APR 1400 Fluidic Device Verification Experiment

Quality Assurance Procedures

Revision No.: - 0 -
Publication Date: October 20, 2003
☐ Controlled copy
☐ Uncontrolled copy
Distributed by: N/A
Distribution Date: N/A

Advanced Reactor Development
KOREA ATOMIC ENERGY RESEARCH INSTITUTE

Prepared by: Chang Hwan Chung — QA coordinator — October 15, 2003 — Date

Reviewed by: In Cheol Chu — FD experiment manager — October 17, 2003 — Date

Approved by: Chul Hwa Song — Project Manager — October 20, 2003 — Date

1. Purpose

This procedure describes training procedures for personnel who will conduct the "APR 1400 Fluidic Device Verification Experiment(hereafter, "FD Verification Experiment")".

2. Procedures

2.1 The Project manager shall establish education/training plans(Form FDQAP-2.1-1) after discussions on the project progress with each manager or a person in charge. Established plans shall be reviewed by the QA manager.

2.2 The fulfillment of education/training for each personnel shall be decided considering followings:

1) Nature, scope, and complexity of the job
2) Education, experience and proficiency of the person

2.3 Each personnel shall be trained on the following items as a minimum regarding the applicable project .

1) Related regulatory commitments and applicable codes and standards
2) Parts of QA manual and QA procedures that are related to his/her job fulfillment.
3) An overview and procedures of the activity to be conducted shall be given to new personnel.

2.4 Each staff shall receive a training on the following area to maintain the proficiency.

1) Changes of related regulatory commitments, codes and standards
2) Changes in QA manual and QA procedures that are related to his/her job fulfillment

2..5 Education/training is performed in the manner of either self learning, CRT (Classroom Training), OJT (On-the-Job Training), etc. and the result is recorded in personal training record(Form FDQAP-2.1-2). In case the personal training record was prepared and maintained according to the other QA program, the existing record can be used continually.

2.6 In case of a group training, the training department or a trainer shall maintain the group training record (form FDQAP-2.1-3,) and send its copies to the applicable manager, or a person in charge, or an individual to be recorded in the personal training record.

3. Attachments

1) Form FDQAP-2.1-1 Education/training plan
2) Form FDQAP-2.1-1 Personal training record
3) Form FDQAP-2.1-1 Group training record

Education/Training Plan

Service Title: APR 1400 Fluidic Device Verification Experiment

Prepared by: Date:	Reviewed by: Date:	Approved by: Date:

No.	Instructor/ Sponsoring department	Title	Audience	Planned date	Method	Hour	Location	Remark

Personal Training Record

Department: Name:

History of Education/Training				
Education/Training	Hour	Period	Type of training	Remark

Group Training Record

Title of the lecture: _____

Date/Hours: _____/_____hours Location: _____

Instructor: _____(Signature)

No.	Department	Name	Signature	No.	Department	Name	Signature

1. Purpose

This procedure describes procedures for preparation, review, approval, distribution, revision and disposal of the documents that specify activities affecting the quality of "APR 1400 Fluidic Device Verification Experiment(hereafter "FD Verification Experiment")" or quality requirements.

2. Scope

This procedure applies to the procedural documents that need revision control and distribution control.

3. Procedures

3.1 Document preparation

3.1.1 Each department director or manager (hereafter, director) is responsible to identify, prepare, and control the documents that specify quality-affecting activities or quality requirements.

3.1.2 Each director shall appoint a personnel to prepare a document according to the applicable requirements for related regulations, contract conditions, and quality assurance manual/procedure, etc.

3.1.3 All documents shall include required items such as document number, title, revision number, revision date, page number, and preparing department. Documents shall be prepared and reviewed according to the applicable procedures and signed by the final approver to have legal effect.

3.2 Review and approval of document

3.2.1 The person who prepare shall have the document reviewed and approved according to Table 3-1.

3.3 Document distribution

3.3.1 The approved document shall be distributed to applicable organizations and personnel. Document distribution shall be controlled through the document distribution register (Form FDQAP-3.1-1), which must include the disribution target and be signed by the receiving department (or personnel) to confirm reception of documents. The uncontrolled copy is exempted from distribution control.

