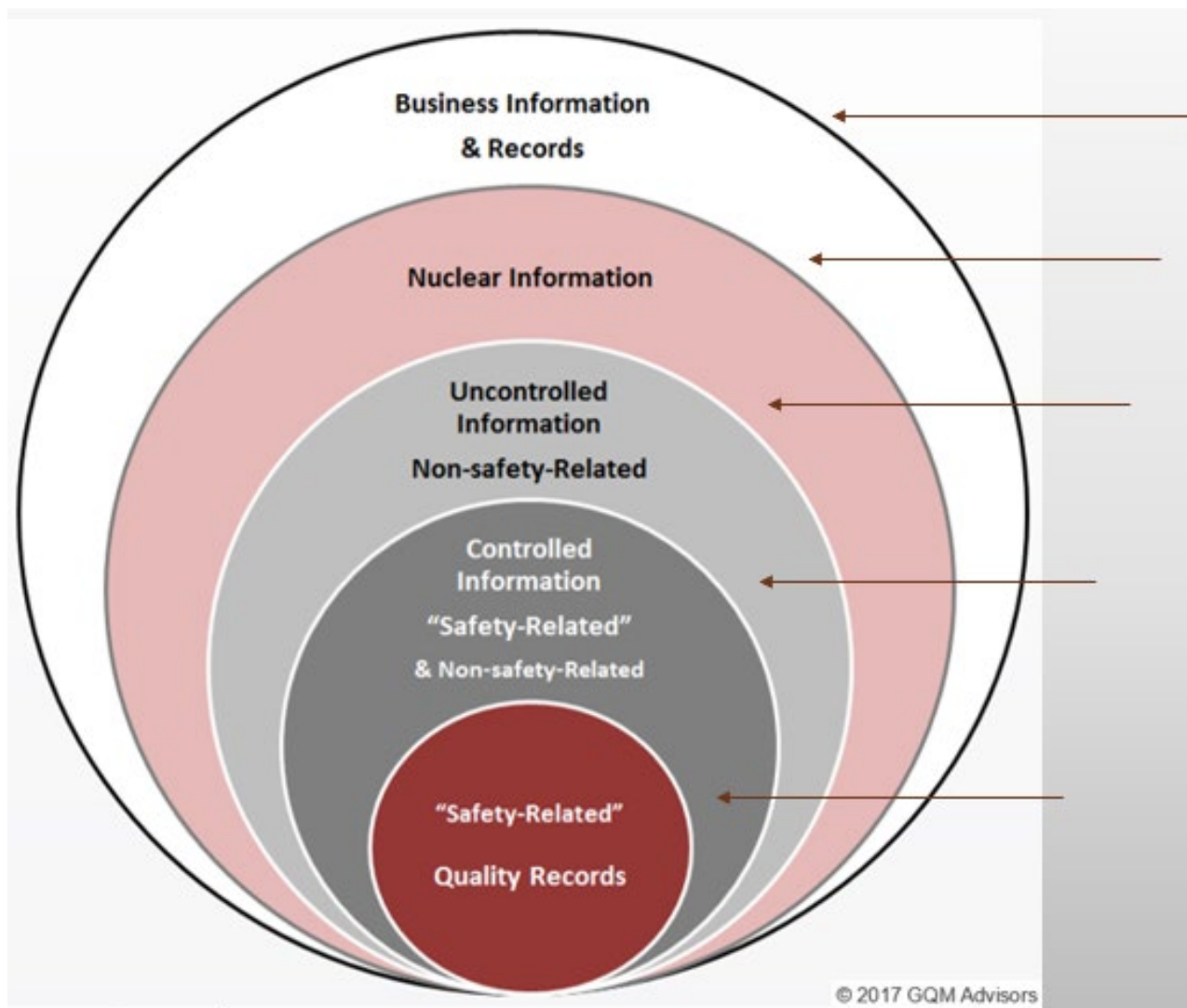
Nuclear Information

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 ‘Critical Legal Aspects’ 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?srsItid=AfmBOooDuja8eMaEyHVSjy294rLq7X5pOndMHwWB-okn754AuRt8NKrS>

