KINS-IAEA Workshop on Safety Review & Inspection Methodologies for Quality Assurance, 13 ~ 17 May 2019, KINS, Korea

Quality Assurance

QA Criteria VII

(17.QA Records; 18.Audits)

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Quality Assurance Requirements

(KEPIC QAP 2011 Addenda = ASME NQA-1 2009 Addenda)

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

Quality Assurance Requirements
(KEPIC QAP 2011 Addenda = ASME NQA-1 2009 Addenda)

KEPIC 전 력 산 업 기 술 기 준
Korea Electric Power Industry Code

QA 품질보증 Quality Assurance

QAP 원자력 품질보증
Nuclear Quality Assurance
[ASME NQA-1 ; 2008 Edition + 2009 Addenda : 일치 / IDT]

2011년 추록
2011. 11. 30 발행

2011 Addenda
Issued on November 30, 2011

KEPIC 정 책 위 원 회
기술품질전문위원회

Board of KEPIC
Quality Assurance T/C

QAP-1

원자력 품질보증 계획요건

REQUIREMENTS FOR QUALITY ASSURANCE PROGRAMS FOR NUCLEAR FACILITIES

QAP-2

원자력 품질보증 기술요건

QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR FACILITY APPLICATIONS

QAP-3

임의부록

NONMANDATORY APPENDICES

(From Former QAP-1 and QAP-2)

Quality Assurance Requirements
(KEPIC QAP-1 / ASME NQA-1)

17. QA Records

Contents

- ☐ **Area of Review**
- ☐ **Requirements**
- ☐ **Verification Practices**
- ☐ **Case of Deviation (KINS Inspection Findings)**

Requirement 17. QA Records

- Area of Review

- Requirement 17 provides for a program which defines requirements and responsibilities for record control activities necessary to provide evidence of quality.

- Control of selection of records (permanent vs. non-permanent) and keeping and maintaining of records (fire rating facilities, etc.) emphasized

Requirement 17. QA Records

- Requirements

100 BASIC

The control of quality assurance records shall be established consistently with the schedule for accomplishing work activities.

Quality assurance records shall furnish documentary evidence that items or activities meet specified quality requirements.

Quality assurance records shall be identified, generated, authenticated, and maintained and their final disposition specified.

Record control requirements and responsibilities for these activities shall be documented.

Requirement 17. QA Records

- Requirements

200 Generation of Records

(a) legible

(b) traceable to associated items and activities and actually reflect the work accomplished or information required

(c) specified in applicable documents, such as design specifications, procurement documents, test procedures, and operational procedures

Requirement 17. QA Records

- Requirements

300 Authentication of Records

(a) Records shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated. Corrections to documents shall be reviewed and approved by the responsible individual from the originating or authorized organization.

(b) Electronic documents shall be authenticated with comparable information as in para. 300(a), as appropriate

(1) with identification on the media; or

(2) with authentication information contained within or linked to the document itself

Requirement 17. QA Records

- Requirements

400 Classification

Records shall be classified as lifetime or nonpermanent and maintained by the Owner, or authorized agent, in accordance with the criteria given in paras. 401 and 402 and consistent with applicable regulatory requirements.

401 Lifetime Records

401.1 Lifetime records are those that meet on or more of the following criteria:

(a) Those that would be of significant value in demonstrating capability for safe operation

(b) Those that would be of significant value in maintaining, reworking, repairing, replacing, or modifying an item

(c) Those that would be of significant value in determining the cause of an accident or malfunction of an item

(d) Those that provide required baseline data for in-service inspections

401.2 Lifetime records are required to be maintained by or for the Owner for the life of the particular item while it is installed in the plant or stored for future use.

Requirement 17. QA Records

- Requirements

402 Nonpermanent Records

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements but need not be retained for the life of the item because they do not meet the criteria for lifetime records.

Nonpermanent records shall be maintained for the identified retention period.

Requirement 17. QA Records

- Requirements

500 Receipt Control of Records

Each organization responsible for the receipt of records shall designate a person or organization responsible for receiving the records.

The designee shall be responsible for organizing and implementing receipt controls for permanent and temporary storage.

Receipt controls shall provide a method for identifying the records received, receipt and inspection of incoming records, and submittal of records to storage.