3.3.2 The receiver of documents shall dispose of the obsolete document and send the latest copies to the locations where the activities specified in the document are being conducted. If the obsolete document is to be preserved as a reference, it shall be clearly marked as "obsolete document" to prevent misuse.

3.4 Document revision

3.4.1 Document shall be revised by the preparing department (or the person who prepared).

3.4.2 Document revision shall follow the same procedure as that for preparation, review, approval, distribution, and control of the original document.

3.4.3 Amendments shall be clearly marked using shades, side lines, or other appropriate methods. All documents shall contain the revision number and date in each page. If the scope of change is so broad that it is difficult to mark all changes, the document shall be marked as " total revision" on the top of each page.

4. Document Number

4.1 Document number for the quality assurance manual and quality assurance procedures

Numbers are assigned according to the Control of Quality Assurance Manual and Procedure(FDQAP-4.1) procedure.

4.2 Experimental procedure

The numbers are assigned according to Control of Experimental Procedures (FDQAP-4.2).

5. Attachments

1) Table 3.1-1 Preparer, reviewer, and approver of each document
2) Form FDQ-3.1-1 Document distribution register

Table 3.1-1 Preparer, reviewer, and approver of each document

Division / Document type	Prepared by	Reviewed by	Approved by
QA Manual	QA coordinator	Project manager	Vice president of advanced reactor development
QA Procedures	QA coordinator	Experiment/ Evaluation manger	Project manager
Experimental procedure/ Technical document	Experimental executor or experiment manager	QA coordinator /Experiment manager	Project manager

Document distribution register

Reception date
Received by(signature)

Distributing department: APR 1400 Fluidic Device Verification Experiment Project

Document No.:					
Title:					
Distribution control No.	Rev.	Rev.	Rev.	Rev.	Rev.
	Distribution target (department)				
	(Name)				

1. Purpose

This procedure describes preparation and control procedures for the quality assurance manual and quality assurance procedures (hereafter, "QAM/QAP") for the "APR 1400 Fluidic Device Verification experiment (hereafter, "FD verification experiment")".

2. Preparation and Distribution

2.1 The quality assurance manual shall be prepared by the QA coordinator, reviewed by the project manager, and approved by the vice president of advanced reactor development.

2.2 The quality assurance procedure shall be prepared by the QA coordinator, reviewed by the related manager, and approved by the project manager.

2.3 The QAM/QAP shall contain a title, revision number, revision date, page number with the total number of pages on every page (see Example 1 and 2).

2.4 A control number is assigned to the controlled copy to be written on the title page, whereas it is not assigned to the uncontrolled copy. The uncontrolled copy may be distributed as a reference by the QA coordinator to external organizations or an individual.

2.5 The QA coordinator shall distribute and control the controlled copy according to Document Control(FDQAP-3.1) procedure so that it can be used in the applicable activities.

2.6 A department or an individual to whom the controlled copy of the QAM/QAP was distributed is responsible to maintain its latest copy.

3. Revision and Disposal

3.1 The revision of the QAM/QAP shall comply with the applicable procedures of

FDQAP-3.1.

3.2 The revised QAM/QAP shall be distributed with a table of contents. The old copy shall be collected by the distributor or disposed of by the user.

3.3 If the old document is to be preserved as a reference, it shall be marked as "obsolete document" to prevent misuse.

3.4 The original copy of the old document shall be filed under the category of "old document" in the quality assurance document register.

4. Assessment of adequacy and validity of the Quality Assurance Program

4.1 The QA manager shall annually assess the adequacy and validity of the quality assurance program with consideration of the following and prepare the report.

