Joint KINS-IAEA-ANNuR/ANSN/FNRBA
BPTC Course on Nuclear Safety,
19 ~ 30 September 2022, KINS, Korea

Quality Assurance

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Korea Institute of Nuclear Safety

Contents

I. Introduction - QC/QA/MS/L&M

IAEA
International Atomic Energy Agency
Atoms for Peace and Development

CONVENTION ON NUCLEAR SAFETY (CNS)

ARTICLE 13 QUALITY ASSURANCE

Each Contracting Party shall take the appropriate steps to ensure that quality assurance programmes are established and implemented with a view to providing confidence that specified requirements for all activities important to nuclear safety are satisfied throughout the life of a nuclear installation.

I. Introduction - QC/QA/MS/L&M

Quality: The totality of features and characteristics for an Item or Services that bear on its ability to satisfy a defined requirements. [IAEA Safety Series 50-C-QA (1988)]. The degree to which a product, process or service satisfies specific requirements. [IAEA Safety Standards GS-R-3 (2006)]

Quality Control (QC): A process by which entities review the quality of all factors involved in production[Wikipedia]. A part of quality management focused on fulfilling quality requirements. [ISO 9000]

Quality Assurance (QA): All those **planned and systematic actions** necessary to **provide adequate confidence** that a structure, system, or component **will perform satisfactorily** in service.

[ASME NQA-1, and Appendix B to 10 CFR Part 50]