Requirement 17. QA Records

- Requirements

600 Storage

601 General

(a) Records shall be stored at a predetermined location(s) in facilities, containers, or a combination thereof, constructed and maintained in a manner that minimizes the risk of loss, damage, or destruction from

(1) natural disasters such as winds, floods, or fires

(2) environmental conditions such as high and low temperatures and humidity

(3) infestation of insects, mold, or rodents

(4) dust or airborne particles

(b) Activities detrimental to the records shall be prohibited in the storage area.

(c) Access to the processing, storage, and retrieval of records shall be limited to authorized personnel.

(d) Provisions shall be made to prevent damage from harmful conditions (such as excessive light, stacking, electromagnetic fields, temperature, and humidity), as applicable to the specific media utilized for record storage.

Requirement 17. QA Records

- Requirements

602 Facility Types

There are equally satisfactory methods of providing storage, single or dual.

602.1 Single storage consists of a storage facility, vault, room, or container(s) with a minimum two-hour fire rating.

The design and construction of a single storage facility, vault, room or container shall be reviewed for adequacy by a person competent in fire protection or contain a certification or rating from an accredited organization.

Requirement 17. QA Records

- Requirements

602.2 Dual facilities, containers, or a combination thereof shall be at locations sufficiently remote from each other to eliminate the chance exposure to a simultaneous hazard. Facilities used for duel storage are not required to satisfy the requirements of para. 602.1, but shall meet the requirements of para. 601.

603 Temporary Storage

When temporary storage of records (such as for processing, review, or use) is required, the storage facility of container shall provide a one-hour fire rating, unless dual storage requirement of para. 602.2 are met.

Requirement 17. QA Records

- Requirements

700 Retention

(a) Record retention period shall be documented.

(b) Record shall be maintained for their retention periods.

800 Maintenance of Records

(a) Records shall be protected from damage or loss.

(b) Records controls shall provide for retrievability within planned retrieval times based upon the record type or content.

(c) The methods for record changes shall be documented.

(d) Provisions shall be established to ensure that no unacceptable degradation of the electronic record media occurs during the established retention period.

(e) Provisions shall be made to ensure that the records remain retrievable after hardware, software, or technology changes.

(f) Provisions shall be established to ensure that the following when records are duplicated or transferred to the same media or to a different media for the purposes of maintenance or storage:

(1) duplication or transfer is appropriately authorized

(2) record content, legibility, and retrievability are maintained

Requirement 17. QA Records

- Verification Practices

- KINS focuses during inspection;
- Whether selection of QA records reflects properly the commitments of applicable codes and SAR?
- Whether records providing evidence that defect or nonconformity is properly corrected are properly furnished?
- Permanent records produced during design, procurement, manufacturing, installation, commissioning, operation be controlled with special care

Requirement 17. QA Records

- Discussions
- Characteristics of Documents and Records

Documents	Records
- Provide written information about policies, processes, and procedures - Communicate information to all persons who need it - Must me changed when a processes, or procedure, etc. changes - Establish formats for recording and reporting information by the use of standardized forms	- Collected information produced by the users of the documents - Need to be easily retrieved and accessed - Contain information that is permanent and does not require updating - Not to be revised - Become an evidence showing how the past work done

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

200 List of Typical Lifetime Records (for reactor licensee)

201 Design and Safety Basis Records

(a) Applicable codes and standards used in design

(b) Computer programs or corresponding mathematical model

(c) Design drawings

(d) Design calculations and record of checks

(e) Approved design change request

(f) Design variations

(g) Design reports

(h) Design verification data

(i) Design criteria or Design Input Data

(j) Design Specification and amendments

(k) Safety, hazards, and accident analysis reports

(l) Stress reports for code items

(m) Systems descriptions

(n) Systems process and instrumentation diagrams

(o) Technical analysis, evaluations, and reports

(p) Software evaluation reports and acceptance test plans and reports

(q) Software verification and validation data

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

Typical Lifetime Records (continued)

202 Procurement Records

(a) Procurement specification

(b) Purchaser order and contracts (un-priced) including amendments.