1) Whether or not the QA related organization changed
2) Suitability of organization and job assignment
3) Whether or not there is any omission or error in QA requirement
4) Suitability and performance efficiency of QA requirement
5) Results of quality trend analysis of problems found through the external audits and non-conforming items, etc. (In some cases, the quality trend analysis may be separately conducted from the assessment of the validity of the quality assurance program.)
6) Other items related to the adequacy of the quality assurance program

4.2 Assessment report of adequacy and validity of QA program (Form FDQAP-4.1-1) should be prepared including following items:

1) adequacy of quality assurance organization
2) adequacy of organization and job assignment

3) Whether or not there is any omission of QA requirements (Customer requirement, law, applied code and standard)
4) Necessity of revision of QAM/QAP
5) Suggestions to guarantee the implementation of QA program
6) Other items related to the adequacy of QA program

4.3 Followings should be fulfilled if necessary from the review result of QA program:
1) Revision of QAM/QAP
2) Suggestion to change organization, improvement of QA system, or suggestion to improve to guarantee the fulfillment of QA program

5. Attachments

1) Form FDQAP-4.1-1 Assessment report of adequacy and validity of QA program
2) Example 1, Form of Quality Assurance Manual
3) Example 2, Form of Quality Assurance Procedures

Assessment report of adequacy and validity of QA program

Document title:

Item to review	Result		Related provision and review opinion
	Satisfaction	Dissatisfaction	
1. QA related organization 2. Adequacy of organization and job assignment 3. Whether or not there is any omission of QA requirements (Customer requirement, law and applied code and standard) 4. Adequacy and performance efficiency of QA requirement (Reviewed including QA procedures) 1) Organization 2) QA program 3) Instructions and procedures 4) Document control 5) Experiment and inspection 6) Control of measuring and experiment equipment 7) Control of nonconforming experiment 8) Quality assurance record			

5. Countermeasure and suggestion to review results

Prepared by:	Reviewed by:	Approved by:
QA coordinator	QA manager	Project manager

(Example 1) Form of Quality Assurance Manual

KAERI	APR 1400 Fluidic Device Verification experiment Quality Assurance Manual Chapter OOOOOOO	Rev. No. x Rev. Date mm. dd. yyyy Page No. /

"Main body"

(Example 2) Form of Quality Assurance Procedures

KAERI	APR 1400 Fluidic Device Verification experiment Quality Assurance Procedure FDQAP-X.Y OOOOOOO	Rev. No. x Rev. Date mm. dd. yyyy Page No. /

"Main body"

1. Purpose

This procedure describes control procedures for preparation, review, approval, distribution, and revision of experimental procedures for the "APR 1400 Fluidic Device Verification Experiment(hereafter, "FD Verification Experiment")".

2. Procedures

2.1 Preparation

2.1.1 The project manager for the FD verification experiment shall select a personnel to prepare each experimental procedure.

2.1.2 The assigned personnel prepares the experimental procedure including the applicable items among the following items. The experimental procedure shall be prepared in compliance with Example 4.2-1(title page) and Example 4.2-2 (main body) if possible.

1) Purpose
2) Scope
3) References
4) Experimental conditions, check and preparation
5) Experimental facility and equipment
6) Experimental method and procedures
7) Method for analyzing the experimental results
8) Form
9) Other

2.1.3 Numbers for the experimental procedures shall be assigned as follows:

FD-EP-xx

FD : Acronym for this project (**F**luidic **D**evice)
EP : Acronym for **E**xperimental **P**rocedures
xx : Serial number

2.2 Review and Approval

2..2.1 The experimental procedure shall be reviewed by QA coordinator and each experiment-related manager and approved by the project manager. The person who prepare the experimental procedure may add additional reviewers according to its need.

2.3 Distribution, Revision, and Disposal

2.3.1 Distribution, revision, and disposal of the experimental procedures shall comply with the applicable procedures of the quality assurance procedure FDQAP-3.1.