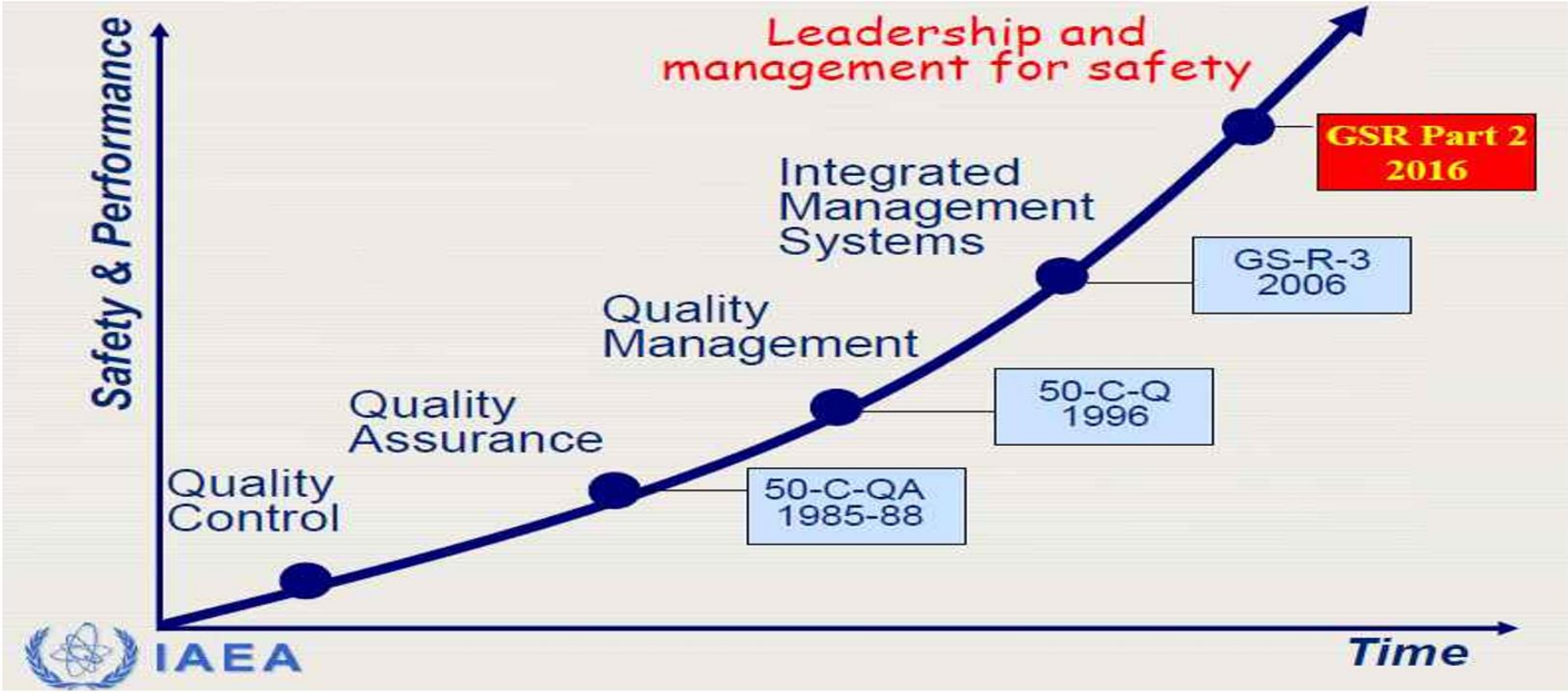
I. Introduction - QC/QA/MS/L&M

QC vs. QA

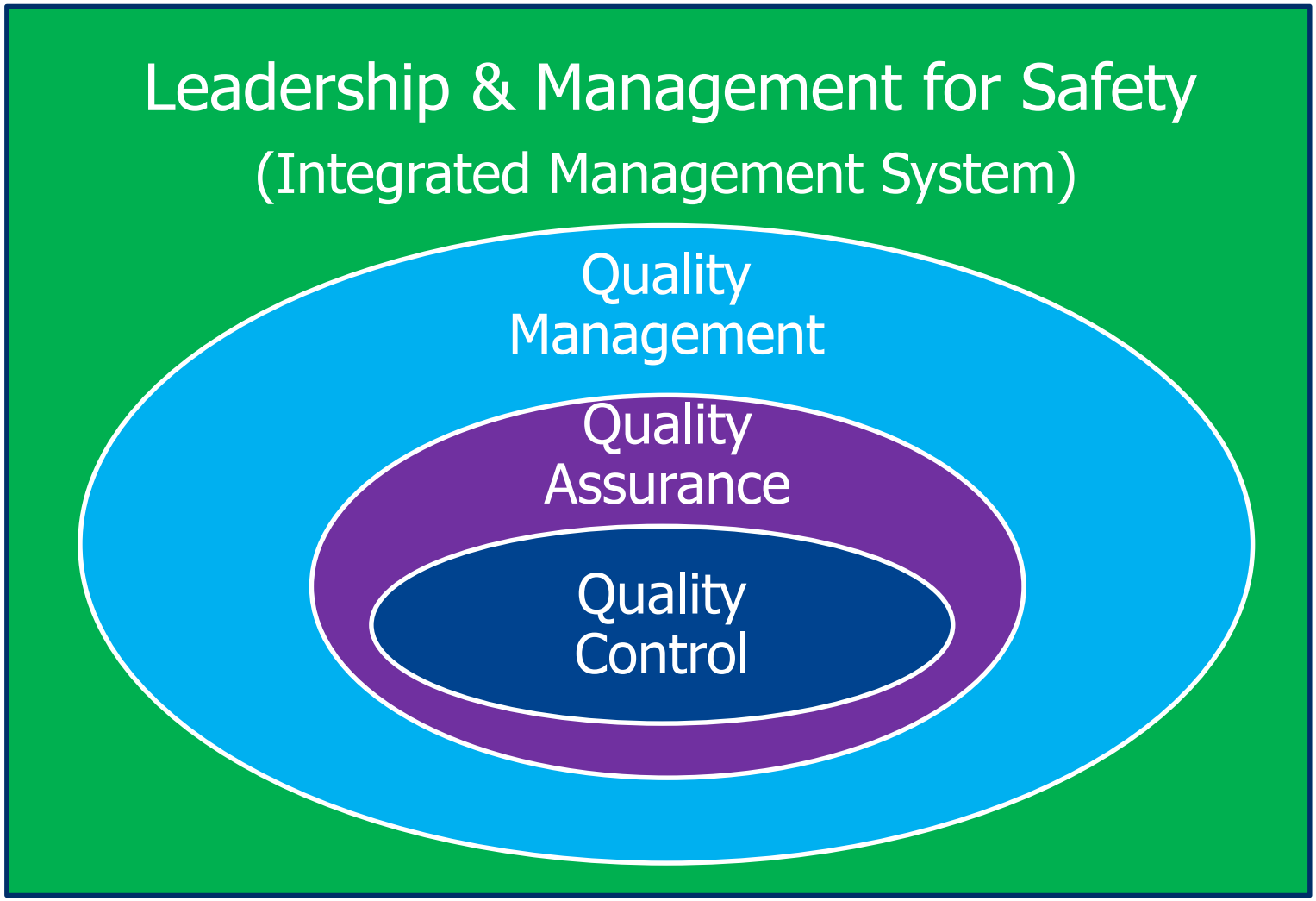
	Quality Control	Quality Assurance
Focus on	Reactive process	Proactive process
How	Finding & eliminating sources of quality problems	Establishing quality management system and assessing its adequacy
What	Achieving product quality	Preventing quality problems through planned and systematic activities
Responsibility	QC team	Everyone on the team involved
As a tool	Corrective tool	Managerial tool
Orientation	Product-oriented	Process-oriented

I. Introduction - QC/QA/MS/L&M

Evolution of Terminology in IAEA Documents



I. Introduction - QC/QA/MS/L&M



I. Introduction - QC/QA/MS/L&M

Management system (MS): A set of **interrelated or interacting elements** that establishes policies and objectives and which enables those objectives to be achieved in a safe, efficient and effective manner. The **management system integrates all elements** of an organization's objectives to be achieved. [IAEA Safety Standards, No. **GS-R-3 (2006)**]

Leadership and Management (L&M):

It emphasizes that **leadership for safety**, **management for safety**, and **integrated management system**, and a systematic approach are essential to the specification and application of adequate safety measures and the fostering of a strong safety culture.

