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QA Criteria I : Organization & QA Program

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CONTENTS

1. Organization

1. Organization

I. Area of Review

- *Man / Machine System*
  - Machine ➡ Safe Operation
  - Man ➡ Radiation Safety, Safety Culture (IAEA GS-R-3)
- The level of *authority and responsibility of organizations* responsible for assuring the safety of SSC and activities in nuclear power reactors and related facilities are described
- The sufficient *independence from cost and schedule* consideration is provided in the *QA organization*

1. Organization

I. Area of Review (continue)

- Organizational Structure
  - Organizations *performing quality verifying functions (QVO)* : Quality Assurance and quality inspection
  - Organizations *performing activities affecting quality (QAO)* : Siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning

1. Organization

II. Requirements

- 100 Basic

– Define Responsibilities *for QA Program*

– Document the *Structure, Functional responsibilities, Levels of authority, and Line of communications of* those organizations for *activities affecting quality*

- 200 Structure and Responsibility

– 201 General:

(a) Senior management establishes overall expectation for QA Program

1. Organization

II. Requirements (continue)

(b) *Quality is achieved and maintained* by those assigned for *performing work (QAO)*

(c) *Quality achievement is verified* by those *not directly responsible for performing the work (QVO)*

(d) Authority of QA is *direct access to responsible management level* and *Organizational freedom including sufficient independence from cost and schedule* when opposed to safety function considerations

1. Organization

II. Requirements (continue)

(d) Verification function of QA:

(1) to *identify* quality problems;

(2) to *initiate, recommend, or provide solutions* to quality problems through designated channels;

(3) to *verify implementation* of solutions; and

(4) to assure that further processing, delivery, installation, or use is *controlled until proper disposition* of a non-conformance, deficiency, or unsatisfactory condition has occurred.

1. Organization

□ II. Requirements (continue)

- 202 Delegation of Work:

  Any or all of the *work may be delegated* to other persons or organizations but shall retain responsibility therefor

- 300 Interface Control

  The responsibilities, interfaces, and authority of each organization shall be *clearly defined and documented*.

1. Organization

III. Verification Practices

- QA Policy:

  The QA policy shall be established by the president or vice president, and *sufficient authority shall be given to the QA management*.

- Organization Chart:

  The chart shall clearly *show the inside and outside organizations* which carry out their own functions.

1. Organization

III. Verification Practices (continue)

- QA responsible organizations:
  (1) *QA management positions shall be equal or higher* than the top management position, which perform work (engineering, purchase, construction and operation) with direct responsibility on quality
  (2) They shall have *authority to issue and control the NCR and CAR including Work Stop*
  (3) They shall have responsibility for *approving the QA program.*
  (4) They shall *not have responsibility* for other work *unrelated to QA.*

1. Organization

□ IV. Cases of Deviation

- *Independence of QA was not appropriate*:

  In QA manual (QC-110, Rev.36) of Crosby, Valve supplier, chapter 1 Organization states that QA manager shall *report* all quality related issues *to the director of technical division* who is in charge of design and engineering.

- *Responsibilities of organization were not appropriately described*:

  In QA manual (NQAM-001, Rev.12) of Sung-il SIM, high pressure boundary pipe supplier, chapter 1 does not describe the *responsibility of division director of manufacturing* and responsibilities of *manufacturing departments* which are located in 3 different areas.

2. QA Program

2. QA Program

I. Area of Review

- *QA objects:*

  Identification of SSC and activities to an extent consistent with their importance to safety

- *Control over Activities:*

  1) Appropriate *equipment*
  2) Suitable *environmental condition*
  3) *Prerequisites* for the performance of activities

- *Education and training of personnel* performing activities to achieve and maintain *suitable proficiency*

- *Status and adequacy* of the QA program

2. QA Program

II. Requirements

- **100 Basic**
  - **Documented *QA Program shall be* Planned, implemented, and maintained in accordance with *this QAP-1***
  - ***Identify the activities and items* to which it applies**
  - **Provide *control over activities* affecting quality to an extent consistent with their importance**
  - **Provide assurance that the activities affecting quality are *performed satisfactorily***
  - **Provide suitably *controlled condition***

2. QA Program

II. Requirements (continue)

- **100 Basic (continue)**
  - **QA Program shall provide for indoctrination, training, and qualification as necessary of personnel performing or managing activities affecting quality to ensure that *suitable proficiency is achieved and maintained***
  - **Management shall *regularly assess the adequacy and effective implementation* of the QA program**

