GUIDE NO. AERB/NPP/SG/QA-9

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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

DOCUMENT CONTROL AND RECORDS MANAGEMENT FOR QUALITY ASSURANCE IN NUCLEAR POWER PLANTS

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/NPP/SG/QA-9

DOCUMENT CONTROL AND RECORDS MANAGEMENT FOR QUALITY ASSURANCE IN NUCLEAR POWER PLANTS

Atomic Energy Regulatory Board
Mumbai-400 094
India

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FOREWORD

Activities concerning establishment and utilisation of nuclear facilities and use of radioactive sources are to be carried out in India in accordance with the provisions of the Atomic Energy Act 1962. In pursuance of the objective of ensuring safety of members of the public and occupational workers as well as protection of environment, the Atomic Energy Regulatory Board has been entrusted with the responsibility of laying down safety standards and framing rules and regulations for such activities. The Board has therefore undertaken a programme of developing safety standards, safety codes and related guides and manuals for the purpose. While some of these documents cover aspects such as siting, design, construction, operation, quality assurance and decommissioning of nuclear and radiation facilities, other documents cover regulation aspects of these facilities.

The AERB Safety Codes and safety standards are formulated on the basis of internationally accepted safety criteria for design, construction and operation of specific equipment, systems, structures and components of nuclear and radiation facilities. Safety Codes establish the objectives and set minimum requirements that shall be fulfilled to provide adequate assurance for safety in nuclear and radiation facilities. Safety guides elaborate various requirements and furnish approaches for their implementation. Safety manuals deal with specific topics and contain detailed scientific and technical information on the subject. These documents are prepared by experts in the relevant fields and are extensively reviewed by advisory committees of the Board before they are published. The documents are revised when necessary, in the light of experience and feedback from users as well as new developments in the field.

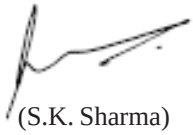
The Code of Practice on Quality Assurance for Safety in Nuclear Power Plants (AERB/SC/QA, 1988) provides the management principles and objectives to be met during the implementation of activities in different phases of the nuclear power plants for assuring safety. This safety guide is one of a series of guides, which have been issued or are under preparation, to describe and elaborate the specific parts of the Code. This safety guide recommends the procedures for the document control and records management. In drafting the guide, relevant International Atomic Energy Agency (IAEA) documents under the Nuclear Safety Standards (NUSS) programme, especially the safety guide on Document Control and Records (50-G-Q3, 1996) have been extensively used.

Consistent with the accepted practice, ‘shall’, and ‘should’ are used in the guide to distinguish between a firm requirement and a desirable option, respectively. Annexures, footnotes, bibliography and list of participants are included to provide further information on the subject that might be helpful to the user. Approaches for implementation different to those set out in the guide may be acceptable, if they provide comparable assurance against undue risk to the health and safety of the occupational workers and the general public and protection of the environment.

For aspects not covered in this guide, applicable and acceptable national and international standards, codes and guides applicable and acceptable to AERB should be followed. Non-radiological aspects of industrial safety and environmental protection are not explicitly considered. Industrial safety is to be ensured through compliance with the applicable provisions of the Factories Act, 1948 and the Atomic Energy (Factories) Rules, 1996.

This guide has been prepared by specialists in the field drawn from Atomic Energy Regulatory Board, Bhabha Atomic Research Centre, Indira Gandhi Centre for Atomic Research and Nuclear Power Corporation of India Limited and other consultants. It has been reviewed by the relevant AERB Advisory Committee on Codes and Guides and the Advisory Committee on Nuclear Safety.

AERB wishes to thank all individuals and organisations who have prepared and reviewed the draft and helped in its finalisation. The list of persons, who have participated in this task, along with their affiliations, is included for information.



(S.K. Sharma)
Chairman, AERB

DEFINITIONS

Assessment

Systematic evaluation of the arrangements, processes, activities and related results for their adequacy and effectiveness in comparison with set criteria.

Atomic Energy Regulatory Board (AERB)

A national authority designated by the Government of India having the legal authority for issuing regulatory consent for various activities related to the nuclear and radiation facility and to perform safety and regulatory functions, including their enforcement for the protection of site personnel, the public and the environment against undue radiation hazards.

Audit

A documented activity performed to determine by investigation, examination and evaluation of objective evidence, the adequacy of, and adherence to applicable codes, standards, specifications, established procedures, instructions, administrative or operational programmes and other applicable documents, and the effectiveness of their implementation.

Commencement of Operation of Nuclear Power Plant

The specific activity/activities in the commissioning phase of a nuclear power plant towards first approach to criticality, starting from fuel loading.

Commissioning

The process during which structures, systems and components of a nuclear or radiation facility, on being constructed, are made functional and verified in accordance with design specifications and found to have met the performance criteria.

Construction

The process of manufacturing, testing and assembling the components of a nuclear or radiation facility, the erection of civil works and structures, the installation of components and equipment and the performance of associated tests.

Contractor

An individual or organisation rendering service (e.g. design, construction, inspection, review, maintenance and/or supplying items).

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation in a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Documentation

Recorded or pictorial information describing, defining, specifying, reporting or certifying activities, requirements, procedures or results.

Document Control

The act of assuring that documents are reviewed for adequacy, approved for release by authorised personnel and distributed to and used at the location where the prescibed activity is performed.

Grading (QA)

Category or rank given to entities having the same functional use but different requirements for quality.

Inspection

Quality control actions, which by means of examination, observation or measurement, determine the conformance of materials, parts, components, systems, structures as well as processes and procedures with predetermined quality requirements.

Item

A general term covering structures, systems, components, parts or materials.

Nuclear Safety

The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of site personnel, the public and the environment from undue radiation hazards.

Operation

All activities following and prior to commissioning performed to achieve, in a safe manner, the purpose for which a nuclear/radiation facility is constructed, including maintenance.

Quality

The totality of features and characteristics of an item or service that have the ability to satisfy stated or implied needs.

Quality Assurance (QA)

Planned and systematic actions necessary to provide the confidence that an item or service will satisfy given requirements for quality.

Quality Control (QC)

Quality assurance actions, which provide means to control and measure the characteristics of an item, process or facility in accordance with the established requirements.

Records

Documents, which furnish objective evidence of the quality of items and activities affecting quality. They include logging of events and other measurements.

Responsible Organisation

An organisation having overall responsibility for siting, design, construction, commissioning, operation and decommissioning of a facility.

Review

Documented, comprehensive and systematic evaluation of the fulfillment of requirements, identification of issues, if any.