Management systems will integrate safety, health, environmental, security, **quality**, human-organizational-factor, societal and economical elements. [IAEA Safety Standards, No. **GSR Part 2 (2016)**]

I. Introduction - QC/QA/MS/L&M

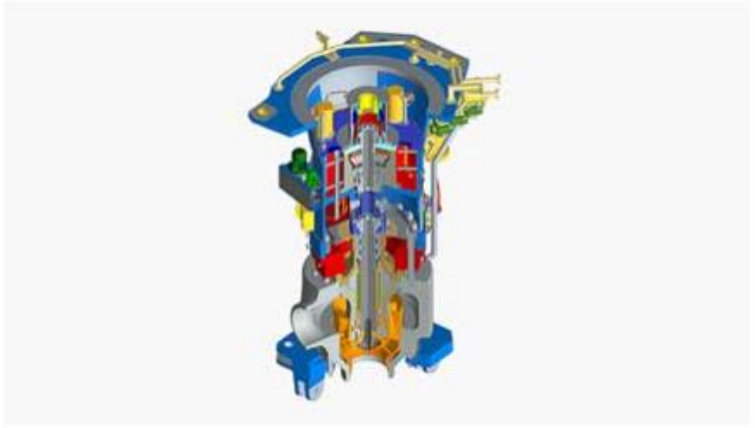
Characteristics of Nuclear Items

	Non-nuclear Items	Nuclear Items
Method of Fabrication	Various Items & Mass-production	Sole Items & Small Quantity in production
Duration of Production	By Hourly/Daily Basis	By Monthly /Yearly Basis Long-Lead Items
Quality Verification	Verified by manufacturer	Verified by Third Party personnel
Methods of Quality Verification	Inspecting Product Quality	Observing Processes and/or Inspecting Quality Records
Purpose of Quality Activity	Customer Satisfaction	Safety & Reliability
Qualification Requirements	Usually Not Required	Qualification for Personnel, Equipment, Procedures

Example of Large Scale Nuclear Components (Long-Lead Items)

Nuclear Reactor and Internal Structure

Steam Generator



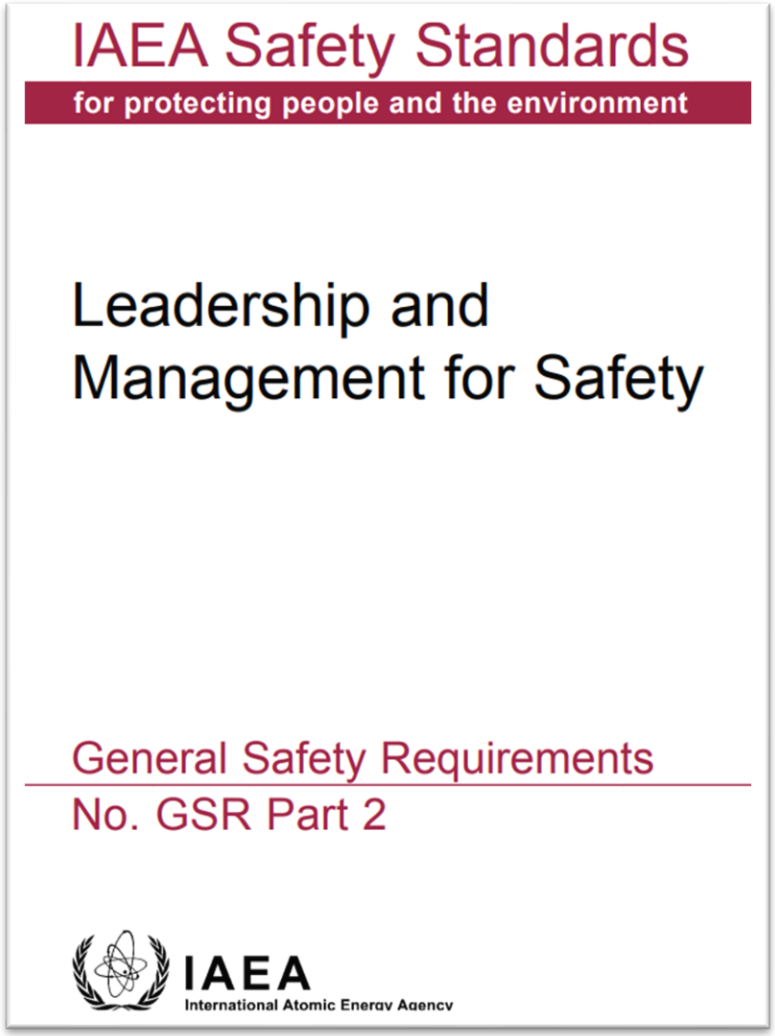
Nuclear Reactor Coolant Pump

Pressurizer

II. Requirements of Nuclear QA

II. Nuclear QA Requirements

GSR Part 2 (14 requirements)