- **Technical Guidelines**

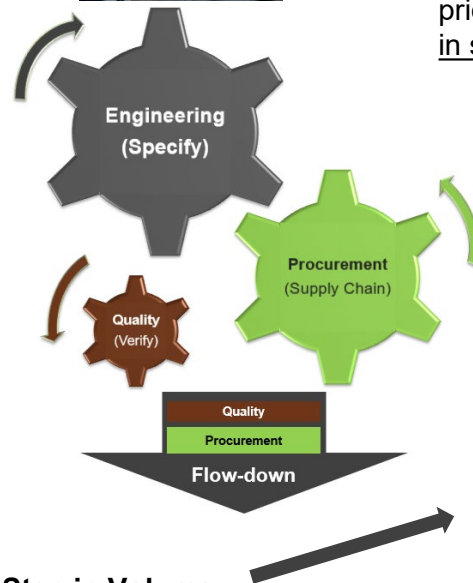
- **NIRMA TG 11-2011, Authentication of Records & Media**
- **NIRMA TG 15-2011, Management of Electronic Records**
- **NIRMA TG 16-2011, Software Quality Assurance Documentation & Records - Electronic Media**
- **NIRMA TG 21-2011, Required Records Protection, Disaster Recovery & Business Continuation**

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

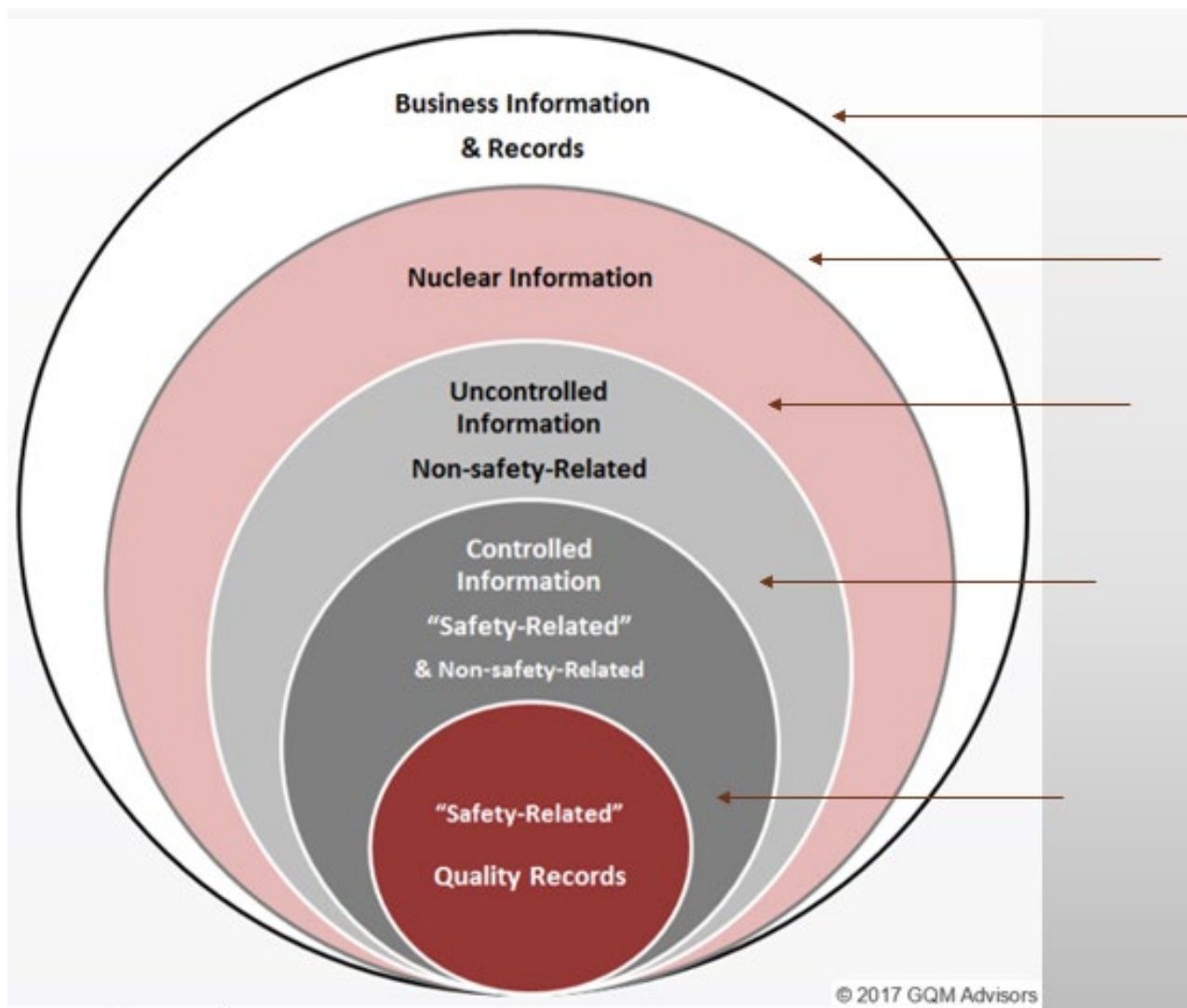
What Needs to be There