203 Manufacturing Records

(a) Applicable code data reports

(b) As-built drawings and records

(c) Certificate of compliance

(d) Inspection and test data

(e) Heat treatment records

(f) Location of weld filler material

(g) Major defect repair records

(h) Nonconformance reports

(i) Performance test procedure and results records

(j) Pipe and fitting location report

(k) Pressure test results (hydrostatic or pneumatic)

(l) NDE final results or review/ evaluation results

(m) Welding procedures

(n) Welder qualification reports

(o) Certified Material Test Report

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

Typical Lifetime Records (continued)

204 Installation Construction Records

204.1 Civil

(a) Check-off sheets for tendon installation

(b) Concrete design mix report, cylinder test reports and charts

(c) Concrete placement records

(d) Inspection reports for channel pressure tests

(e) Material property reports

(f) Pile drive log and load test reports

(g) Procedure for containment vessel pressure proof test and leak rate tests and results

(h) Reports for periodic tendon inspection and testing

(i) Subsurface investigation results

(j) Embed as-built

204.2 Welding

(a) Test results

(b) Heat treatment records

(c) NDE procedures

(d) Material property records

(e) NDE final results or review/ evaluation results

(f) Weld location diagram

(g) Welding procedure

(h) Welding qualification

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

Typical Lifetime Records (continued)

204.3 Mechanical

(a) Cleaning procedures and results

(b) Code data reports

(c) Installed lifting and handling equipment procedures, inspection, and test data

(d) Lubrication procedures

(e) Material properties records

(f) Pipe and fitting location reports

(g) Pipe hanger and restraint data

(h) Pressure test results (hydrostatic or pneumatic)

(i) Safety valve response test procedures

(j) NDE final results or review/ evaluation results

204.4 Electrical and I&C

(a) Cable installation procedures and results; pulling tension data, separation data, splicing procedures, and terminating procedures

(b) Certified cable test reports

(c) Relay test procedures

(d) Voltage breakdown test results on liquid insulation

204.5 General

(a) As-built drawings and records

(b) Final inspection reports and releases

(c) Nonconformance reports, causal analysis, and trending

(d) Specifications and drawings

(e) Construction records

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

Typical Lifetime Records (continued)

205. Preoperational and Start-up Test Records

(a) Power source procedures and results

(b) Final system adjustment data

(c) Pressure test results (hydrostatic or pneumatic)

(d) Initial start-up heat procedures and results

(e) Initial reactor/facility loading data, test procedures and results

(f) Instrument AC system and inverter test procedures and reports

(g) On-site emergency power source energizing procedure and test reports

(h) Facility load ramp change data

(i) Power transmission substation test procedures and results

(j) Power transmission substation test procedures and results

(k) Preoperational test procedures and results

(l) Primary and secondary auxiliary power test procedures and results

(m) Reactor/facility protection system tests and results

(n) Start-up logs

(o) Start-up test procedures and results

(p) Station battery and DC power distribution test procedures and reports

(q) Water chemistry report

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

Typical Lifetime Records (continued)

206 Operational Records

(a) Records and drawing changes identifying facility design modifications made to systems and equipment described in the FSAR

(b) New and irradiated fuel/nuclear material inventory, fuel/nuclear material transfer, and assembly fuel/nuclear material-depletion history records

(c) Off-site environmental monitoring survey records

(d) Spent fuel/nuclear material shipping records

(e) Facility radiation and contamination survey results

(f) Radiation exposure records for individuals entering radiation control areas

(g) Records of gaseous and liquid radioactive material released to the environs

(h) Records of transient or operational cycles for those facility components designed for a limited number of transients or cycles

(i) Training and qualification records for current members of the facility operating staff

(j) In-service inspection records

(k) Records of reviews performed for changes made to procedures or equipment, or reviews of tests and experiments

(l) Surveillance activities, inspections, and calibrations required by the technical specifications records

(m) Records of reactor/facility tests and experiments

(n) Changes made to operating procedures

(o) Low-level radioactive waste shipments records

(p) Sealed source leak test results

(q) Records of annual physical inventory of al sealed source material

Requirement 17. QA Records

- Discussions

KEPIC QAP-3, Non-mandatory Appendix 17A-1

Typical Lifetime Records (continued)

206 Operational Records (continued)

(r) Logs of facility operation covering times interval at each power level

(s) Records and logs of maintenance activities, inspections, repair, and replacement of principal items of structures, systems, and component

(t) Water chemistry reports

(u) Operational, shift supervisor, and control room logs

(v) Event reports

(w) Fire protection records

(x) Nonconformance/corrective action reports

(y) Facility equipment operations instructions

(z) Emergency plan and procedures

(aa) Quality assurance and quality control manuals

(bb) Applicable records noted in other sections of this Non-mandatory Appendix for any modifications or new construction applicable to structures, systems, or components