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14 Requirements of IAEA GSR Part 2

1. Achieving the fundamental safety objective
2. Demonstration of leadership for safety by managers
3. Responsibilities of senior management for the management system
4. Goals, strategies, plans, and objectives
5. Interaction with interested parties
6. Integration of management system
7. Application of the graded approach to the management system
8. Documentation of the management system
9. Provision of resources
10. Management of processes and activities
11. Management of the supply chain
12. Fostering a culture of safety
13. Measurement, assessment and improvement of the management system
14. Measurement, assessment and improvement of leadership for safety and of safety culture

II. Nuclear QA Requirements

ISO 9001(28 requirements)

INTERNATIONAL STANDARD

ISO 9001

Fifth edition
2015-09-15

Quality management systems — Requirements

Systèmes de management de la qualité — Exigences

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II. Nuclear QA Requirements

ISO 9001(28 requirements)

INTERNATIONAL STANDARD

ISO 9001

Fifth edition
2015-09-15

Quality management systems — Requirements

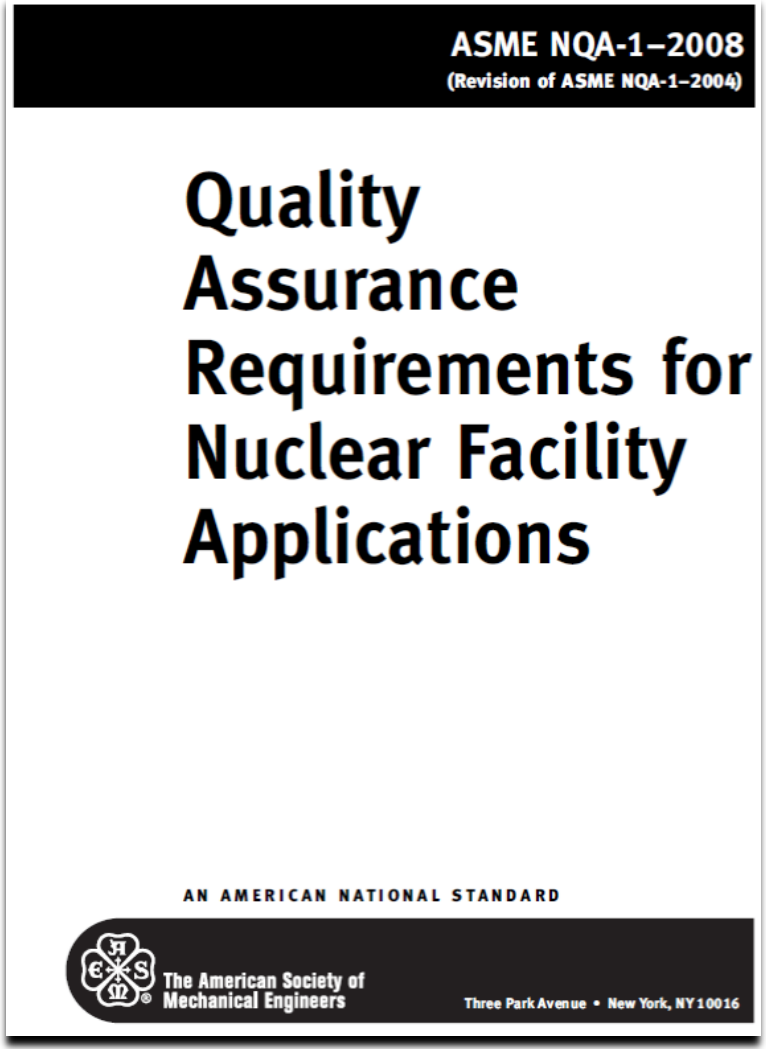
Systèmes de management de la qualité — Exigences

28 Requirements of ISO 9001

7 Areas	28 Requirements
4. Context of organization	4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the quality management system 4.4. Quality management system and its processes
5**. Leadership**	5.1 Leadership and commitment 5.2 Policy 5.3 Organizational roles, responsibilities and authorities
6. Planning	6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them 6.3 Planning of changes
7. Support	7.1 Resources 7.2 Competence 7.3 Awareness 7.4 Communication 7.5 Documentation information
8. Operation	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and development of products and services 8.4 Control of externally provided processes, products and services 8.5 Production and service provision 8.6 Release of products and services 8.7 Control of nonconforming outputs
9. Performance evaluation	9.1 Monitoring, measurement, analysis and evaluation 9.2 Internal audit 9.3 Management review
10. Improvement	10.1 General 10.2 Nonconforming and corrective action 10.3 Continual improvement

II. Nuclear QA Requirements

ASME NQA-1 (18 requirements)