Safety

(See 'Nuclear Safety').

Site

The area containing the facility defined by a boundary and under effective control of the facility management.

Siting

The process of selecting a suitable site for a facility including appropriate assessment and definition of the related design bases.

Specification

A written statement of requirements to be satisfied by a product, a service, a material or a process, indicating the procedure by means of which it may be determined whether the specified requirements are satisfied.

Supplier

An individual or organisation under contract for furnishing items or services. This includes various levels or kinds of procurement, e.g. as undertaken by vendors, sellers, contractors, sub-contractors, fabricators and consultants.

Testing (QA)

The determination or verification of the capability of an item to meet specified requirements by subjecting the item to a set of physical, chemical, environmental or operational conditions.

Validation

The process of determining whether a product or service is adequate to perform its intended function satisfactorily.

Verification

The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services or documents conform to specified requirements.

Vendor

A design, contracting or manufacturing organisation supplying a service, component or facility.

CONTENTS

1. INTRODUCTION

1.1 General

1.1.1 This safety guide is part of the AERB's set of codes and guides for assurance of safety in nuclear power plants. It gives requirements and recommendations for document control and records management of any organisation engaged in performing work affecting safety in nuclear power plants. The basic requirements for document control and records are given in AERB Code of Practice on Quality Assurance for Safety in Nuclear Power Plants-AERB Code No. SC/QA, hereinafter referred to as 'the Code'.

1.1.2 Methods and solutions for fulfilling the basic requirements of the Code other than those set out in this safety guide may be acceptable provided they result in at least the same level of nuclear safety.

1.2 Objective

This safety guide provides recommendations on acceptable ways to fulfil the basic requirements of the Code on document control and records, with respect to preparation, review, approval, control, issuance, distribution, storage and maintenance.

1.3 Scope

This safety guide applies to the quality assurance (QA) programme of the responsible organisation (RO), i.e. the organisation having overall responsibility for the nuclear power plant, as well as to QA programmes of participating organisations in each stage of a nuclear power plant and covers items, services and processes impacting nuclear safety. It may, with appropriate modifications, if required, also be usefully applied at nuclear installations other than nuclear power plants.

2. GENERAL CONSIDERATIONS

2.1 General

1.1.1 For each nuclear power plant, a document control system shall be established which should provide for the preparation, review, approval, issuance, distribution, revision, validation, suspension and cancellation, storage and retention, and retrieval of documents essential to the management, performance and verification of work.

2.1.2 In the document control system, the responsibilities of each participating organisation or functional organisation position should be defined and documented.

2.1.3 The types of documents include, but are not limited to design documents and documents pertaining to QA programme, safety requirements, calculations, computer codes, drawings, purchase orders and related documents, supplier documents (supplier means an individual or organisation under contract for furnishing items or services), work instructions, inspection instructions, inspection and test reports, assessment reports, maintenance and operating procedures.

2.1.4 Management should identify the documents needed to perform the various processes in the organisation and should provide guidance to the organisation and personnel preparing them. The guidance should cover aspects such as scope, contents, policies, applicable codes and standards, type, hierarchy, stage of the document etc.. The guidance should take into consideration feedback of experience. It should be recognised that additional or new documents may become necessary as a result of plant modification or as a result of assessment of existing processes. The guidance should also highlight the need to indicate the status of the document such as preliminary, released for information or for implementation, voided/superseded, etc.

2.1.5 Management should establish a document control centre at responsible organisation (RO) as well as its constituent units for issuance, distribution and maintenance of documents.

2.2 Grading[1]

2.2.1 Nuclear safety is the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A graded approach, based on the relative importance to nuclear safety of each item,

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[1] For further guidance see IAEA Technical Report Series No.328 on 'Grading of Quality Assurance Requirements'.

service or process, shall be used. The graded approach should reflect a planned and recognised difference in the applications of specific QA requirements.

2.2.2 Aspects of document control and records management that could be graded include:

- The need to apply controls to the preparation of documents and records.
- The need and extent of validation.
- The degree of review and the level of persons involved.
- The level of approval.
- The need for distribution lists.
- The types of documents which can be supplemented by temporary documents.
- The need to archive superseded documents.
- The need to categorise, register, index, retrieve and store document records.
- The retention time of records.
- The responsibilities for the disposal of records.
- The types of storage media.

2.2.3 Grading identification should be clearly marked on the document to enable all downstream activities to adopt appropriate QA requirements.

3. DOCUMENT CONTROL

3.1 General

3.1.1 Management should use a document control procedure applicable to all its constituent organisations and units as part of its QA programme.

3.2 Preparation of Documents

3.2.1 When documents are in their preparatory phase, they should be marked and controlled so that their draft status clearly distinguishes them from issued documents.

3.2.2 An appropriate document identification system should be established. Each document should be uniquely identified.

3.2.3 Standard forms should be identified and controlled, whether these are stand alone or are part of another document.

3.2.4 The need for traceability of a document to related hardware or software should be determined.

3.2.5 During preparation, activities described by the documents should be assessed using the grading system, so that the appropriate controls are chosen and included.

3.2.6 The preparation of document shall be done by knowledgeable and identified individuals.

3.2.7 The document prepared should be legible.

3.3 Review of Documents and Confirmation of Acceptability

3.3.1 Documents shall be reviewed before issue. The review should comprise a critical examination of the need for and the adequacy of the document, against prescribed requirements, guidelines and relevant modifications taking into account the safety significance of the document.

3.3.2 The document review system should identify the organisations or individuals responsible for reviewing the documents. The individuals responsible for preparation and review should be different.

3.3.3 The reviewing organisation or individuals shall have access to the relevant information upon which to base an effective review and to ensure that safety considerations are adequately addressed.

3.3.4 The reviewing organisation or individuals shall be competent in the specific topic they are being asked to review.

3.3.5 A record of review shall be prepared showing the date of the review, the reviewer(s) and the outcome. The outcome of the review shall be considered and satisfactorily resolved.

3.3.6 One aspect of review involves validating the implementation of the document through simulation, mock-up, walk-throughs or the like. This validating process is usually applied to significant working level instructions and procedures.

3.4 Approval of Documents

3.4.1 Documents shall be approved according to a prescribed method before they are issued for use. The responsibilities for approval should be clearly defined by the management.

3.4.2 Where acceptance by, or approval of, AERB (see AERB Code No.SC/G) is required, this should be obtained before the document is issued for use.