2.3.2 The original copy of the obsolete experimental procedures shall be preserved by the FD experiment manager.

3. Attachments

1) Example 4.2-1 Form of Title Page of the Experimental Procedures
2) Example 4.2-2 Form of Main Body of the Experimental Procedures

Example 4.2-1
Form of Title Page of the Experimental Procedures

Doc. No.: FD-EP-YY
Rev. No.: 0
Date: Dec. 01, 2003

Title of the Experimental Procedures

(Title in English: optional)

Prepared by: _____ Date: _____

Reviewed by: _____ Date: _____
Experiment manager

Reviewed by: _____ Date: _____
QA coordinator

Approved by: _____ Date: _____
FD verification experiment project manager

Advanced Reactor Development

KOREA ATOMIC ENERGY RESEARCH INSTITUTE

Example 4.2-2
Form of Main Body of the Experimental Procedures

KAERI	APR 1400 Fluidic Device Verification Experiment ○ ○ ○ ○ ○ Experimental Procedures	Doc. No. Rev. No. Rev. Date mm. dd. yyyy Page No.: # / ##

″ Main Body ″

1. Purpose

This procedure describes control procedures for "APR 1400 Fluidic Device Verification Experiment(hereafter, "FD Verification Experiment")" to comply with quality requirements, technical requirements, and regulatory requirements.

2. Procedures

2.1 Preparation of the experimental plan

2.1.1 The experimental plan for this project may be substituted with the project execution plan, and experiments shall be conducted in compliance with the experimental procedure. If an experimental plan needs to be prepared for each experiment, it shall be done as follows:

2.1.1.1 The experimental plan shall include the following items as a minimum:

1) Experiment overview
2) Experimental facility and equipment
3) Prerequisites for experiments (conditions for test environment, calibration requirements, etc.)
4) Treatment of experimental data and methods for recording and documentation of results

2.1.1.2 The experimental plan shall be prepared by the experimenter, reviewed by the QA coordinator, and approved by the project manager.

2.1.1.3 Revision of the experimental plan shall follow the same procedure as that for the initial experimental plan.

2.2 Experiment execution

2.2.1 Experiments shall be executed according to the approved experimental

procedure, related code and standard, or requests of regulatory authority.

2.2.2 Experiments shall be executed by a trained personnel.

2.2.3 Experimental data, information, and the content of inspection required for the data sheet shall be recorded before and after each experiment according to the applicable experimental procedure.

2.2.4 Experimental equipment shall be calibrated to maintain the required degree of precision and accuracy.

2.3 Preparation of experimental report

2.3.1 The experimental report may be substituted with the final report to be submitted at the completion of the contract. The final report shall include the following items as a minimum:

1) Experimental items
2) Experiment date
3) Experimenter and/or recorder
4) Experimental equipment
5) Experimental method and procedure or the title of the document that specifies the experimental procedure
6) Experimental results
7) Actions taken in connection with non-conformities
8) Evaluation of experimental results

2.3.2 The final report shall be reviewed by the QA coordinator before submission.

2.4 Report of experimental results

2.4.1 Experimental results shall be documented and controlled according to the applicable experimental procedure.

1. Purpose

This procedure describes activities to inspect the compliance of the "APR 1400 Fluidic Device Verification Experiment(hereafter, "FD Verification Experiment")" with established procedures or requirements.

2. Scope

This procedure applies to important experimental activities, for which the project manager for the "FD verification experiment" considers inspections necessary.

3. Procedures

3.3.1 The experimenter shall prepare the inspection plan (Form FDQAP-5.2-1), have it reviewed by the FD experiment manager, and send it to the QA coordinator 5 days prior to the first day of experiment execution in order for the QA coordinator to be able to select inspection points.

3.3.2 The QA coordinator shall select inspection points on the inspection plan received and sign it before returning it to the experimenter.

3.3.3 The experimenter shall notify the QA coordinator of a specific experimental schedule 3 days (working days) prior to experiment execution so that the QA coordinator can inspect.

3.3.4 If the inspector fails to arrive at the inspection site by the pre-scheduled time for experiments, experimental activities selected as witness points can be executed, whereas experimental activities selected as hold points can be executed only after they are approved by the inspector (in writing or verbally).

3.3.5 Non-conformities discovered during the inspection shall be controlled according to Control of Nonconforming Experiment(FDQAP-7.1) procedure.