(cc) Evaluation of results or reportable safety concerns as required by regulations

(dd) Annual environmental operating report

(ee) Annual facility operating plan

(ff) Records to support licensing conditions such as safeguards and special nuclear material accountability

(gg) Results for in-use testing

Requirement 17. QA Records

•Discussions

KEPIC MNA 4000 Quality Assurance

Table 4200.17-1, Lifetime QA Records (for manufacturer)

1. Index to lifetime records
2. Data Reports
3. Design Specification
4. Design Output Documents
5. Overpressure Protection Report
6. Certified Material Test Report (CMTR) and documentation providing traceability to location used, if required
7. Heat treatment records
8. Capacity certification test reports of pressure relief devises
9. Final hydrostatic and pneumatic test results
10. Final nondestructive examination reports; final radiographic film or images as specified by the Owner for KEPIC-MI application
11. Material repair records when required by KEPPIC-MN
12. Welding procedures and procedure qualification records
13. As-build drawings of containments
14. Containment fabrication specification

Requirement 17. QA Records

- Case of Deviation (KINS Inspection Findings)

Title	Inadequacy of Scope and Classification for QA Records (Issued in July 2017)
Nonconformance	According to the QA Manual of a certain reactor, QA records shall be controlled by written procedures. There are two procedures in the reactor; 'QA Records Control Procedure' and the 'Document Control Procedure'. And document control shall be controlled in a consistent manner. However, two nonconformances were found in the two procedures above mentioned as follows. 1. QA Records Control Procedure does not include two QA records, the Nonconformance Evaluation Results and the Nonconformance Reports 2. Transfer frequency, document type, etc. stipulated in the Document Control Procedure is not consistent to those in the QA Records Control Procedure.

Requirement 18. Audits
(KEPIC QAP-1 / ASME NQA-1)

18. Audits

Contents

- ☐ **Area of Review**
- ☐ **Requirements**
- ☐ **Verification Practice**
- ☐ **Case of Deviation (KINS Inspection Findings)**

Requirement 18. Audits

- Area of Review

Requirement 18 provides for planned and scheduled audit to verify compliance with all aspect of the QA program and to determine its effectiveness

Requirement 18. Audits

- Requirements

100 BASIC

Audits shall be performed

- to verify compliance to quality assurance program requirements,
- to verify that performance criteria are met, and
- to determine the effectiveness of the program.

These audits shall be performed in accordance with written procedures or checklists by personnel who do not have direct responsibility for performing the activities being audited.

Audit results shall be documented and reported to and reviewed by responsible management. Follow-up action shall be taken where indicated.

Requirement 18. Audits

- Requirements

200 Scheduling

Audits shall be scheduled in a manner to provide coverage and coordination with ongoing activities, based on the status and importance of the activity.

Scheduled audits shall be supplemented by additional audits of specific subjects when necessary to provide adequate coverage.

Requirement 18. Audits

- Requirements

300 Preparation

301 Audit Plan

The auditing organization shall develop an audit plan for each audit. This plan shall identify the audit scope, requirements, audit personnel, activities to be audited, organizations to be notified, applicable documents, schedule, and written procedures or checklist.

302 Personnel

Audit personnel shall have sufficient authority and organizational freedom to make the audit meaningful and effective.

303 Selection of Audit Team

An audit team shall be identified prior to the beginning of each audit. This team shall contain one or more Auditors, on being designated Lead Auditor who organizes and directs the audit.

The Audit team shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

Requirement 18. Audits

- Requirements

400 Performance

Elements selected for audit shall be evaluated against specified requirements. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

500 Reporting

The audit report shall be signed or otherwise endorsed by the Lead Auditor and issued to the audited organization. The contents of the report shall

(a) Describe the audit scope

(b) Identify auditors and persons contacted

(c) Summarize audit results, including a statement on the effectiveness of the elements audited

(d) Describe each reported adverse audit finding

Requirement 18. Audits

- Requirements

600 Response

Management of the audited organization or activity shall investigate adverse audit findings, schedule corrective action, including measures to prevent recurrence of significant conditions adverse to quality, and notify the appropriate organization in writing of action taken or planned. Audit responses shall be evaluated by or for the auditing organization.