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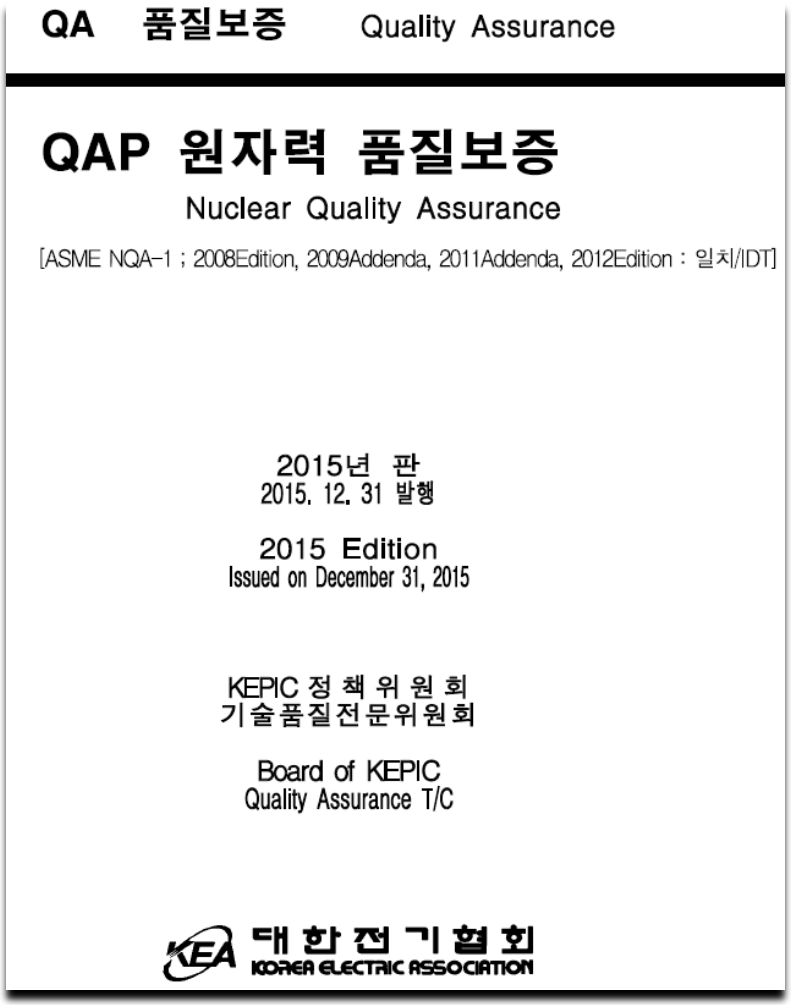
(A detailed Contents precedes each NQA Part.)

II. Nuclear QA Requirements

KEPIC QAP (identical to the ASME NQA-1)



QA 품질보증 Quality Assurance

QAP 원자력 품질보증

Nuclear Quality Assurance

[ASME NQA-1 ; 2008Edition, 2009Addenda, 2011Addenda, 2012Edition : 일치/IDT]

2015년 판
2015. 12. 31 발행

2015 Edition
Issued on December 31, 2015

KEPIC 정 책 위 원 회
기술품질전문위원회

Board of KEPIC
Quality Assurance T/C

KEA 대 한 전 기 협 회
KOREA ELECTRIC ASSOCIATION

QAP(2015년 판) QAP(2015 Ed.)

목차(CONTENTS)

상세한 목차는 각 QAP에 명시하였습니다(A detailed Contents precedes each QAP).

18 Requirements

II. Nuclear QA Requirements

NQA-1 vs. ISO-9001

ASME NQA-1	ISO-9001
Safety-driven standard	Process-based standard
Prescriptive and stringent	Flexible in how its requirements are met
Nuclear safety requirements	Customer-satisfaction requirements

Examples of NQA-1 requirement seen stricter than ISO-9001:

- independence of personnel performing design verification, etc.;
- software controls, including software verification and validation, etc.;
- disposition of nonconforming items;
- internal and external audits;
- indoctrination, training, qualification, and evaluation of personnel

NQA-1, Part 4, Subpart 4.3 provides the "Guide to Modification of an ISO 9001 Quality Program to Meet the NQA-1 Requirements"

II. Requirements of Nuclear QA

Korea is adopting the NQA-1 as QA requirements by Regulation.

The **18 requirements** to be discussed from now on are the requirements of the **ASME NQA-1, Part 1** "**Requirements for Quality Assurance Programs** for Nuclear Facilities."

NQA-1 Part 1 sets forth requirements for the establishment and execution of quality assurance programs for the siting, design, construction, operation, and decommissioning of nuclear facilities.