What we Say is There

What is Actually There

Requirements & Configuration Management

Controlled Information ~ 'Safety-Related'



Operations Policy Statement

Nuclear Information Policy Statement

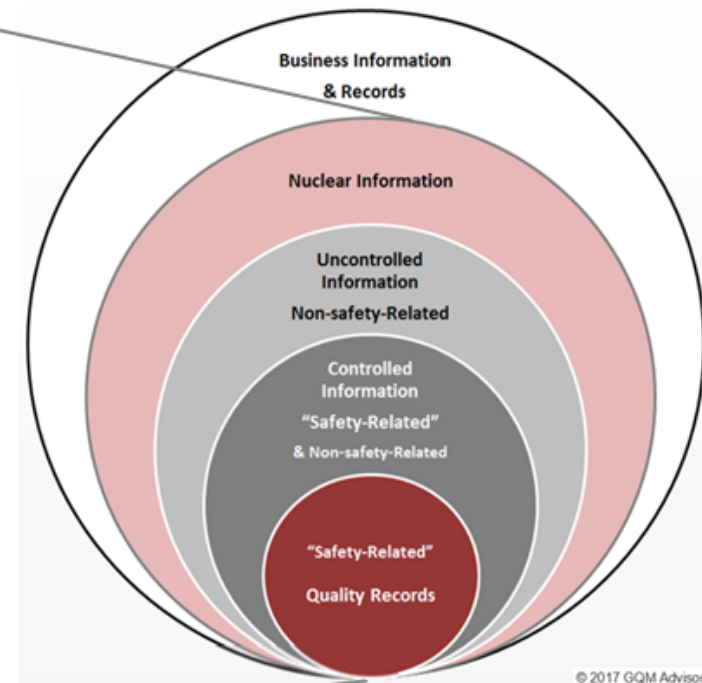
The identification and overall management of Nuclear Information is a critical business element for ensuring compliance and effective daily operations. Guidance and oversight is the responsibility of the Chief Operations Officer.