3.5 Issue and Distribution of Documents

3.5.1 A document issue and distribution system should be established, utilising up-to-date distribution lists. Those participating in an activity shall be aware of, have access to, and use the documents, which have been approved for performing the activity. The system shall ensure that changes to documents are communicated simultaneously to all relevant/affected persons and organisations. Controlled copies are subject to revision update. They are distributed according to document control procedure and should be identified at the time of distribution by distinct identification.

3.5.2 The issued documents should be marked so that their use becomes clear, especially if their use is restricted to a specific purpose. Examples of marking include the indication that the document is approved for use in engineering, procurement, manufacturing, construction or operation.

3.5.3 The system for distributing and storing documents should be secure.

3.5.4 To preclude the use of non-applicable documents and to ensure control of current documents, the distributor may employ an appropriate acknowledgement system. This would require the recipient to indicate receipt of the document and to return or dispose off the previous issue/revision by destroying or stamping the document suitably.

3.5.5 Master copies of documents should be retained until they are superseded or withdrawn. The need to archive master copies of superseded documents should be considered.

3.5.6 Uncontrolled copies (copies which are not controlled copies and circulated for ‘information only’) of documents may be supplied, provided they clearly

indicate they are not subject to intimation for document revision. Implementation shall not be taken up based on such documents.

3.5.7 Revision status of document should be clearly identified and a master list established to identify such revision. Authorised agency to maintain the master list should be identified.

3.6 Temporary Documents

3.6.1 Under certain circumstances, a temporary document may be required to cover an activity for a limited period. This will be necessary when an immediate amendment to an existing document cannot be justified.

3.6.2 Temporary documents should be subject to the same controls as permanent documents. Temporary documents should have a defined period of validity. When this period expires the document should be withdrawn or integrated into an appropriate document or the temporary period of validity should be renewed.

3.7 Document Change Control

3.7.1 Changes to documents shall be subject to the same level of review and approval as the original documents. Changes to documents are to be reviewed and approved by the same organisation(s) that performed the original review and approval unless some other organisation(s) is/are designated by the RO.

3.7.2 The reviewing and approving individual(s)/organisation shall have access to pertinent background data or information upon which to base their review or approval.

3.7.3 A modification to one document may affect other document(s). Affected documents should be identified and revised accordingly.

3.7.4 Modifications to documents should be highlighted in the document(s) by the use of sidelining or other suitable means.

3.8 Suspension or Cancellation of a Document

3.8.1 When a document is suspended or cancelled, it should be removed from use.

3.8.2 Suspension and cancellation notices should uniquely identify the reference and issue numbers of the document to which they apply and give their effective date of application and reasons for suspension/cancellation. In the case of suspension notices, the duration of suspension should also be provided.

3.8.3 Suspensions and cancellation notices should be distributed to all controlled copy holders, to preclude the use of suspended or cancelled document(s).

3.9 Documents External to the Responsible Organisation

3.9.1 A registration system should be established and maintained to record and control the receipt of documents and amendments to documents, which are generated and controlled externally.

3.9.2 The system should, as a minimum, register the receipt date of the document, its reference number, title, date of issue and/or issue status and the person or persons to whom it was passed for distribution or if appropriate, assessment.

3.9.3 Documents from external sources should be reviewed by designated personnel to ensure their suitability before acceptance and use.

3.10 Document Archives

3.10.1 When documents which were subjected to the formal issue process are withdrawn from use, the master copies should be archived as records wherever required, following the guidance of Section 4.

3.10.2 An appropriate storage system should be established and maintained (see Annexure-I and II).

4. ESTABLISHMENT OF A RECORDS SYSTEM

4.1 General

4.1.1 An appropriate records system shall be established and implemented by the RO. The records system should ensure that records are specified, prepared, authenticated and maintained, as required by applicable codes, standards and specifications. Examples are records of siting, design, construction, commissioning, operation and decommissioning. The records should include the results of inspections, tests, reviews, assessments, monitoring of work performance and material analysis; test materials and specimens; plant operation logs and related data such as training and qualifications and other appropriate data.

4.1.2 The responsibilities for maintaining and operating the records system should be clearly defined and documented.

4.1.3 The records systems should ensure that records are:

- categorised
- registered upon receipt
- readily retrievable
- indexed and placed in their proper location within the record facility files with the retention time clearly identified
- stored in a controlled environment
- corrected or supplemented to reflect the actual plant status
- properly disposed off.

4.1.4 A master list with all categorised records indicating latest status should be maintained.

4.2 Categorisation of Records

4.2.1 Records should be categorised as permanent or non-permanent according to their importance to safety. An example of a system used for categorisation is provided in Annexure-III.

4.2.2 Records, which meet one or more of the following, may be considered as permanent.

- Describing the as-manufactured condition of items accepted for use in the installation;
- Describing the as-built condition of the installation;
- Providing evidence that the nuclear installation has been tested and commissioned in accordance with the design intent;

- Providing required baseline data for in-service inspection;
- Demonstrating capability for safe operation;
- Demonstrating that staff are competent to perform their work;
- Demonstrating that the plant is being operated, tested and inspected in accordance with design requirements and approved instructions;
- Demonstrating that the plant is being maintained in accordance with design requirements and the approved maintenance programme and instructions;
- Confirming design reliability assessment by plant performance history;
- Demonstrating compliance with statutory and regulatory requirements;
- Providing information for maintenance, rework, repair, replacement or modification of an item including the details on spares;
- Demonstrating that the quality of originally installed or replacement items meets the specified requirements
- Providing information for decommissioning
- Recording the investigation of an accident, malfunction or non-conformance.

4.2.3 Records such as QA programmatic documentation, QA procedures and assessment reports should be considered as non-permanent.

4.3 Administration of Records

4.3.1 The applicable design specifications, procurement documents, construction procedures, test procedures, operational procedures or other documents should specify the records to be generated by, supplied to, or held for the RO. Such records should be considered valid only if dated, stamped, initialled, signed or otherwise authenticated by authorised personnel. They may be originals or reproduced copies. The copying of records from one medium to another may result in the records not being legally admissible. The records system should therefore ensure that records are kept in the appropriate medium and that copying to maintain image quality during the storage time is adequately controlled. All records should be legible, complete, identifiable to the item, service or process involved and made of appropriate material to resist deterioration for the required retention time.

4.3.2 Records in the form of hard copy alone should be considered valid unless the records in the devices such as micro-diskettes and laser discs are authenticated with electronic signatures appropriately by the RO.

4.3.3 Records should be listed in an index which indicates:

- The title or unique identification of the record and the item, service or process it is related to
- The organisation or person generating the record
- Date of generation of the record
- The retention time of the record
- Storage medium of record
- The location of the record in the storage location
- Revision dates and the persons approving the revisions

The method of indexing should be established before receipt of the record. The index should provide sufficient information to identify both the item and the relevant record.