18 Requirements of Nuclear QA (NQA-1)

1. Organization	10. Inspection
2. Quality Assurance Program	11. Test Control
3. Design Control	12. Control of Measuring and Test Equipment
4. Procurement Document Control	13. Handling, Storage and Shipping
5. Instructions, Procedures, and Drawings	14. Inspection, Test, and Operating Status
6. Document control	15. Control of Nonconforming Items
7. Control of Purchased Items and Services	16. Corrective Action
8. Identification and Control of Items	17. Quality Assurance Records
9. Control of Special Processes	18. Audits

18 Requirements of Nuclear QA (NQA-1)

Requirement 1: Organization

- **Authority and duties** of persons and organizations performing activities affecting safety-related functions shall be clearly established and delineated in writing
- Persons and organizations performing QA functions shall have **sufficient authority** and **organizational freedom** to identify quality problems and to initiate and recommend solutions and verify implementation of solutions
- Persons and organizations performing QA functions shall report to management level so that the required authority and organizational freedom, including sufficient **independence from cost and schedule** when opposed to safety considerations, are provided

I. Introduction - QC/QA/MS/L&M

Quality Affecting activities

Activities Affecting the Safety-related Functions	=	Activities affecting safety-related functions include both the performing **functions of attaining** quality objectives and the quality **assurance functions**. The quality assurance functions are those of (1) **assuring** that an appropriate **quality assurance program is established and effectively executed**; and (2) **verifying**, such as by checking, auditing, and inspecting, that **activities affecting the safety-related functions have been correctly performed**. [**Appendix B to Part 50 of 10 CFR, USA** – Quality Assurance Criteria for NPPs and Fuel Reprocessing Plants]

Safety-related Functions = **Quality Attaining Functions** + **Quality Assurance Functions**

18 Requirements of Nuclear QA (NQA-1)

Requirement 2: Quality Assurance Program

- **QA program** shall be established at the earliest practical time consistent with the schedule for accomplishing the activities
- **Identify Structure, System and Components (SSCs)** to be covered by QA program
- **Indoctrination, training and qualification of personnel** performing quality affecting activities to assure that suitable proficiency is achieved and maintained JQC(job qualification certificate), inspector certificate, auditor certificate, etc.
- **Regularly review** for the adequacy of the QA program

18 Requirements of Nuclear QA (NQA-1)

Requirement 3: Design Control

- **Design basis** shall be documented
- **Deviations** from the design basis shall be controlled
- **Design interfaces** shall be identified
- **Adequacy of design shall be verified by either design review, alternative calculations, or suitable testing programs**
- **Design adequacy verification** shall be performed **independently** by a person other than those who performed the original design
- **Design changes** shall be handled in the same manner as original design

Requirement 4: Procurement Document Control

- **Regulations, applicable design bases, and other requirements** shall be included in procurement documents
- Procurement documents shall require **suppliers** to have a quality assurance program

18 Requirements of Nuclear QA (NQA-1)

Requirement 5: Instructions, Procedures, and Drawings

- Quality affecting activities shall be **prescribed by** and **performed in accordance with documented instructions, procedures, or drawings**
- Instructions, procedures, and drawings shall include appropriate **quantitative and qualitative acceptance criteria**

18 Requirements of Nuclear QA (NQA-1)

Requirement 6: Document Control

- **Measures shall be established** to control documents such as instructions, procedures, and drawings, including changes thereto, which prescribe activities affecting quality
- These measures shall assure that documents are reviewed **for adequacy** and approved **for release** by authorized personnel and distributed to and used at the location where the prescribed activity is performed
- Changes to the documents **shall be controlled**

18 Requirements of Nuclear QA (NQA-1)

Requirement 7: Control of Purchased Items

- Measures shall be established to assure that **purchased items and services** **conform to procurement documents**
- Provisions shall be provided for **suppliers evaluation and selection**, objective evidence furnished by suppliers, **examination of items upon delivery**

Requirement 8: Identification and Control of Items

- **Controls** shall be established to assure that **only correct and accepted items are used** or installed
- **Identification** shall be maintained **on the items** or in documents **traceable** to the items, or in a manner that assures that identification is established and maintained

18 Requirements of Nuclear QA (NQA-1)

Requirement 9: Control of Special Processes

- Measures shall be established to assure that **special processes**, including welding, heat treating, and non-destructive testing, are controlled and accomplished by **qualified personnel** using **qualified procedures**

Special Process:

A process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product

Requirement 10: Inspection

- A program for inspection of safety-related activities shall be established and executed to verify conformance with the documented instructions, procedures, and drawings
- Such inspection shall be performed by individuals **other than those who performed the activity being inspected *(independence)***
- Examinations, measurements, or tests of material or products processed shall be performed for each work operation to assure quality
- If **hold points** are indicated in a quality affecting document, beyond which **work shall not proceed without consent** of its designated representative

18 Requirements of Nuclear QA (NQA-1)

Requirement 11: Test Control

- **Establish test program** to assure that **all testing** required to demonstrate that structures, systems, and components will operate satisfactorily in service **is identified and performed by written test procedures**
- Test program shall **includes**, as appropriate, **proof test prior to installation**, **pre-operational tests**, and **operational tests** during nuclear power plant
- **Test results** shall be **documented and evaluated** to assure that test requirements have been satisfied

18 Requirements of Nuclear QA (NQA-1)

Requirement 12: Control of Measuring & Test Equipment

- Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly **controlled, calibrated, and adjusted** at specific periods to maintain accuracy within necessary limits
- When measuring and test equipment is found to be out of calibration, an evaluation shall be made and documented of **the validity of previous inspection or test results** and acceptability of items previously inspected or tested.

