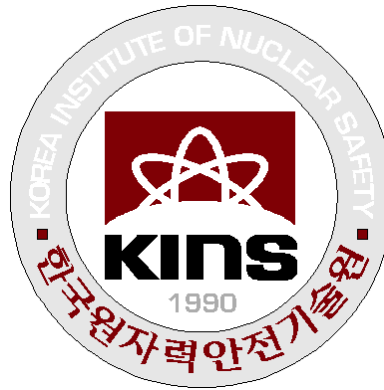


QA Criteria VI : Test Control, NCR & CAR



Jaehun LEE

Korea Institute of Nuclear Safety

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11. Test Control

11. Test Control

I. Area of Review

- The test program is established to ensure all tests are conducted according to documented procedures to *guarantee the normal operation of SSC*
- Detailed *test plan of computer program* such as the provision of verification method and test prerequisites are appropriately described

11. Test Control

II. Requirements

- 100 Basic
 - To verify conformance of an item or computer program to *specified requirements* and to demonstrate *satisfactory performance* for service shall be *planned and executed*
 - *Characteristics* to be tested and *test methods* to be employed *shall be specified*
 - *Test results* shall be *documented* and their conformance with acceptance criteria *shall be evaluated*

11. Test Control

II. Requirements (continue)

- 200 Test Requirements

(a) *Test requirements and acceptance criteria* shall be provided or approved by *the responsible design organization*

Required tests such as prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests *shall be controlled*

Computer program tests including software design verification, factory acceptance tests, site acceptance tests, and in-use tests shall be controlled.

11. Test Control

II. Requirements (continue)

- 200 Test Requirements (continue)

(a) *Required tests* shall be controlled under *appropriate environmental conditions* using the tools and equipment necessary to conduct the test in a manner to fulfill test requirements and acceptance criteria.

The tests performed shall obtain the *necessary data with sufficient accuracy for evaluation and acceptance*.

(b) Test requirements and acceptance criteria shall be based upon *specified requirements* contained in applicable *design documents*, or other pertinent *technical documents*.

11. Test Control

II. Requirements (continue)

- 200 Test Requirements (continue)
 - (c) *Temporary changes* are required approval
 - (d) *Test requirements and acceptance criteria for computer program*
 - (1) *Software* design verification testing
 - (2) Computer program acceptance testing shall ensure that it *satisfies the requirements* and *identify differences between expected and actual results* in the operating environment
 - (3) *In-use computer programs testing* shall demonstrate required performance over the range of operation

11. Test Control

II. Requirements (continue)

- 300 Test Procedures (other than for computer programs)
 - (a) Test procedure shall include *test objectives, provisions to meet the prerequisites, suitable environmental conditions, adequate instrumentation, necessary monitoring* is performed
 - Prerequisites* shall include (1) calibrated instrumentation, (2) appropriate equipment, (3) trained personnel, (4) condition of test equipment and the item to be tested, (5) suitable environmental conditions (6) provisions for data acquisition
 - (b) *As an alternative* to para. 300(a) appropriate sections of related documents, such as *ASTM methods, Supplier manuals, equipment maintenance instructions, or approved drawings or travelers with acceptance criteria*, may be used

11. Test Control

II. Requirements (continue)

- 400 Computer Program Test Procedures

(a) For those computer programs used in *design activities*, computer program test procedures shall provide correct results. For those computer programs used for *operational control*, computer program test procedures shall provide for demonstrating required performance over the range of operation of the controlled function or process. The procedures shall also provide *for evaluating technical adequacy through comparison of test results from alternative methods* such as hand calculations, calculations using comparable proven programs, or empirical data and information from technical literature

11. Test Control

II. Requirements (continue)

- 400 Computer Program Test Procedures (continue)
 - (b) *In-use test* procedures shall be developed and documented to permit *confirmation of acceptable performance* of the computer program in the operating system. In-use test procedures shall be performed after the computer program is *installed on a different computer*, or when there are significant changes in the operating system. *Periodic in-use manual or automatic self-check in-use tests* shall be prescribed and performed for those computer programs in which computer program errors, data errors, computer hardware failures, or instrument drift can affect required performance

11. Test Control

II. Requirements (continue)

- 400 Computer Program Test Procedures (continue)