700 Follow-up Action

Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

800 Records

Audit records shall include audit plans, audit reports, written replies, and the record of completion of corrective action.

Requirement 18. Audits

- Verification Practices

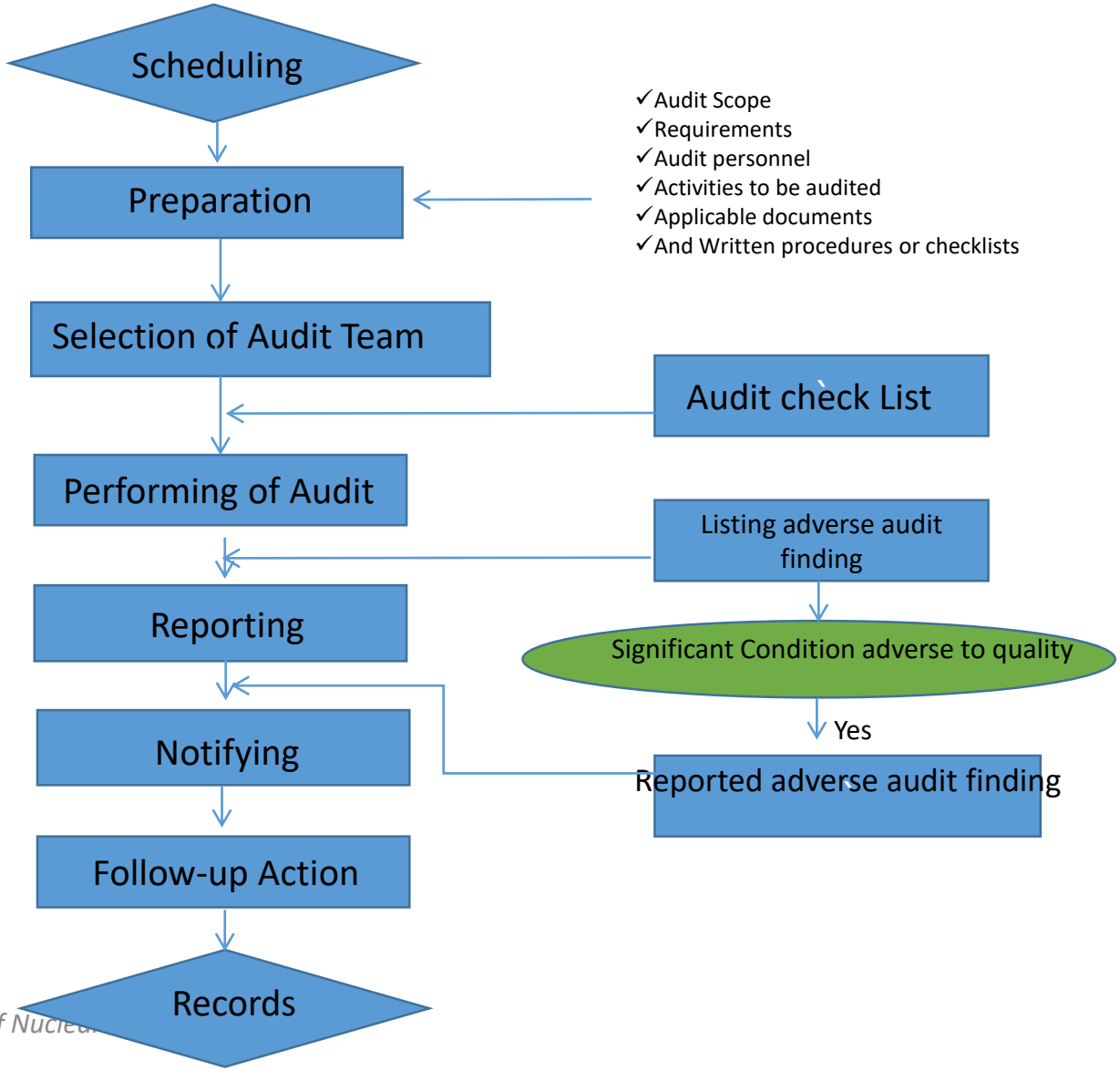
KINS focuses on;

- Whether the licensee and its contractors performs internal and external (suppliers) audits periodically
- Whether the audit results are documented and reported to responsible management
- Whether the follow-up actions are taken where indicated