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

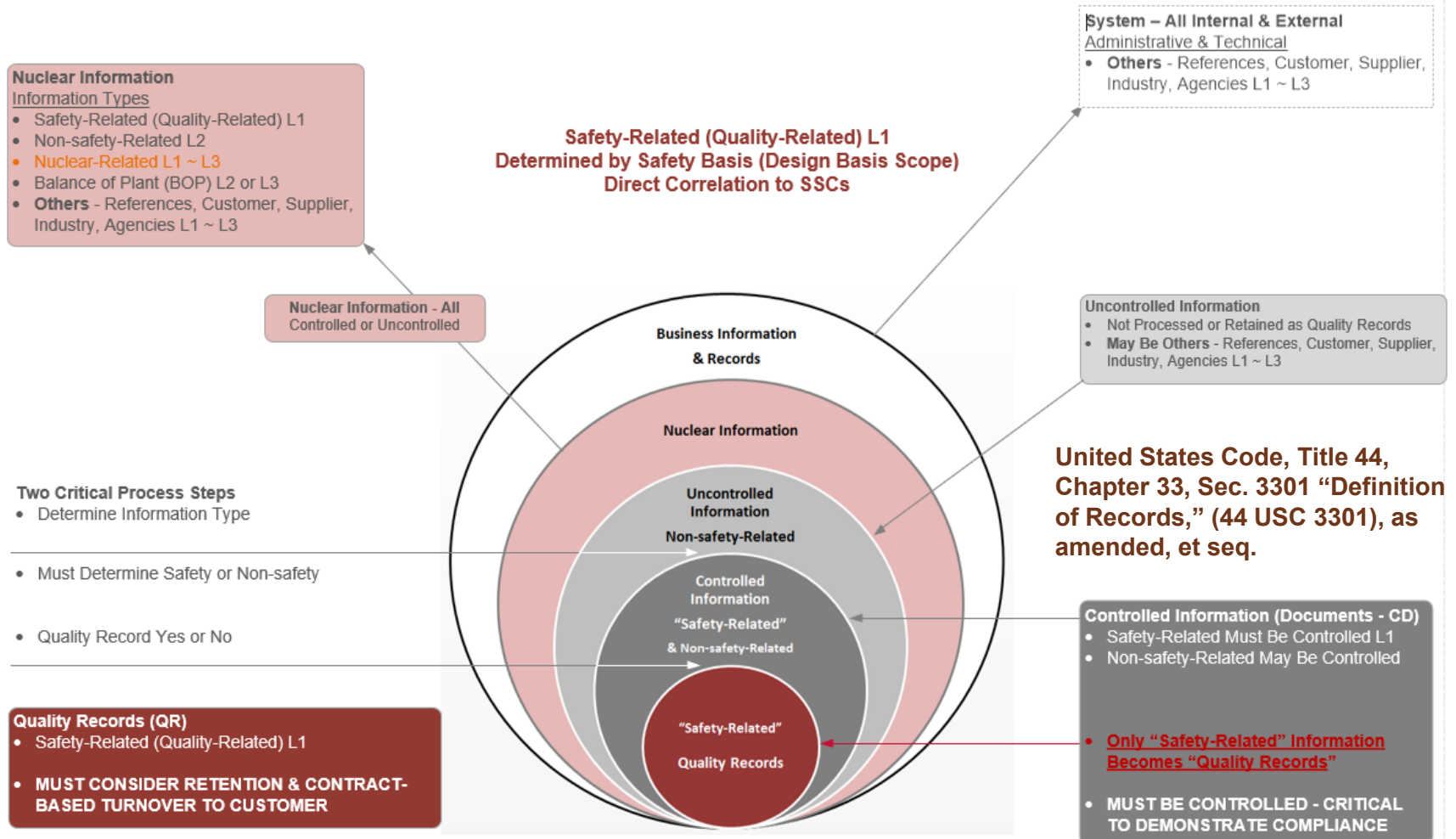
- AA BB CC Document Management
- XX YY ZZ Records Management

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.



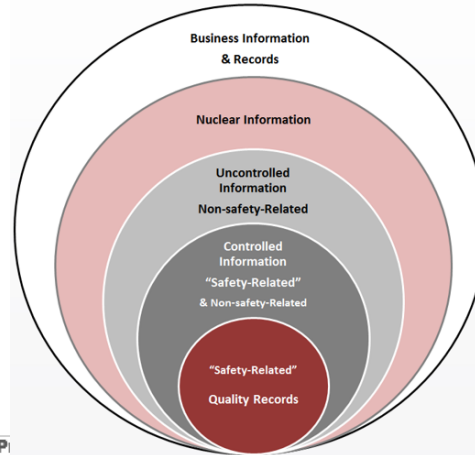
Critical Information ~ Elements



Critical Information ~ Process

Two Critical Process Steps

- Determine Information Type
- Must Determine Safety or Non-safety
- Quality Record Yes or No