4.3.4 The RO should specify retention times for all records. Annexure-IV describes a process for the allocation of retention times.

4.3.5 Guidance is given in Annexure-I on the choice of storage media for the different record retention times.

4.3.6 When records are to be corrected or supplemented, the organisation originating the records should review the correction for approval. When this is not possible, another authorised person or organisation should be assigned.

4.3.7 The correction or supplement should include the date and the identification of the person making the correction or supplement.

4.4 Receipt of Records

4.4.1 Management should devise the methodology and establish a plan for the receipt of records and ensure that records are available at the required time.

4.4.2 The receipt control of records should ensure that the records are complete, legible and in a form suitable for storage.

4.5 Retrieval and Accessibility

4.5.1 Records shall be indexed, filed, stored and maintained in facilities which allow ready retrieval when required.

4.5.2 The records should be accessible during the specified retention time. Access to retention locations should be controlled.

4.5.3 Consideration should be given to the off-site storage and/or access to documents that would be required in emergency conditions.

4.6 Storage and Preservation

4.6.1 The RO should establish storage and location requirements for the maintenance, preservation and protection of records and associated test materials and specimens from the time of receipt until their disposal. A record storage system should include the following:

- Description of the document or record storage facility. Examples of storage facilities are given in Annexure-II.
- Description of the filing system to be used.
- A method for verifying that the records received are in agreement with the transmittal document and that the records are in good condition;
- A method for verifying that the identification of records agree with the index of records;
- Rules governing access to, and control of, the files;
- A method for maintaining control of accountability for records removed from the storage facility;
- A method for filing corrected or supplementary information and voiding or disposing off of records that have been superseded;
- Periodic checking to ensure that the records are not damaged, deteriorated or missing.

4.6.2 Continued ability to read the data must be assured, taking into account any technological changes that may occur.

4.6.3 Records shall be stored in such a manner as to prevent deterioration. Examples of storage methods for different storage media are given in Annexure-II.

4.6.4 Paper records should be firmly attached in binders, or placed in folders or envelopes for storage on shelves or in containers. Steel file cabinets or safes are preferred.

4.6.5 Records which are processed by special methods should be packaged and stored as recommended by the manufacturer's instructions, in line with applicable standards. Examples are: radiographs, photographs, microfilm, magnetic tapes, micro -diskettes, laser discs and those records which might be sensitive to light, pressure, humidity, magnetic fields, dust and temperature. Special requirements for the packaging and storage of test materials and specimens should be taken into account. When the records are stored in devices such as micro-diskettes and laser discs, guide note indicating the version, procedure for usage etc. should be provided.

4.6.6 Records which are stored electronically should have as long a life span as possible. Electronic records shall be re-written periodically depending on the life span of the electronic storage media as per the specification of the electronic records. Everytime an archive is re-written, the user has to decide between keeping the old files as they are or converting to a more up-to-date medium considering such factors as accessibility, readability, durability and the preservation of authenticity.

4.6.7 Record storage facilities should protect the contents from possible damage or destruction by such causes as fire, flooding, insects and rodents and from possible deterioration by adverse environmental conditions such as light, temperature and humidity.

4.6.8 Amongst others, the following features should be considered in the construction of a storage facility:

- Location and security
- Type of construction, including structural features and internal surface treatment.
- Pipe work layout and drainage
- Ventilation, temperature and humidity control
- Fire prevention, detection and fighting
- Electromagnetic protection

Where it is not practicable to provide suitable storage conditions, consideration should be given to the provision of a duplicate set of records stored in a separate facility. In that case, the location and construction features of both facilities should be such that the probability of simultaneous destruction, loss or deterioration of records is sufficiently low.

4.7 Inspection of Records

4.7.1 Inspection of the record storage facility shall be done at least once a year to ensure that :

(a) the facility is adequate and that necessary environmental and other protective measures are in effect; and

(b) the records have been updated based on data resulting from plant maintenance, repair, modifications and/or replacement of items.

4.7.2 Sampling inspection of records shall be done at least once a year to check aspects such as receipt control, retrievability and also to ensure that records are not deteriorating due to improper handling or storage practices.

4.8 Disposal

4.8.1 The RO should identify who is responsible for transfer or disposal of records.

4.8.2 Upon transfer of the records, the RO or its designated person should acknowledge their receipt and process them. Access to records accumulated at locations not under the control of the RO should be agreed.

4.8.3 Records categorised in accordance with sub-section 4.2.1 to 4.2.3 should be retained for the minimum period specified by the RO. After this period these records may be disposed off by, or with the agreement of the RO.

ANNEXURE - I

STORAGE MEDIA FOR RECORDS

A-1.1 Storage Media

Examples of media, which may be used to store records, are:

- Paper pH between 6 and 9
- 35mm film roll
- Silver-gelatin type microfilm or X-ray film
- Microfiche
- Magnetic tape or disc
- Optical laser disks
- Hardware such as graphite samples, weld samples or other materials which have been or are able to be subjected to qualification testing
- Electronic firmware (computer or component)

Records that require special processing and control, such as computer codes and software and information stored on high density media or optical disks, should be maintained and controlled to ensure they are readily retrievable and usable.

A-1.2 Recommended Retention Time of Record Storage Media

The following media are considered to be acceptable for records with retention periods of upto 30 years:

- Hard paper copy retained in a controlled environment with an indexing system to allow retrieval in a reasonable time, for example, one working day;
- Microfilm or other microforms prepared appropriately and stored in adequate conditions;
- Punched paper tape or cards where the information is stored as physical artifacts on a paper/card medium. The storage should be in equivalent environmental conditions to hard paper copy.
- Magnetic media stored and maintained appropriately, such as disc packs, storage modules, disk cartridges and magnetic tape on open spool.

The following media are considered to be acceptable for records with retention times of up to five years.

ANNEXURE - I (CONTD.)

- Any of those media with retention times of up to 30 years or optical discs. Records using optical disc media may be held for periods beyond five years provided that periodic checks are made for any deterioration in image quality. The record should be copied onto a new optical disc if any deterioration of image quality is found. This may be before the manufacturer's certified lifetime of the original disc is exceeded.

The following media are considered to be acceptable for records with retention times of up to three years:

- Any of those media with retention times of five years or 30 years or flexible disk cartridges (floppy disks) and magnetic tape cartridges stored and maintained appropriately.

The preparation and storage requirements for the different media should reflect the manufacturer's guidance.