2. QA Program

II. Requirements (continue)

- 200 Indoctrination and Training
  - Indoctrination and training of personnel performing activities affecting quality to assure that *suitable proficiency is achieved and maintained*

- 300 Qualification
  - Qualification of personnel and the minimum requirements *shall be designated in the written procedures.*

2. QA Program

II. Requirements (continue)

- 301 Nondestructive Examination (NDE):
  The qualification of NDE personnel shall apply *KEPIC-MEN A1*
- 302 Inspection and Test:
  (1) The initial capabilities of a candidate shall be determined by an evaluation of the candidate's education, experience, training, and either test results or capability demonstration.

2. QA Program

II. Requirements (continue)

- 302 Inspection and Test (continue):
  - (2) Reevaluated at periodic intervals *not to exceed 3 years*
  - (3) Any person who has *not performed inspection or testing activities* in the qualified area *for a period of 1 year* shall be reevaluated

2. QA Program

II. Requirements (continue)

- 303 Lead Auditor:
  1. Communication Skills. The Lead Auditors shall have the *capability to communicate effectively*
  2. Training.
     - *Knowledge and understanding* of QAP and other nuclear related codes, standards, regulations, and regulatory guides
     - *Auditing techniques* of *examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings*

2. QA Program

II. Requirements (continue)

- 303 Lead Auditor (continue):
  - *Planning audits* of activities affecting quality
  - *On-the-job training* to include applicable elements of the audit program

3. Audit Participation
   - In a minimum of *5 QA audits* as auditor within a period of time not to exceed 3 years, One audit shall be *a nuclear QA audit*

4. Examination
   - Comprehension of & ability to apply knowledge
   - *Oral, written, practical, or any combination* of three

2. QA Program

II. Requirements (continue)

- 303 Lead Auditor (continue):

  5. Maintenance of proficiency
     - Participation in the *audit*
     - *Review and study* of codes, standards, procedures, instructions, and other documents related to QA program and program auditing
     - Participation in *training programs*

  6. Requalification
     Lead Auditors who *fail to maintain* their proficiency *for period of 2 years* or more shall require requalification

2. QA Program

II. Requirements (continue)

– 304 Auditor:

Competence of personnel for performance of the various auditing functions shall be developed.

(a) *Orientation* to provide a working knowledge for implementing audits and reporting results.

(b) Training shall include methods of *examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings*.

(c) On-the-job training, guidance, and counseling *under the direct supervision of a Lead Auditor.*

2. QA Program

II. Requirements (continue)

– 305 Technical Specialist:
The auditing organization shall establish requirements for use of *technical specialists*

- 400 Records of Qualification
(a) The qualification of inspection, test, and Lead Auditor personnel shall be certified in writing
(b) The organization shall identify *any special physical characteristics needed* in the performance of activity
(c) Qualification examination *activities may be delegated* to an independent certifying agency

2. QA Program

II. Requirements (continue)

- 500 Records

  Records of implementation for indoctrination and training may take the form of attendance sheets, training logs, or personnel training records.

  Records of indoctrination and training shall include the following: (a) attendance sheets, (b) training logs,

  (c) Personnel training records

  The employer shall *establish and maintain records* for indoctrination and training: and qualification and requalification