(c) Test procedures or plans shall specify the following:

(1) required tests and test sequence (2) required ranges of input parameters (3) identification of the stages at which testing is required (4) criteria for establishing test cases (5) requirements for testing logic branches (6) requirements for hardware integration (7) anticipated output values (8) acceptance criteria (9) reports, records, standard formatting, and conventions

11. Test Control

II. Requirements (continue)

- 500 Test Results

Test results shall be documented and maintained. Test results *shall be evaluated by the responsible authority*

- 600 Test Records

- Test records shall be established and maintained to indicate *the ability of the item or computer program* to satisfactorily *perform its intended function or to meet its requirements*

11. Test Control

II. Requirements (continue)

- 601 Test Records

(a) item tested (b) date of test (c) tester or data recorder (d) type of observation (e) results and acceptability (f) action taken in connection with any deviations (g) person evaluating test results

- 602 Computer Program Test Records

(a) computer program tested including system software used (b) computer hardware used (c) test equipment and calibrations, where applicable (d) date of test (e) tester or data recorder (f) simulation models used, where applicable (g) test problems (h) results and applicability (i) action taken in connection with any deviations noted (j) person evaluating test results (k) acceptability

11. Test Control

III. Verification Practices

- Inspection of Production Test:
 - 1) the *test procedures and instructions* of equipment test are appropriately set up and implemented *in accordance with the requirements* of Safety Analysis Report and applicable codes & standards
 - 2) the *test results are evaluated* according to the acceptance criteria and *approved* by qualified personnel
 - 3) *Subcontracted testing* shall be controlled

11. Test Control

IV. Cases of Deviation

- *Approval of Test Control Procedure was not appropriate:*

In QA Manual (QAMZN5702, Rev.5) of KSB, Centrifugal Charging Pump supplier, paragraph 11.3 states “Manager of Integrated Management Department shall approve the test procedures.”

Contrary to this requirement *‘Test Procedure of Pump Performance (US4 35705, Rev.1)’ was approved by Project Manager*

11. Test Control

IV. Cases of Deviation (continue)

- *Approval of Test Control Procedure was not appropriate:*

In 'Effective Computer Program List (Rev.1)' of KOPEC, Architect Engineer, Computer Code for design analysis GTSTRUDL (Version 27-29) and PSDAP were not listed and there were *no objective evidences of In-Use test*

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15. Control of Nonconforming Items

15. Control of Nonconforming Items

I. Area of Review

- Measures are established to *prevent inadvertent use or installation* of nonconforming materials, parts and components
- *Control history* of such items are preserved as the *QA records*

15. Control of Nonconforming Items

II. Requirement 15

- 100 Basic

- Items that do not conform to specified requirements shall be controlled to *prevent inadvertent installation or use*
- Controls shall provide for *identification, documentation, evaluation, segregation and disposition* of nonconforming items, and for *notification* to affected organizations

15. Control of Nonconforming Items

II. Requirement 15 (continue)

- **200 Identification:**

Identify by legible *marking or tagging, or other methods not detrimental* to the item, on either the item, the container, or the package containing the item

- **300 Segregation:**

- Placing them in a clearly identified and designated *hold area*
- *Other precautions* shall be employed due to physical conditions such as size, weight, or access limitations

15. Control of Nonconforming Items

II. Requirement 15 (continue)

- 400 Disposition

- 401 Control

Nonconforming Items shall be evaluated and *recommended dispositions* shall be proposed. Further processing shall be *controlled pending the evaluation and an approved disposition by authorized personnel*

15. Control of Nonconforming Items

II. Requirement 15 (continue)

- 400 Disposition (continue)

- 402 Responsibility and Authority

The responsibility and authority for the *evaluation and disposition* of nonconforming items shall be defined.

Responsibility for the control of further processing, delivery, installation, or use of nonconforming items shall be *designated in writing*

15. Control of Nonconforming Items

II. Requirement 15 (continue)

- 400 Disposition (continue)

- 403 Personnel

Personnel performing evaluations to determine a disposition shall have

- (a) demonstrated *competence* in the specific area they are evaluating
- (b) an *adequate understanding* of the requirements
- (c) access to pertinent background information

15. Control of Nonconforming Items

II. Requirement 15 (continue)

- 400 Disposition (continue)
- 404 Disposition

A disposition, such as *use-as-is, reject, repair, or rework* shall be made and documented. *Technical justification* for the acceptability of a nonconforming item dispositioned *repair or use-as-is* shall be documented.