ANNEXURE - II

DOCUMENT AND RECORD STORAGE FACILITIES

A-2.1 General

All quality documents and records should be securely stored and maintained in such a way that they are readily retrievable in facilities that provide a suitable environment to minimise deterioration or damage and to prevent loss.

The type of storage facilities required depends on factors such as the records media, environmental conditions (including insect or fungal infestation and rodent), safety significance (duplication of copies in diverse locations), duration of retention and security.

Records should be retained in facilities appropriate to the media. Care should be taken to ensure that record media requiring different storage environments are not stored in the same area. In particular, cellulose nitrate film should be stored in a separate facility.

Unsuitable environments can cause more damage to records than any other single factor. A dry or polluted atmosphere may lead to embrittlement of documents; dampness and poor ventilation may cause the growth of mould; excess heat may accelerate chemical damage. All three conditions can lead to irreparable damage to records. Careful control and observation of temperature, humidity and ventilation within the records facility is therefore essential. In general, low temperatures with adequate air movement are preferable.

Fire precautions, including limitations on the distance to reach means of escape and the physical dimensions of the storage facility, are the subject of national legislation and local by-laws. The fire precautions adopted, however, should be designed to protect the contents and structure of the facility from damage caused by fire fighting operations, as well as to ensure the safety of staff and limit the fire to its source. The possibility of fires or explosions in adjacent facilities and the proposed type of fire fighting chemicals to be employed to counter such events should be taken into account when the facility is chosen.

Loose material should not be permitted and smoking should be prohibited at all times in the storage facility.

Precautions should be taken during the storage and handling of records to avoid finger marks, dust or scratching on microfilm records (by the provision of suitable hand covering), unnecessary bending or cracking of paper (by the suitable positioning on adequately designed storage) and failure of components due to static discharge (by the provision of static handling precautions).

ANNEXURE - II (CONTD.)

Records entering the record archive facility should be registered. To protect the integrity of the records, the facility should be secure, and wherever possible copies of archieved records should be used for reference purposes rather than permitting the removal of the master record.

A2.2 Microfilm Storage Facilities for Up to Ten Years

The following storage conditions are considered suitable for the storage of microfilm records for a time not longer than that sufficient for general business purposes. Such a time might be ten years, but could vary depending on specific conditions.

- Relative humidity and temperature requirements for the storage of microfilm

  The relative humidity of the storage facility should not exceed 60% and the temperature should not rise above 25^{O}C. Rapid changes of humidity and temperature should be avoided.

- Protection of microfilms against fire and water

  Microfilms using safety film are difficult to ignite and combustion speed is low. To provide effective protection of microfilms against fire, as much attention should be paid to the presence of steam as to high temperatures. The protection available in a given room should take into consideration conditions special to that room and also the following general conditions:

  Microfilm stored at 40% relative humidity can withstand a dry heat of 120^{O}C for a time of 24 hours without appreciable loss of legibility and printability. At a dry heat of 150°C some distortion may take place after 6 hours but individual microfilms of texts or figures are still printable. The action of dry heat of 180°C for at least 6 hours causes deformation of microfilms and reproduction generally becomes impossible.

  In the presence of water vapour, temperature of 90^{0}-110^{O}C produce serious distortions and cause adhesion of coils or surfaces in contact; prolonged action or condensation will make the emulsion melt. Fireproof cabinets and safes thermally insulated by water vapour production are therefore not suitable for storing microcopies unless they have an inner moisture-proof chamber or the films are placed inside suitably sealed airtight containers. To obtain complete protection from fire, safes or cabinets should be protected from the

action of water resulting from leaks, fire sprinklers or flooding, by being stored above basement levels on shelves at least 150mm from the ground. If films are immersed in water, allowing them to dry, even partially, will cause the layers to stick together. The films should be placed in water filled containers until they can be washed and dried properly.

- Chemical contamination

  Various noxious emanations can cause slow deterioration and a gradual fading of the image on film. Danger is presented by peroxides which may originate from bleaching agents, glues, varnishes and other products used in manufacturing storage cabinets for film containers. Hydrogen sulphide, ozone, sulphur dioxide, sulphur trioxide, ammonia and oxides of nitrogen are the most common, but not the only, atmospheric gases which harm film. Such fumes should be eliminated or an alternative store found.

  Chemical products in the immediate vicinity of the films may also cause the presence of other impurities in the atmosphere. If dust and liquid particles suspended in the air are deposited on the microfilm, they may impair its legibility and cause permanent scratching. Microcopies on silver image film should be kept neither with other photographic records which do not conform to these recommendations, nor with those films explicitly excluded, such as microfilm on a nitrate film base. Cross-contamination between microcopies can occur by the transfer of free thiosulphate to sodium (or ammonium) thiosulphate free film if they are stored with the emulsion sides in contact. Radiographs and other photographic media should be stored in chemically benign envelopes. Multiple films stored in envelopes should be separated by benign sleeves or separators.

A 2.3 Additional Recommendations for Archival of Microfilms in Excess of Ten Years

- Air purification

  Air should be filtered to remove dust, purified of noxious gases and circulated by means of forced draught.

- Relative humidity

  If sealed airtight containers are not used, the air in the archival storage

facility should be conditioned to maintain the relative humidity at a level between 20% and 40%. If air conditioning is used, dehumidifiers using calcium chloride or other chemical desiccants should not be used. An electrical dehumidifier is recommended. If dehumidifiers are used, they should be of a type that does not produce rapid changes in the relative humidity.

- Temperature of archival premises

  The temperature in the archival storage should be maintained between 15°C and 25°C, but preferably should not exceed 20°C. If film, which has been stored at a low temperature, is handled in a room where the temperature or relative humidity is comparatively high, condensation will occur on the cold film surfaces. In these circumstances the film should not be removed from its closed container or the place where it is stored until the storage temperature has been brought up to the approximate temperature of the room where the film is to be handled.

- Containers

  The following two types of container are recommended:

  (i) The closed non-airtight container

  (ii) The sealed airtight container

  If the recommendations for relative humidity and temperature of the archives are observed, containers for storage of microfilm can be of the closed non-airtight type. Sealed airtight containers should be used if there are no other means of protection against the danger of an ambient atmosphere of which the relative humidity or temperature goes beyond the limits recommended in this annexure or which contains chemical impurities or dust. The containers used should be made from materials meeting the requirements below. These containers may be placed in boxes of paper or board, but such boxes should not be used alone.