Requirement 13: Handling, Storage and Shipping

- Measures shall be established to control the handling, storage, and shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to **prevent damage or deterioration**
- Special **protective environments**, such as inert gas, atmosphere, specific moisture levels, and temperature levels, shall be specified and provided

Requirement 14: Inspection, Test, and Operating Status

- Measures shall be established **to indicate**, by the use of markings such as **stamps, tags, labels, routing cards**, or other suitable means, **the status of inspections and tests performed** upon individual items of the nuclear power plant
- These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, **to preclude inadvertent bypassing of such inspections and tests**
- Measure shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant, such as by tagging valves and switches, **to prevent inadvertent operation**

Requirement 15: Control of Nonconforming Items

- Measures shall be established to control materials, parts, or components which do not conform to requirements in order to **prevent their inadvertent use of installation**
- These measures shall include procedures for **identification, documentation, evaluation, segregation, disposition, and notification** to affected organization

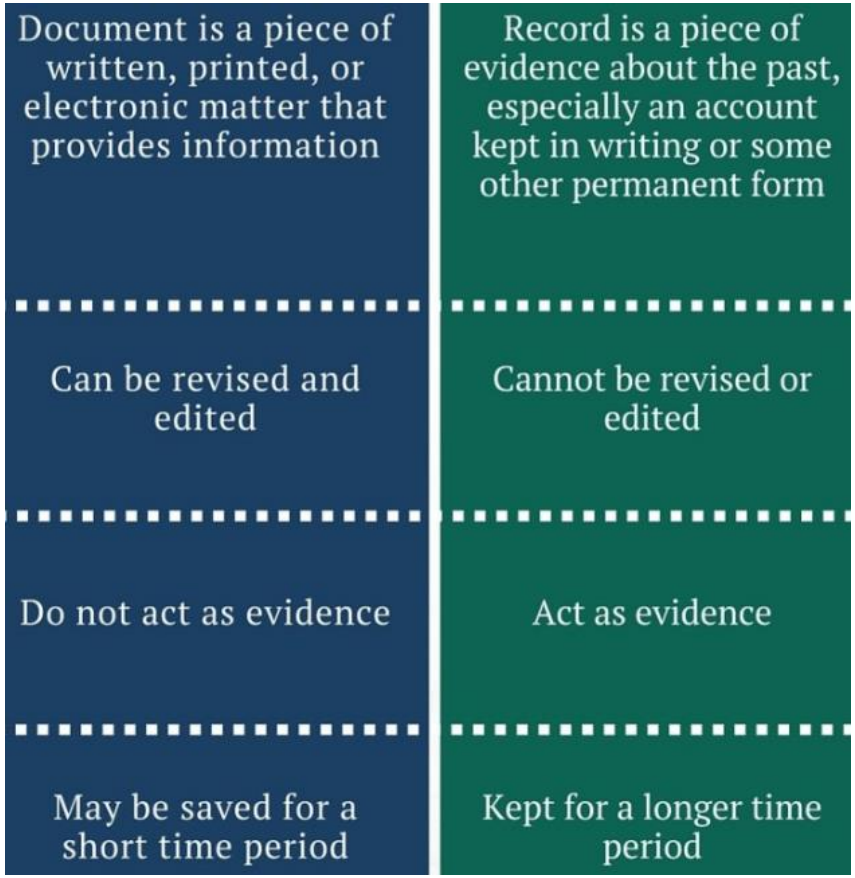
Requirement 16: Corrective Action

- Measures shall be established to assure that **conditions adverse to quality**, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are **promptly identified** and **corrected**
- In the case of significant conditions adverse to quality, the measures shall assure that the **cause of the condition is determined** and **corrective action is taken** to preclude repetition
- The significant condition, its cause, and the corrective action taken shall be documented and **reported to** appropriate levels of management

18 Requirements of Nuclear QA (NQA-1)

Requirement 17: Quality Assurance Records

- Sufficient records shall be maintained to furnish **evidence of activities** affecting quality
- Quality assurance records shall be **identified, generated, authenticated**, and **maintained**, and their final **disposition** specified
- Records shall be classified as **Lifetime** or **Nonpermanent**



18 Requirements of Nuclear QA (NQA-1)

Requirement 18: Audits

- A comprehensive system of planned and periodic audits shall be carried out **to verify compliance with** all aspects of **the QA program** and **to determine the effectiveness of the program**
- The audits shall be performed in accordance with the written procedures or check lists by appropriately trained and **qualified personnel** not having direct responsibilities in the area being audited
- For internal audit, **personnel having direct responsibility for performing the activities being audited shall not be involved** in the selection of the audit team. ***(independence)***

