

CODE NO. AERB/NPP/SC/QA (Rev. 1)



GOVERNMENT OF INDIA

CODE NO. AERB/NPP/SC/QA (Rev. 1)

AERB SAFETY CODE

**QUALITY ASSURANCE
IN
NUCLEAR POWER PLANTS**



ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY CODE NO. AERB/NPP/SC/QA (Rev. 1)

**QUALITY ASSURANCE
IN
NUCLEAR POWER PLANTS**

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**Atomic Energy Regulatory Board
Mumbai-400 094
India**

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Order for this code should be addressed to:

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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 and subsequent amendments. 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 (AERB) has been entrusted with the responsibility of laying down safety standards and enforcing rules and regulations for such activities. The Board has, therefore, undertaken a programme of developing safety codes, standards and related guides and manuals for the purpose. While some of the documents cover aspects such as siting, design, construction, operation, quality assurance and decommissioning of nuclear and radiation facilities, other documents cover regulatory aspects of these facilities.

Safety codes and standards are formulated on the basis of internationally accepted safety criteria for design, construction and operation of specific equipment, structures, systems 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. 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.

AERB Safety Code on 'Quality Assurance in Nuclear Power Plants' [AERB/NPP/SC/QA (Rev. 1)] provides basic requirements to be adopted for establishing and implementing quality assurance programme for assuring safety. These basic requirements apply to the QA programme of the responsible organisation as well as any other organisation in each stage of the life of the nuclear power plant such as siting, design, construction, commissioning, operation and decommissioning. In drafting this code, extensive use has been made of the information contained in the relevant documents of IAEA, specially, Code of Safety Series No.50-C/SG-Q titled 'Quality Assurance for Safety in Nuclear Power Plants and Other Nuclear Installations' and Safety Requirements No. GS-R-3, titled 'The Management Systems for Facilities and Activities'. This code is a revision of the 1988 edition of Code of Practice on Quality Assurance for Safety in Nuclear Power Plant (AERB Code No. SC/QA). This revision is issued to reflect developments that have taken place since then.

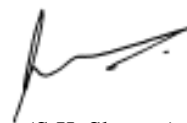
Footnotes and bibliography are included to provide information that might be helpful to the user. Approaches for implementation different to those set out in guides may be acceptable, if they provide comparable assurance against undue risk to the health and safety of the occupational workers and the general public, and protection of the environment.

For aspects not covered in this safety code, applicable national and international standards, codes and guides, acceptable to AERB, should be followed. Non-radiological aspects, such as industrial safety and environmental protection, are not explicitly considered in this code. 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 code applies only for nuclear power plants built after the issue of the document. However, during periodic safety review, a review for applicability of the current code for existing facilities would be performed.

This code has been revised in-house by officers of Atomic Energy Regulatory Board. 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

Acceptance Criteria

The standard or acceptable value against which the value of a functional or condition indicator is used to assess the ability of a system, structure or component to perform its design function or compliance with stipulated requirements.

Accident

An unplanned event resulting in (or having the potential to result in) personal injury or damage to equipment which may or may not cause release of unacceptable quantities of radioactive material or toxic/hazardous chemicals.

Accident Conditions

Substantial deviations from operational states, which could lead to release of unacceptable quantities of radioactive materials. They are more severe than anticipated operational occurrences and include design basis accidents as well as beyond design basis accidents.

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.

Certification (of Personnel)

The formal process of certifying personnel by an authority for performing the various activities in nuclear and radiation facilities.

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.

Component

The smallest part of a system necessary and sufficient to consider for system analysis.

Consent

A written permission issued to the ‘consentee’ by the regulatory body to perform specified activities related to nuclear and radiation facilities. The types of consents are ‘licence’, ‘authorisation’, ‘registration’ and ‘approval’, and will apply according to the category of the facility, the particular activity and radiation source involved.

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).

Criteria

Principles or standards on which a decision or judgement can be based. They may be quantitative or qualitative.

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.

Design

The process and results of developing the concept, detailed plans, supporting calculations and specifications for a nuclear or radiation facility.

Disposition

An act to determine how a departure from a specified requirement is to be handled or settled.

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 prescribed activity is performed.

Emergency

A situation which endangers or is likely to endanger safety of the site personnel, the nuclear/radiation facility or the public and the environment.

Emergency Exercise

A test of an emergency plan with particular emphasis on coordination of the many inter-phasing components of the emergency response, procedures and emergency personnel/agencies. An exercise starts with a simulated/postulated event or series of events in the plant in which an unplanned release of radioactive material is postulated.