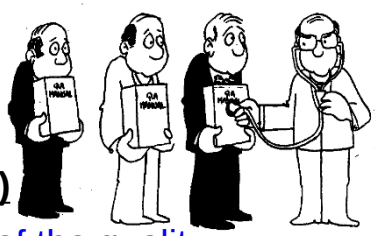
Requirement 18. Audits

Verification Practices

Audit flow



Requirement 18. Audits



• Discussions

- **Purpose of QA Audit (KEPIC QAP-3 Non-mandatory Appendix 18A-1)**

(a) To determine the status, adequacy, and implementation effectiveness of the quality assurance program that has been developed and documented

(b) To verify by examination and evaluation of objective evidence whether quality assurance program elements, items, processes, work areas, or records, as appropriate, conform to specified requirements

(c) To evaluate the effectiveness of the organizational controls and verification activities, as directed by management

(d) To evaluate strengths and weaknesses of work processes, process monitoring, and process control systems

(e) To determine whether the work processes and control systems are effective in producing a product of desired quality

(f) To provide management with an evaluation of the performance of the product to specified requirements

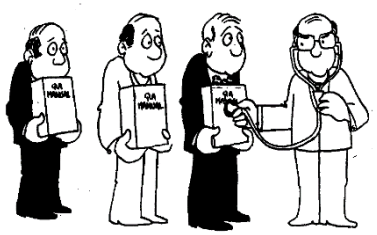
(g) To evaluate problems and errors in work process execution that will affect specified product performance

(h) To evaluate management effectiveness in responding to independent audit results

(i) To report audit findings of deficiencies to all levels of management who should be informed and who should take corrective action

(j) To verify that corrective action has been planned, initiated, or completed

Requirement 18. Audits



• Discussions

- **Audit Methods (KEPIC QAP-3, Non-mandatory Appendix 18A-1)**

Audits should be performed using the following methods:

(a) Review of documentation, including procedures and work instructions, for completeness and adequacy

(b) Examination of work areas for evidence of implementation of procedures and instructions

(c) Observation of processes for evidence of achievement of specified results and evidence that performance criteria are being met

(d) Examination of personnel training and qualification records where special skills are required

(e) Reexamination of selected work that has been accepted, such as products, design calculations, and drawings, and comparison of findings with applicable requirements and the previous basis for acceptance

(f) Examination of process controls, and records to determine conformance with specifications

Requirement 18. Audits

• Discussions

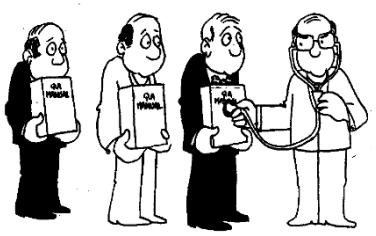
- **Audit Methods (KEPIC QAP-3, Non-mandatory Appendix 18A-1)**

Problems and Errors

When an auditor or team member finds a systematic or technical problem with an item or an outcome of a work process, it is important that the auditor or team member inform the audited organization representatives so they may investigate the facts behind the problem.

Post-audit Conference

At the conclusion of the audit, a post-audit conference should be held by the auditor or audit team with management of the audited organization to present audit results and clarify misunderstandings. It is desirable that agreement be reached on audit results at the post-audit conference.



Requirement 18. Audits

- Case Study (KINS Inspection Finding)

Title	Nonconformance of QA Auditor Designation (Issued in December 2016)
Nonconformance	According to QAP-1, Requirement 18. Audits, 3.1, QA audit shall be performed by the person(s) who is not directly responsible for the work to be audited. However, the QA audit of a certain reactor was performed by a person from the audited organization. - Audit No. : 2016-QA-1100-PM-102 - Auditor Organization : Quality Inspection Team - Audit Area : 15. Control of Non-conformance Item

Requirement 18. Audits

- Case of Deviation (KINS Inspection Finding)

Title	Nonconformance of QA Lead Auditor Qualification (Issued in September 2018)
Nonconformance	According to the procedure of a certain reactor, QA Lead Auditor and Auditor shall be qualified in accordance with the written procedure. The procedure describes that credit 2 is given to a certificate issued by a national entity or a certified organization as accredited by the government. However, credit 2 was given to the persons who obtained certificates issued by the reactor management (self issued certificates) and eventually a few lead auditors were qualified as lead auditors with the misgiven credits and this is a violation of the procedure.

Always we keep watching our Atomic Power

Thank You

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