- General precautions for the long term protection of microfilm records

  The use of non-corroding materials for containers is recommended but whatever the materials used for the containers, their corrosion resistance coating and their airtight seals should not melt, ignite, decompose, develop fumes, distort or be subjected to excessive dimensional changes when subjected to a temperature of 150°C for 4 hours.

Care should be taken to avoid the deterioration or damage which may result from the rust, rubber joints, rubber bands and gum on certain types of envelope, and of lignin and other peroxide forming substances contained in certain wooden materials.

Microcopies stored in roll form may be mounted either on reels or on cores. Rolls more than 30 mm long wound on cores should be laid flat unless the core itself is carried on a horizontal spindle which prevents the lower part of the film from supporting the load of the core and its contents.

A 2.4 Additional Precuations for Sealed Airtight Film Containers

- Fire

  The container should be of a type, which will prevent steam reaching the film in the event of fire. Containers with a high resistance to corrosion are recommended. The container and its airtight seal should withstand an excess pressure inside the container of 70 kPa without rupture of the seal or other injurious effects.

- Relative humidity

  The relative humidity inside a sealed airtight container should be within 20% to 40% at the storage temperature. Relative humidity exceeding 60% encourages the formation of mould, which, in time, can completely destroy the image. Below 15% the film tends to curl and become more brittle as the relative humidity decreases.

A 2.5 Storage Facilities for Paper

- Relative humidity and temperature requirements for the storage of paper

  The relative humidity of the storage facility for paper should be within the range 55 to 65% and the temperature should be within the range 13 to 18°C. However, if the paper is in bound volumes and is little used, it may be stored at a relative humidity of 40%.

A 2.6 Storage Facilities for Magnetic Tape or Disc, Optical Laser Disc, Hardware, Electronic Firmware

Magnetic tapes or discs, optical laser discs, electronic firmware and general hardware records should be archived in accordance with the manufacturer's requirements or the component media. The retention requirements should be consistent with the life expectancy of the media and should provide for rejuvenation and backup.

ANNEXURE - III

EXAMPLES OF RECORDS AND THEIR RETENTION CATEGORIES

This Annexure indicates examples of types and retention categories of records of safety related items and activities. It is recognised that the nomenclature and type of records may vary from organisation to organisation and alternative categories may be chosen at the discretion of the RO. In general, procedures are classified as non-permanent and results are classified as permanent, on the basis that the recorded results can be interpreted without recourse to the procedures. However, where interpretation of the results depends on knowledge of the procedure, both should be classified as permanent.

Permanent records are those whose retention time is 30 years or more from date of operation or lifetime of the plant, whichever is more. For retention period of non-permanent records refer Annexure IV.

TYPE OF RECORDS	CATEGORIES	
	Permanent	Non-Permanent
1. Design Records		
Design basis information (DBI)	*	
Detailed project report (DPR)	*	
As built drawings	*	
Codes and standards in design	*	
Design calculations	*	
Design change requests		*
Design change notices (DCNs), Field change notices (FCN)		*
Engineering change notices (ECNs)	*	
Design drawings	*	
QA manual, design procedures and manual		*
Design basis report (DBR)	*	
Design notes (DN)		*
Records of check and review of design documents, design review meetings		*
Technical specifications	*	
QA audit reports		*
Preliminary safety analysis report (PSAR)		*
Final safety analysis report (FSAR)	*	

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Seismic analysis report	*	
Design manuals	*	
Valve specifications sheet	*	
Flow sheets/process diagrams	*	
Instrumentation specifications sheet	*	
Electrical schematic diagrams	*	
2. Procurement Records		
Procurement procedures		*
Technical specifications	*	
Vendor qualification records		*
QA audit reports on vendors		*
Receiving records		*
Shipping release/QS inspection reports	*	
Supplier's QA programme manual		*
Purchase orders/work orders	*	
Inspection reports/test certificates	*	
List of spares received/ordered	*	
Requisition,indent,tender document, technical evaluation, purchase recommendation, QS requisition, QAP		*
3. Manufacturing Records		
As built drawings	*	
Manufacturer's drawings	*	
Manufacturing procedure		*
Test certificates/test reports	*	
Cleaning procedures		*
History docket/end reports	*	
Non-destructive testing (NDT) procedures	*	
NDT reports	*	
Electronic control verification test results		*
Ferrite test procedure	*	
Ferrite test results		*
Forming and bending procedure qualifications		*

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Heat treatment procedures		*
Heat treatment records	*	
Hot bending procedure		*
Measuring and test instrumentation and tooling calibration procedures and records		*
Liquid penetrant examination procedures		*
Liquid penetrant examination final results	*	
Location diagram	*	
Magnetic particle examination procedure		*
Magnetic particle examination final results	*	
Major defect repair records	*	
Material property reports	*	
Non-conformance/Design concession requests (DCRs)	*	
Packaging receiving storage procedures		*
Performance tests reports	*	
Performance test procedure		*
Manufacturers' instruction manual (MIs)	*	
Pipe and fitting location report	*	
Pressure test procedure		*
Pressure test results	*	
Leak test procedure		*
Leak test results	*	
Product equipment calibration procedure		*
Product equipment calibration records		*
QA audit reports		*
QA manuals procedures and instructions		*
Radiographic procedures		*
Radiographic review forms and radiographs	*	
Ultrasonic examination procedures		*
Ultrasonic examination results	*	
Welding materials control procedures		*
Welding personnel qualification		*

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Welding procedures and procedures qualification		*
Work processing and sequencing documents		*
4. Civil Construction Records		
Aggregate test reports	*	
Coarse aggregate source approval and test reports	*	
Normal fine aggregate (natural sand) source approval and test reports	*	
Heavy aggregate source approval and test reports	*	
Batch plant operation reports		*
Cement grab sample reports		*
Cement source approval and test reports/suppliers test certificate	*	
Water source approval and test reports	*	
Water chemical analysis report		*
Check-off sheets for tendon installation	*	
Concrete mix design report for various grades	*	
Buildingwise compressive strength reports	*	
Field concrete data	*	
Concrete super plasticisers evaluation and test reports	*	
Pre-stressing and grouting records	*	
Inspection reports for channel tests	*	
Critical EPs fabrication and testing reports	*	
Records related to long term structural monitoring	*	
Material property reports on reinforcing steel	*	
Material property reports on reinforcing steel splice sleeve material	*	
Reinforcement welding and splicing test reports	*	
Material property reports on structural steel and bolting	*	
RB consolidation grouting report	*	
Material property reports for pre-stressing cables	*	
Pre-stressing records	*	