3.3,6 Inspection records shall be documented in the inspection plan and include the following items:

1) Inspection items
2) Inspection date
3) Inspector name and signature
4) Inspection results
5) Unsatisfactory items found and corrective actions

4. Attachment

1) Form FDQAP-5.2-1 Inspection plan

KAERI	INSPECTION PLAN	Page /

Project Title:

Inspection Item	Procedure No.	Witness point	Inspected by		Remarks
			KAERI		
1. ○○○○ Test					
1)		W			
2)		H			
3) Test log		R			

Inspection Results:

Prepared by:	Reviewed by:
QA:	Approved by:

Codes for witness point :
W: Witness point, H: Hold point, R: Report review

1. Purpose

This procedure describes calibration and control procedures for measuring and experiment/test equipment (hereafter, "equipment") used for the "APR 1400 Fluidic Device Verification Experiment (hereafter, "FD Verification Experiment")" to maintain the required precision and accuracy.

2. Scope

This procedure applies to the equipment directly used for experiments and for acceptance evaluation during the inspection.

3. General

3.1 If forms and lists have been already prepared and maintained by other type of QA manual, no separate forms and lists are needed for this procedure.

4. Procedures

4.1 Selection of equipment being calibrated

4.1.1 The characteristics test manager shall select equipment being calibrated with consideration of equipment type, measurement scope, degree of precision, and frequency of use.

4.1.2 The equipment manager shall prepare and maintain the comprehensive equipment list (Form FDQAP-6.1-1) for equipment being calibrated and controlled.

4.2 Establishment of calibration cycles

4.2.1 The institute's own calibration cycle can be established with consideration

of characteristics of equipment, usage, degree of precision, use environment, cycle of use, or frequency of use. If it is not possible, the "Integrated notification of operational rules for accredited calibration laboratories" shall be used.

4.3 Preparation of equipment history record card

4.3.1 The equipment manager shall prepare and maintain the equipment history record card (Form FDQAP-6.1-2) for equipment being calibrated.

4.4 Calibration

4.4.1 The equipment manager shall calibrate equipment within the scheduled calibration cycle either by delegating the calibration work to calibration laboratories or using the institute's own calibration equipment. A calibration label shall be attached to equipment after calibration.

4.5 Control of nonconforming equipment

4.5.1 Equipment not being used due to failure, not yet being calibrated, repair, or other reasons shall be identified by attaching a tag (Form FDQAP-6.1-3) or isolated to prevent its use.

4.6 Handling and storage of equipment

4.6.1 The degree of precision shall be specified in the history record card for equipment requiring the level of accuracy and degree of precision, and equipment shall be stored in a way to maintain the degree of precision. If special storage conditions are required, or special handling requirements are specified in the user manual for the applicable equipment, equipment shall be handled and stored according to the instructions in the user manual and related requirements shall be recorded in the equipment history record card.

4.6.2 Equipment not being used continuously does not need periodical calibration, except for calibration right before use. This type of equipment needs to be

appropriately stored, and "Do not use" tag shall be attached to equipment to identify it as spare/preservation item.

5. Attachments

1) Form FDQAP-6.1-1 Comprehensive equipment list
2) Form FDQAP-6.1-2 Equipment history record card
3) Form FDQAP-6.1-3 "Do not use" tag

KAERI

Comprehensive Equipment List

Page /

No.	Equipment No.	Equipment Name	Degree of precision	Manufactured year	Purchased year	Calibration Cycle	Calibration date	Next calibration due	Remarks

KAERI	Equipment History Record Card		
Equipment/Model Name (including serial No.)			
Manufactured year		Degree of precision	
Purchased year		Calibration cycle	

Calibration Status

Calibration date	Calibrated by	Calibration Results	Next Calibration Due	Verified by

History Records

(Installation, inspection, adjustment, repair, transfer, lease, and other)

Day/Month/Year	Content	Verified by

◉ DO NOT USE

Equipment :

Serial No. :

☐ To be calibrated

☐ Not yet calibrated

☐ Failure

☐ Under repair/maintenance

☐ Under inspection

☐ Spare/preservation item

☐ Disposal

☐ Other

FDQAP-6.1-3

1. Purpose

This procedure describes disposition procedures for a part of experimental work or experimental results not conforming to requirements for the "APR 1400 Fluidic Device Verification Experiment (hereafter, "FD Verification Experiment")".