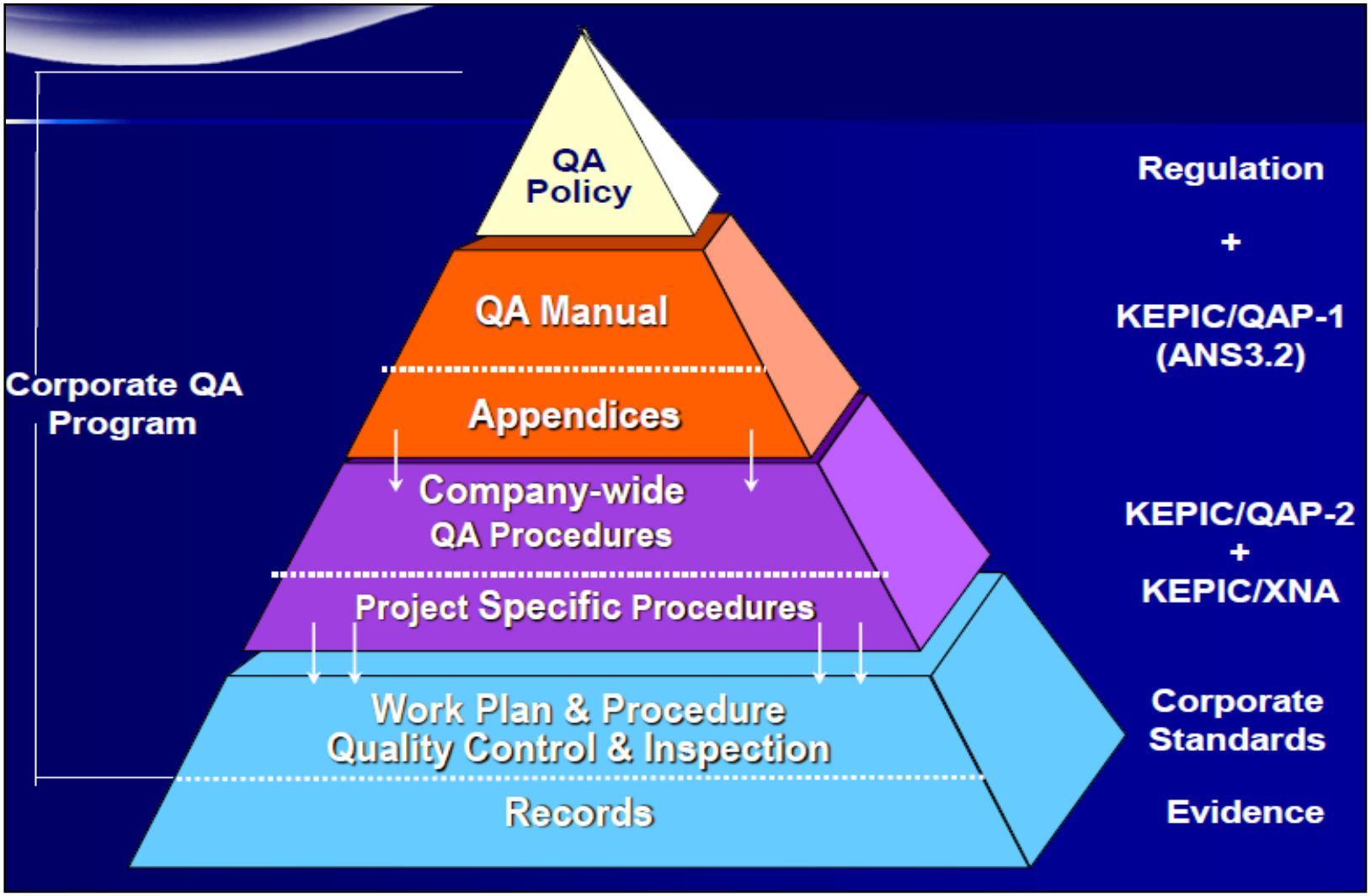
2. QA Program

III. Verification Practices

- QA Program:
  1) As for the content of the QA manual already approved by the Regulatory Authority, *its change* shall be submitted for *review and approval* before it is implemented
  2) *Alternatives and exceptions* shall be clearly *identified*, and *proof for suitability* shall be included in the application documents.

2. QA Program

III. Verification Practices



2. QA Program

III. Verification Practices

- Status and Adequacy of QA Program:
  - Prescheduled and documented *evaluation*
  - *Corrective measures* shall be identified and traced
- Identification of SSC with their importance to safety:

1) Reactor and Other facilities related with safety
prescribed by the Law : *Safety Class 1, 2, 3*

2) Quality Class of SSC in Korean Industry
- Q Class : *Safety Related Items* such as RCS, ECCS, etc.
- AQ Class : *Safety Impact Items* such as T/G, etc.
- S Class : Industrial Standard Items

2. QA Program

IV. Cases of Deviation

- *Training was not performed*:

  In QA Manual (Rev.7) of Westinghouse, paragraph 2.2.1.3 "The Quality System Supervisor shall schedule training session when revision to the QA Manual or Policies and Procedures reflect significant changes in operation methods." Contrary to this requirements new procedures such as NSNP 16.6 Rev.0, have been released *without any such training sessions* occurring.

2. QA Program

IV. Cases of Deviation

- *Timeframe of training was not specified*:

  In FCD QA Manual (Rev.34) of Flowserve Valve, the quality program *does not specify a timeframe* during which training on QA Manual revision or other quality system requirements will be completed.

Always we keep watching our Atomic Power

Thank You

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