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Rock anchor testing reports	*	
Mix water analysis		*
Pour clearance record (Pour cards)	*	
Pile loading test reports	*	
RB proof test / integrity / leak testing procedures and reports	*	
RB V1 / V2 test reports	*	
Construction completion/system transfer certificates	*	
Reinforcing steel splice		*
Operator qualification reports		*
Release to place concrete		*
Reports for periodic tendon inspection	*	
Reports on high strength		*
Bolt torque testing		*
Slump test results		*
Soil foundation investigation reports	*	
User's tensile test reports on reinforcing steel		*
User's tensile test reports on reinforcing steel splices		*
5. RB Paint Materials		
Material property test reports and certificates	*	
Paint application and test reports for RB containment	*	
6. Nuclear Components/Fuel Handling Equipment		
Ferrite test procedures		*
Clearance and surface treatment reports	*	
Assembly procedures	*	
Erection/installation procedures	*	
Heat treatment procedures		*
Heat treatment records	*	
Alignment procedures	*	
Inspection and alignment reports	*	
Liquid penetrant testing procedure		*
Liquid penetrant test final result	*	
Procedure qualification records		*

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Magnetic particle test final results	*	
Major weld repair procedures and results	*	
Non-destructive testing procedure		*
Non-destructive test reports	*	
Weld fit-up reports		*
Weld location diagrams	*	
Welding procedures	*	
Welding inspection records and radiographs	*	
Welding filter metal material reports	*	
Welding material control procedures		*
Test station qualification records	*	
Checklist / record sheet route card	*	
Testing reports	*	
Equipment / components erection and alignment reports	*	
Critical EPs alignment reports (before and after concreting)	*	
Manufacturer's drawings	*	
Testing schemes	*	
RV/PRV calibration reports	*	
System testing reports	*	
Commissioning test reports	*	
7. Piping		
Manufacturer's drawings	*	
Testing scheme	*	
Welding inspection	*	
Alignment reports	*	
Equipment erection reports	*	
Mechanical joint inspection reports	*	
Hanger and support erection reports	*	
Hot/cold setting reports for supports and RVs	*	
Thermal insulation reports	*	
Pre-service inspection procedures		*

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Pre-service inspection reports	*	
Commissioning test reports / results	*	
8. Mechanical-Piping		
Chemical composition for thermal insulation		*
Chemicals tests of water used for mixing insulation cement		*
Cleaning procedures and results		*
Code data reports	*	
Installed lifting and handling equipments inspection and test data	*	
Data sheets or logs on equipment, installation, inspection and alignment		*
Documentation of systems check-off (logs or data sheets)		*
Erection procedures for mechanical components	*	
Hydro-test procedures and results	*	
Installed lifting and handling equipment procedures, inspection and test data	*	
Leak test procedures and results	*	
Lubrication procedures	*	
Lubrication records		*
Material property records	*	
Work orders	*	
Condenser tube rolling / seal welding procedures	*	
Testing procedures		*
Procedures qualification records		*
Check lists / records sheets	*	
Equipment / components	*	
Erection / alignment reports		
Welding inspection reports / radiographs	*	
Mechanical joints inspection report	*	
Testing reports	*	
Commissioning test reports	*	

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Thermal insulation erection reports	*	
Pipe and fitting location reports	*	
Pipe and fitting material property reports	*	
Hanger and support erection / setting reports	*	
Safety valve response test procedures	*	
Safety valve response test results		*
9. Electrical and Instrumentation and Control		
Cable laying and cable sealing procedure		*
Erection checklist		*
Cable splicing procedures	*	
Control cable termination and connection procedure	*	
Test reports	*	
Electrical inspector clearance certificate		*
Field workmanship checklist or equivalent log		*
Instrument testing for calibration reports		*
Relay testing and calibration report	*	
Pre-commissioning checklist for IR value continuity, resistance, earthing etc.		*
Voltage breakdown tests on liquid insulation	*	
Integrated test reports of individual systems (Computer operator information system, digital recording system, programmable digital comparator system, programmable logic controllers etc.)	*	
Commissioning test reports / results	*	
Tube welding procedure and machine qualifications	*	
Tube welding performance record	*	
Inspection reports to erection activities	*	
Helium leak test reports	*	
Pre-commissioning test reports	*	
RB containment cable penetration sealing qualification test report	*	
10. General		
As-built drawings	*	

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Calibration of measuring and test equipment and instruments procedures and reports		*
Certificate of inspection and test personnel qualification		*
Field audit reports		*
Field QA manuals		*
Final inspection reports and release	*	
Non-conformance reports	*	
Special tool calibration records		*
Specification and drawings	*	
Clearance from statutory authorities	*	
Construction completion certificate	*	
11. Pre-operational and start-up test records		
Automatic emergency power source transfer procedures and results	*	
Instrument AC systems inverters test procedures and reports	*	
Main and auxiliary power transformer test procedures and results	*	
Off-site power source energizing procedures	*	
On-site emergency power source energizing procedures and test reports	*	
Plant load ramp change data	*	
Plant load step change data	*	
Power transmission substation test procedure and results	*	
Pre-operational test procedure and results	*	
Primary and secondary auxiliary power test procedure and results	*	
Reactor protection system tests and results	*	
Start-up logs	*	
Start-up problems and resolutions		*
Start-up test procedures and results	*	

ANNEXURE - III (CONTD.)

TYPE OF RECORDS	CATEGORIES	
	Permanent	**Non-Permanent**
Station battery and DC power distribution test procedures and reports	*	
System lubricating oil flushing procedures		*
Water chemistry reports	*	
12. O & M Records		
Control engineer log	*	
Chronological log		
Shift charge engineer log	*	
Significant event reports	*	
Event reports	*	
Root cause analysis reports	*	
Technical bulletins		*
Field change notices	*	
Field change requests		*
Station operation review committee minutes	*	
Station personnel qualification records		*
Plant operating procedures		*
Emergency operating procedures		*
Off-site and on-site emergency procedures		*
Plant flow-sheets and EDs		*
Plant personnel radiation records	*	
Overexposure committee review records	*	
Technical audit reports	*	
QA procedures		*
QA audit reports		*
Station surveillance reports	*	
ISI reports	*	
Equipment maintenance reports / history cards	*	
Spares records		*
Heavy water loss records	*	
Waste disposal records	*	
Environment survey records		*

ANNEXURE - IV

(Section 4.3.4)