2. Scope

This procedure applies to nonconformities that significantly affect the quality of experimental results.

3. Procedures

3.1 Identification of nonconformities and preparation of nonconformity report

3.1.1 When the project participant discovers a nonconformity in experimental work, he or she shall immediately prepare the nonconformity report (Form FDQAP-7.1-1) and send it to the QA coordinator, and the project manager stops the applicable experimental work. The applicable equipment or material found to be the root cause of nonconformity shall be tagged as "non-conforming item"(Form FDQAP-7.1-1), isolated or controlled by other appropriate methods to prevent its use until completion of nonconformity.

3.1.2 The QA coordinator shall publish the nonconformity report (NCR) received and register it to the nonconformity control register (Form FDQAP-7.1-3). Numbers for the NCR are assigned as follows:

FD - NCR - YY - xx

FD: Acronym for this service
NCR: Acronym for nonconformity report
YY: Two digits of the applicable year (e.g., 03 for 2003)
XX: Serial number in the applicable year

3.2 Selection of disposition methods

3.2.1 The QA coordinator shall send the NCR, which is registered in the NCR control register, to the project manager to select disposition methods and determine corrective actions.

3.3.2 One of the following methods will be selected for disposition of nonconformity, for which necessary corrective actions and related conditions shall be provided. Proper supplementary data for corrective actions requested, application procedures, and requirements for retest or re-experiment shall be provided as well.

1) Use-as-is

If a non-conforming experimental work is considered as not affecting the quality of experimental results based on contractual requirements, related technical criteria, or other technical review, the experimental work executed is considered valid, without the need for a separate corrective action.

2) Repair

If a non-conforming experimental work can be recovered or corrected to comply with initial requirements

3) Re-test

If the experimental work clearly violates requirements, therefore its correction is impossible, it is determined to retest the non-conforming part of the experiment.

4) Reject

If it is determined to reject the non-conforming experimental work.

3.3.3 For the non-conforming experimental work considered as use-as-is or repair, technical validity or reasons of disposition methods shall be documented.

3.3.4 The person in charge of nonconformity disposition shall send the NCR containing disposition methods, disposition actions, or plans to the QA coordinator, who reviews the report and return it to the person in charge of nonconformity.

3.4 Disposition method and verification

3.4.1 The nonconformity disposition department shall execute corrective actions according to disposition methods and related requirements, which shall be recorded in the NCR and verified by the QA coordinator.

3.4.2 If a nonconformity is satisfactorily handled, it shall be verified by the QA coordinator and the non-conforming item tag is removed to complete disposition of nonconformity.

3.4.3 The non-conforming experimental work considered reject shall be rejected or identified and controlled.

3.5 QA records

The completed NCR and related base data shall be preserved as QA records.

4. Attachments

1) Form FDQAP-7.1-1 Nonconformity report
2) Form FDQAP-7.1-2 Non-conforming item tag
3) Form FDQAP-7.1-3 nonconformity report control register

Nonconformity Report

Report No.:

Item:			Issue date:
Related procedure (application specified):			
· Description of Nonconformity:			
Reported by:	Name:	Signature:	Date:
Project manager	Name:	Signature:	Date:
QA coordinator	Name:	Signature:	Date:
· Disposition method : ☐ Use-as-is ☐ Repair ☐ Re-test ☐ Reject · Disposition action or plan:			
Disposition representative	Name:	Signature:	Date:
QA coordinator	Name:	Signature:	Date:
· Corrective action:			
Person in charge of corrective action	Name:	Signature:	Date:
Project manager	Name:	Signature:	Date:
Corrective result confirmation: ☐ Satisfied ☐ Unsatisfied			
QA coordinator	Name:	Signature:	Date:

Non-conforming Item

NCR No.:

Attached by:

Phone No.:

1. This identification tag must always remain attached on the non-conforming item until nonconformity completion.

2. This identification tag must not be removed without permission.

FDQAP-7.1-2

Nonconformity report control register

Report No.	Detailed description of nonconformity	Disposition method	Date Reply date	Completed date Signature of person in charge of completion

1. Purpose

This procedure describes control procedures for quality assurance records created during the execution of the "APR 1400 Fluidic Device Verification Experiment (hereafter, "FD Verification Experiment")"

2. Definition of Terms

2.1 Quality Assurance Records

Completed documents that provide quality-related evidences for items or services affecting quality

2.2 Lifetime Records

Quality assurance records that need to be maintained for the life of the item being used or the project

2.3 Nonpermanent Records

Quality assurance records that need to be preserved for the minimum period specified, or until the time point required by the contract

3. Procedures

3.1 General

3.1.1 Table 8.1-1 presents major quality assurance records created during this project and their preservation periods.

3.1.2 The project manager shall appoint a person in charge of controlling quality assurance records.

3.1.3 Quality assurance records are divided into lifetime and nonpermanent records and stored in a place equipped with a facility to prevent damage or

loss before being transferred to a customer.

3.1.4 If necessary, quality assurance records shall be corrected by the organization that created the records, and the corrected portion shall be signed by the corrector and dated (No correction tape or White-out allowed).

3.2 Control of quality assurance records

3.2.1 The person in charge of controlling quality assurance records organizes the records by record type as follows, or using other appropriate methods:

1) Data created during experiment execution

- It is preserved as a quality assurance record after being filed according to experiment types
- Data automatically created and stored in the computer system is identified and stored in computer storage media as a quality assurance record.
- Handwritten measurement data transferred to the computer system is to be preserved as a quality assurance record in computer storage media after its accurate transfer is confirmed.
- Data stored in computer storage media must be backed up.

2) Experimental result report (experimental log or experimental report)

- This is preserved as a quality assurance record in a separate file according to experiment types.
- If the experimental result report obtained from the computer or automation system satisfies requirements for the experimental result report specified in the experimental procedure, it shall be printed and signed(by experiment executor, reviewer, verifier, etc.) and preserved as a quality assurance record.

3) Quality assurance manual/procedure, and experimental procedure(obsolete)

Obsolete copies shall be filed under the "obsolete file" according to document types and preserved as a quality assurance record.

4) Personal training record

A personal training record of test personnel shall be preserved and controlled collectively after being filed under the "personal training record" for each test personnel.

5) Inspection Plan

It shall be preserved and controlled after being filed under the "inspection plan" for each experiment.

6) Calibration certificate

It shall be preserved with the equipment history record card for each equipment, or filed under the "calibration certificate" for each equipment.

7) Nonconformity report (responsibility of QA coordinator)

It shall be stored and controlled as a quality assurance record after being filed under the "nonconformity report" by the order of issue numbers.

3.2.2 A quality assurance record beyond the preservation period shall be either disposed of or preserved as a reference according to the decision of the project manager.

3.3 Transfer to customer

3.3.1 The project manager shall take every necessary measure to transfer to a customer the applicable quality assurance record requested by the contract.

3.3.2 The institute is not responsible to continue to preserve a quality assurance record that was transferred according to the contract or customer's request

to a customer.

4. Attachment

1) Table 8.1-1 Quality Assurance Records and Preservation Period

Table 8.1-1 Quality Assurance Records and Preservation Period

Type of record	Lifetime	Nonpermanent	
		3 years	5 years
Data created during experiment execution	○		
Experimental results (Experimental log, experimental report, etc.)	○		
Quality assurance manual			○
Quality assurance procedure		○	
Experimental procedure			○
Personal training record		○	
Inspection plan	○		
Calibration cetificate		○	
Nonconformity report	○		