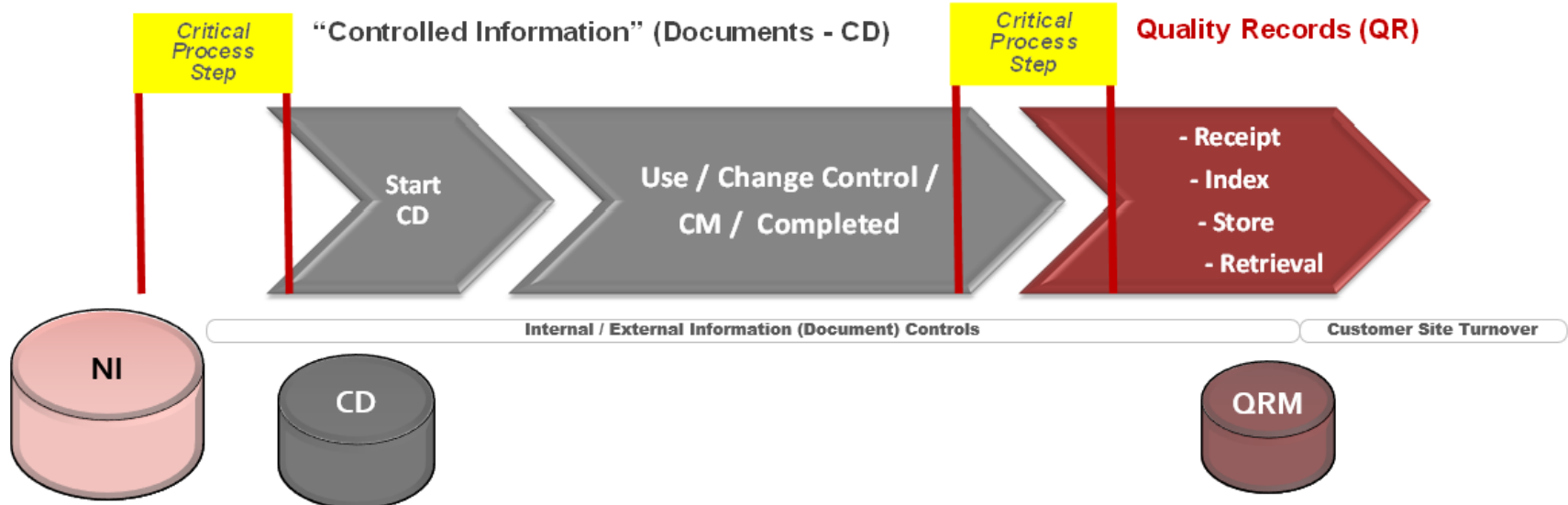


Permanent (Lifetime) – Those records that must be maintained for the life of the particular item while it is installed in the plant or stored for future use.

Non-Permanent – Records that show evidence that an activity was performed in accordance with applicable requirements.

Document Management Process

Record Management 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.

Identification, Preparation, Collection, Index, Retention, Storage, Retrieval, and Disposition of **“Quality Records.”**

“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”

“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
- Customer Contract

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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

Critical Information



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.**

2030

<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.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.

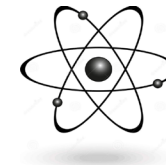
Quality Assurance (QA) Those planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality.

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).

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).



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



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

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.

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

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.

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

<https://beriassociates.thinkific.com/collections>

Is Your C-Suite Aware of ISO19443 **Nuclear Energy-Specific Requirements?**

If NOT Contact



Nuclear CC - Consultancy in the nuclear and manufacturing industry

List of ISO 19443 Certified Companies (nqsa.org)

Does Your C-Suite Operate from A Risk Mitigation Standpoint?

If NOT Contact



Quality + Engineering (qualityplusengineering.com)

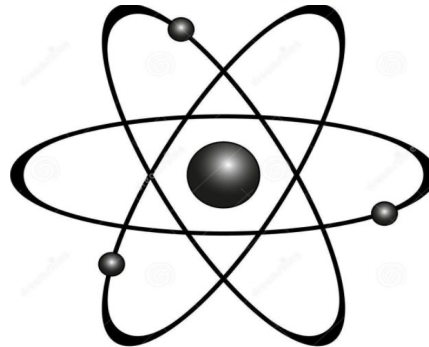
Nuclear Quality Management Advisors

Nuclear Management Systems

~ Focused on Quality ~

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CEO | CQO | Founder
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34 Years ~ Serving Clients



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