Grading

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

In-service Inspection (ISI)

Inspection of structures, systems and components carried out at stipulated intervals during the service life of the plant.

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.

Items Important to Safety (IIS)

The items which comprise :

- those structures, systems, equipment and components whose malfunction or failure could lead to undue radiological consequences at plant site or off-site;
- those structures, systems, equipment and components which prevent anticipated operational occurrences from leading to accident conditions;
- those features which are provided to mitigate the consequences of malfunction or failure of structures, systems, equipment or components.

Maintenance

Organised activities covering all preventive and remedial measures, both administrative and technical, to ensure that all structures, systems and components are capable of performing as intended for safe operation of the plant.

Normal Operation

Operation of a plant or equipment within specified operational limits and conditions. In case of a nuclear power plant, this includes start-up, power operation, shutting down, shutdown state, maintenance, testing and refuelling.

Nuclear Facility

All nuclear fuel cycle and associated installations encompassing the activities from the front end to the back end of nuclear fuel cycle processes and also the associated industrial facilities such as heavy water plants, beryllium extraction plants, zirconium plants, etc.

Nuclear Power Plant (NPP)

A nuclear reactor or a group of reactors together with all the associated structures, systems, equipment and components necessary for safe generation of electricity.

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.

Nuclear Security

All preventive measures taken to minimise the residual risk of unauthorised transfer of nuclear material and/or sabotage, which could lead to release of radioactivity and/or adverse impact on the safety of the plant, plant personnel, public and environment.

Operating Personnel

Members of the site personnel who are involved in operation of the nuclear/radiation facility.

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.

Operational Limits and Conditions (OLCs)

Limits on plant parameters and a set of rules on the functional capability and the performance level of equipment and personnel, approved by the regulatory body, for

safe operation of the nuclear/radiation facility (see also ‘Technical Specifications for Operation’).

Plant Management

Members of the site personnel who have been delegated responsibility and authority by the operating organisation for directing the operation of the plant.

Preventive Maintenance

Maintenance carried out at predetermined intervals or according to prescribed criteria and to reduce the probability of failure or the degradation of the functioning of an entity.

Process

Set of interrelated or interacting activities which transform inputs into outputs.

Qualified Person

An individual who, by virtue of certification by appropriate authorities and through experience, is duly recognised as having expertise in a relevant field of specialisation like quality assurance, radiation protection, plant operation, fire safety or any relevant engineering or safety speciality.

Quality

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

Quality Assurance

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

Quality Control

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.

Regulatory Body

(See ‘Atomic Energy Regulatory Board’).

Regulatory Consent

(See ‘Consent’).

Reliability

The probability that a structure, system, component or facility will perform its intended (specified) function satisfactorily for a specified period under specified conditions.

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').

Safety Culture

The assembly of characteristics and attitudes in organisations and individuals which establishes that as an overriding priority, the protection and safety issues receive the attention warranted by their significance.

Safety System

System important to safety and provided to assure that under anticipated operational occurrences and accident conditions, the safe shutdown of the reactor followed by heat removal from the core and containment of any radioactivity, is satisfactorily achieved. (Examples of such systems are shutdown systems, emergency core cooling system and containment isolation system.)

Services

The performance by a supplier of activities such as design, fabrication, installation, inspection, non-destructive examination, repair and/or maintenance.

Site

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

Site Personnel

All persons working at the site, either permanently or temporarily.

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 process, indicating the procedure by means of which it may be determined whether the specified requirements are satisfied.

Structure

The assembly of elements which supports/houses the plants, equipment and systems.

Surveillance

All planned activities, viz. monitoring, verifying, checking including in-service inspection, functional testing, calibration and performance testing carried out to ensure compliance with specifications established in a facility.

Technical Specifications for Operation

A document approved by the regulatory body, covering the operational limits and conditions, surveillance and administrative control requirements for safe operation of the nuclear or radiation facility. It is also called as “operational limits and conditions”.

Test

An experiment carried out in order to measure, quantify or classify a characteristic or a property of an entity.

Testing

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.

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1. INTRODUCTION

1.1 General

This safety code forms a part of Atomic Energy Regulatory Board's programme for establishing codes, guides and standards for assuring safety in nuclear power plants (NPPs) in India. It provides the basic requirements to be adopted for establishing and implementing quality assurance (QA) programmes related to the safety of nuclear power plants. These basic requirements apply to the overall QA programme of the responsible organisation (RO) as well as to any other QA programmes in each stage of the nuclear power plant.