III. Regulatory Activities for Nuclear QA

III. KINS Regulatory Activities for QA

Legal Basis of QA/Vendor Inspection

- **Nuclear Safety Act**(NSA), Article 16, 22

Construction Permit or operating license holder shall undertake an inspection of the Commission

- **Enforcement Decree** of NSA, Article 31/31-2

The Commission may conduct an inspection (QA/Vendor) under the provisions of Article 16 (or 22) of the NSA

- NSSC **Regulation on Technical Standards**

The provisions of Articles 68 through 85 shall apply (18 QA requirements)

- NSSC **Notice** No. 2016-13

This is to set forth the standards for the detailed quality assurance requirements of nuclear reactor facilities in accordance with Article 67 of the Regulations on Technical Standards

Legal Basis of **Safety Review**

- **Documents subject to be submitted for Construction Permit (CP) as required by the Enforcement Regulation:**

1. Radiation Environmental Report (RER)
2. Preliminary Safety Analysis Report (PSAR)
3. **Quality Assurance Program on Construction**
4. Decommissioning Plans
5. Explanatory Statement on the Purpose of Nuclear Reactor
6. Description of Technical Capabilities
7. Plans for the drafting Accident Management Program

III. KINS Regulatory Activities for QA

Safety Reviews

- KINS reviews "**Quality Assurance Program on Construction Permit (CP) / on Operating License (OL) / on Standard Design Approval(SDA) submitted by** construction/operation/Standard Design applicants.

- To verify the **"Quality Assurance Program submitted on CP or /on OL or /on SDA application" is established in compliance with the regulatory requirements**

III. KINS Regulatory Activities for QA

Regulatory Inspections

– KINS performs **QA Inspections against license applicants or licensees**
  • KHNP, KAERI, KORAD, KEPCO NF

– KINS performs **Vendor Inspections against suppliers**
  • Designers, Manufacturers, Equipment Qualifiers, Service Providers, etc.
  • KEPCO E&C, Doosan Enerbility, Samshin Valve, etc. and their contractors and subcontractors

III. KINS Regulatory Activities for QA

Regulatory Inspections

<table>
<tr><th>Reactor Life Cycle</th><th>Construction →</th><th>Operation→</th><th>Decommissioning</th></tr>
<tr><td rowspan="3">Planned</td><td colspan="3">QA Inspection</td></tr>
<tr><td>Pre-operational Inspection</td><td>Periodic Inspection</td><td>Decommissioning Inspection</td></tr>
<tr><td colspan="3">Vendor Inspection</td></tr>
<tr><td rowspan="2">Daily or As needed</td><td colspan="3">Daily Inspection
(by Site Resident Inspectors)</td></tr>
<tr><td colspan="3">Special Inspection</td></tr>
</table>

III. KINS Regulatory Activities for QA

QA/Vendor Inspections Process

Plan for Annual Inspection

Plan for Unit Inspection

Performing of Unit Inspection (at the premise of the inspected entity)

Issue of Inspection Findings/Recommendations

Issue of Unit Inspection Report

Issue of Annual Report

III. KINS Regulatory Activities for QA

Disposition of QA/Vendor Inspection Results

- **When a KINS Inspection finding** is raised, it is to be addressed by the inspected entity and the adequacy of the corrective action to the finding is **reviewed by the KINS inspector for closure** of the finding
- **QA/ Vendor Inspection report** is released to the **inspected entity** and posted on the Internet for the **public**

Summary & Conclusion

Summary & Conclusion

- The purpose of nuclear QA is to secure safety and reliability of nuclear installations and to enhance public benefit
- Each nation may have its own jurisdiction to establish a national quality assurance requirements. It may have the form of the Leadership and Management System of IAEA GSR Part 2 or the Quality Assurance of the ASME NQA-1 or Quality Management Systems of the ISO-9001
  - Korea adopted the ASME NQA-1 (18 QA requirements)
  - New entrants, the majority of EU nations employed the IAES GSR Part 2 and they also usually require their suppliers to apply the requirements of the ISO-9001
- The importance of Leadership and Integrated management system is emphasized and talked about in IAEA documents stating that nuclear safety and reliability are achieved through a systematic approach with the safety, health, environmental, security, quality, human-and-organizational-factor, societal and economic elements in consideration as a whole
- The 18 Nuclear QA requirements apply to all quality affecting activities in proportionate to the importance to safety and reliability of nuclear facilities
- Regulatory activities in QA include Safety Reviews of licensing document (QA Manual) and Regulatory Inspections called QA Inspection and Vendor Inspection

Safety First KINS,
trusted by the public

Thank You

한국원자력안전기술원
KINS KOREA INSTITUTE OF NUCLEAR SAFETY