- 405 Reexamination

Repaired or reworked items shall be reexamined in accordance with applicable procedures and *with the original acceptance criteria*

15. Control of Nonconforming Items

III. Verification Practices

- Procedure control:
 - 1) *Procedures* shall be established and documented to prepare *how to identify, document, segregate, review, correct, notify to affected organizations, and record* nonconforming items, services, and activities affecting quality.
 - 2) *Responsibility of the QA and other participating organizations* shall be described

15. Control of Nonconforming Items

III. Verification Practices (continue)

- *Non-Conformance Report (NCR):*
 - 1) NCR Log
 - 2) In case of repair, repair process follows *NCR traveler*
- *Root Cause Analysis (RCA)*

The responsible organization should prepares a *RCA to prevent recurrence*
- *Trend Analysis*

The QA organization shall analyze nonconformance reports on a *regular basis to evaluate the quality trends* and *report* critical issues *to the top management*

15. Control of Nonconforming Items

IV. Cases of Deviation

- *QA did not follow the procedure appropriately:*

In QA Manual (QAMZN5702, Rev.5) of KSB, Centrifugal Charging Pump supplier, chapter 15 states “When a nonconformance is identified. Firstly QA issue the Quality Notification (QN) and evaluate the nonconformance whether it is the item to issue the Nonconformance Report (NCR).”

Contrary to this requirement QA *issue only QN without any evaluation* for 14 nonconformance cases of Korean Project.

15. Control of Nonconforming Items

IV. Cases of Deviation (continue)

- *Procedure was not appropriate* :

NCR format in NCR procedure (QCP-1301, Rev.6) of Doosan Engine, emergency diesel engine supplier, does *not include recommended disposition column* but have columns for description of nonconforming condition and evaluation of final disposition

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16. Corrective Action

16. Corrective Action

I. Area of Review

- The measures are appropriate to *immediately identify and correct* the conditions adverse to quality such as fault, malfunction, defect, dislocation and other nonconformance

16. Corrective Action

II. Requirement 16

- 100 Basic

- Conditions adverse to quality shall be *identified promptly and corrected as soon as practicable*
- In the case of *a significant condition adverse to quality*, the cause of the condition shall be determined and *corrective action taken to preclude recurrence*
- The *identification, cause, and corrective action* for significant conditions adverse to quality shall be *documented and reported* to appropriate levels of management.
- *Completion* of corrective actions shall be *verified*.

16. Corrective Action

III. Verification Practices

- Procedure control:
 - 1) *Materials, parts and services with conditions adverse to quality* shall be *identified and corrected immediately* and the QA organization shall document them
 - 2) *Significant conditions adverse to quality* shall be *defined and follow up action shall be delineated*
 - 3) The QA organization shall check if corrective actions are taken properly to *close the Corrective Action Report (CAR)* in a timely manner

16. Corrective Action

III. Verification Practices (continue)

- CAR:
 - 1) CAR Log
 - 2) CAR
- Reporting:

Causes and corrective actions against conditions adverse to quality shall be *documented and reported to supervisors and top management* for review
- Trend Analysis:

The QA organization shall analyze CAR on a *regular basis to evaluate the quality trends* and *report to the top management*

16. Corrective Action

IV. Cases of Deviation

- *Procedure was not followed appropriately:*

In QA Manual of Union Pump, aux. charging pump supplier, chapter 16 states 'QA manager shall verify the corrective action of CAR within 30 days from the issuing date.'

Contrary to this requirement CAR #1350, 1351, and 1352 are *not verified within 30 days*

16. Corrective Action

IV. Cases of Deviation (continue)

- *Procedure was not followed appropriately:*

Because of the qualification of NDE examiner, QA Department of Doosan issued a CAR to POSCO, steel plate supplier, on 5 February 2009 with a *due date until 3 April 2009*

However, QA Department did not issue a new CAR after the due date and *did not close the case until 15 October 2009*

Always we keep watching
our Atomic Power



Thank You



한국원자력안전기술원
KOREA INSTITUTE OF NUCLEAR SAFETY