A TYPICAL PROCESS FOR ALLOCATING RETENTION TIMES OF RECORDS

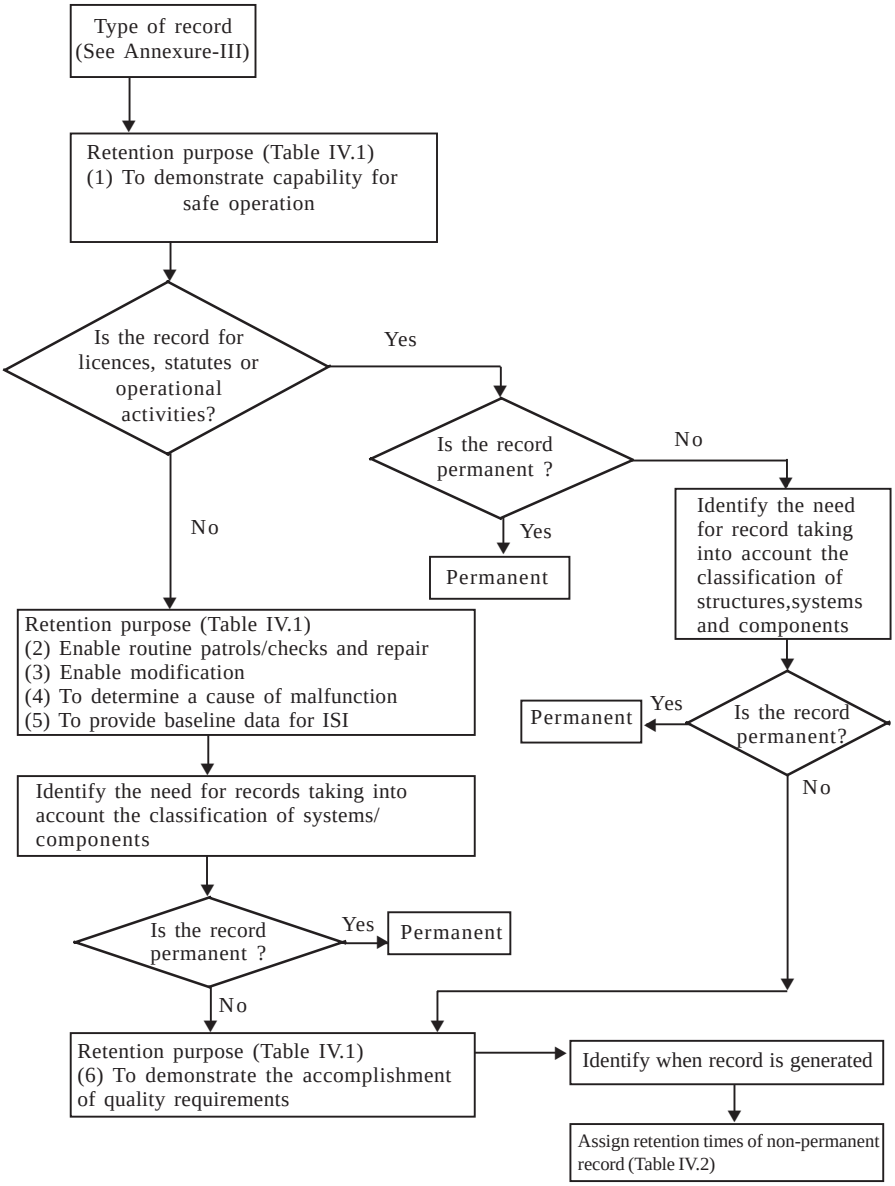

TABLE - IV.1. RETENTION PURPOSE OF QUALITY RECORDS

Retention Purpose	Applicable Records
1. To demonstrate capability for safe operation of nuclear power plant	Necessary quality records at each stage of construction and operation of nuclear power plant for endorsing licences, permits to carry out operation and maintenance when required to report, certify, explain and audit/ review safe operation by requirements such as legal and regulatory.
2. To enable routine patrols/checks periodic inspection and repair of an item	Necessary quality records during operation stage of nuclear power plant, for routine patrols/checks, periodic inspection and repair (including replacement) that maintain safety and stable supplies of electric power and prevent malfunction.
3. To enable modification of an item	Necessary quality record during operation stage of nuclear power plant, for modification which achieve functional improvement of power plant, reflect past experience and preclude recurrence of malfunction.
4. To determine cause of an item's malfunction.	Necessary quality records during operation stage of nuclear power plant, to resolve the cause of a malfunction and actions taken for preventing recurrence.
5. To provide required baseline data for in-service inspections	Necessary quality records during operation stage of nuclear power plant to evaluate degeneration of components.
6. To demonstrate the accomplishment of QA requirements	Additional quality records from those identified above at each stage of construction or operation of nuclear power plant, to prove that the QA activities have been performed as planned and the requirements have been accomplished. These records may support or endorse information contained in reports on the areas covered above.

TABLE IV. 2. RETENTION TIME OF NON-PERMANENT RECORDS

Classification	Retention Time	Remarks
A	Up to start of operation	Up to start of commercial operation (if in operation stage, up to start of operation after completing periodic inspection)
B	Up to completion of first periodic inspection	(1) Completion of first periodic inspection of component. In cases such as turbines for which partial periodic inspection is applied, or those with long intervals for inspection, up to start of operation after completing first major periodic inspection. (2) In operation stages, (1) above is applied at the start of operation after completion of periodic inspection as a starting point.
C	Up to expiry of guarantee	Period guaranteed by contract
D	Up to completion of in-service inspection cycle	Inspection period specified in inspection programme.
E	Up to period specified by law/regulation	
F	Other (specific periods)	(1) Revision: Up to next revision (2) Renewal: Up to next renewal (3) Calibration/check: Up to completion of next calibration/check (4) Audit: Up to next audit (5) Work: Up to completion of next work (6) Others: Periods specified by each organisation

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AERB/SG/QA-1	Quality Assurance in the Design of Nuclear Power Plants	2001
AERB/SG/QA-2	Quality Assurance in the Procurement of Items and Services for Nuclear Power Plants	1998
AERB/SG/QA-3	Quality Assurance in the Manufacture of Items for Nuclear Power Plants	1998
AERB/SG/QA-4	Quality Assurance during Site Construction of Nuclear Power Plants	2001
AERB/SG/QA-5	Quality Assurance during Commissioning and Operation of Nuclear Power Plants	1993
AERB/NPP/SG/ QA-6	Establishing and Implementing a Quality Assurance programme for Nuclear Power Plants	2005
AERB/NPP/SG/ QA-7	Assessment of Implementation of Quality Assurance Programme in Nuclear Power Plants	2005
AERB/NPP/SG/ QA-8	Non-Conformance Control , Corrective and Preventive Actions for Nuclear Power Plants	2006
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