This safety code on 'Quality Assurance in Nuclear Power Plants' supersedes the earlier version (AERB Code No. SC/QA, 1988). This revised code reflects the later developments that have taken place in various areas.

Planned and systematic actions are necessary to provide assurance that item, service or process will perform satisfactorily. For this purpose, comprehensive planning, implementation and assessment appropriate to the task(s) are necessary to assure requisite quality. Hence, establishment and implementation of a QA programme during all stages of a nuclear power plant is essential for assuring safety of the nuclear power plant, site personnel and public.

Through the revised code and related safety guides on QA, it is emphasised that, the managers, those performing the work and those assessing the work, all contribute in ensuring quality and achieving safety. The code recognises that all processes can be planned, performed, assessed and improved.

The RO has to demonstrate the effectiveness of the QA programme to the satisfaction of AERB. The main objective is to facilitate, support and ensure safety in all stages of NPP namely, siting, design, construction, commissioning, operation and decommissioning.

Guidance on fulfillment of the requirements of this code may be found in appropriate safety guides/manuals.

1.2 Objective

The objective of this code is to establish basic requirements for QA in order to enhance nuclear safety by continually improving the methods employed to achieve quality.

1.3 Scope

This code provides the basic requirements for establishment, implementation and continual improvement of QA programme for all stages (siting, design, construction, commissioning, operation and decommissioning) of the nuclear

power plant. The basic requirements apply to the RO and other organisations including designers, suppliers, constructors, manufacturers and operators. The basic requirements laid down in this code can be applied to other nuclear facilities with appropriate modifications.

Security aspects are not covered in this document.

2. MANAGEMENT

2.1 Quality Assurance Programme

RO shall establish, implement, assess and continually improve the QA programme. The QA programme shall include the organisational structure, functional responsibilities, levels of authority and interfaces for those managing, performing, assessing and improving the adequacy of process. The QA programme shall address management process, including planning, scheduling, resource considerations, environmental and security aspects.

If the RO delegates the work of establishing and implementing all or part of an overall programme to other organisations, it shall retain responsibility for the effectiveness of the programme.

The QA programme shall demonstrate the integration of the following three principles:

- (a) Managers providing planning, direction, resources and support to achieve the organisation's objectives
- (b) Staff performing the work to achieve quality
- (c) Staff performing assessments to evaluate effectiveness of management process and work performance.

The QA programme shall be binding on all individuals in the organisation.

RO shall prepare a QA document describing overall QA programme in sufficient detail to demonstrate that the programme is consistent with the requirements of this code. The QA document shall be prepared in a timely manner to enable its application with adequate consideration given to items important to safety. The document shall also outline the special requirements necessary to effectively manage the processes carried out in multiple organisational arrangements such as contractors, sub-contractors and functional units within an organisation.

The QA document shall include the following:

- (a) The policy statements of the organisation
- (b) A description of the QA programme
- (c) A description of the structure of the organisation
- (d) A description of the functional responsibilities, accountabilities, levels of authority and interactions of those managing, performing and assessing work
- (e) A description of the processes and supporting information that explain

how work is to be prepared, reviewed, carried out, recorded, assessed and improved

- (f) Need for identification and control of compliance to applicable codes, standards, specification and practices.

The QA document shall reflect:

- (a) the characteristics of the organisation and its activities, and
- (b) the complexities of processes and their interactions.

2.2 Organisation, Responsibility and Authority

Organisational plan shall be documented showing

- (a) organisational structure,
- (b) functional responsibility,
- (c) levels of authority, and
- (d) lines of internal and external communication.

Functional responsibilities shall be clearly defined distinguishing task performance from task verification and shall be delineated in writing.

Senior management¹ shall establish goals, strategies, plans and objectives of the organisation in an integrated manner so that their collective impact on safety is understood and managed. Senior management shall ensure that measurable objectives to implement the goals, strategies and plans are established through appropriate processes at various levels within the organisation.

Senior management shall ensure that the implementation of the plans is regularly checked.

Senior management in the organisation shall be ultimately responsible for the QA programme and shall ensure that it is established, implemented, assessed and continually improved.

An individual responsible for monitoring overall effectiveness of QA programme shall be identified. He shall have sufficient organisational freedom and authority to implement the programme. He shall report to a management level sufficiently high to assure that considerations such as cost and schedule do not override QA requirements. He shall have specific responsibility and authority for:

¹ 'Senior management' means the person who, or group of people which, directs, controls and assesses an organisation at the highest level. Different terms are used, for example, chief executive officer (CEO), director general, executive team, plant manager, top manager, vice-president, managing director, station director, director and CMD.

- (a) coordinating the development and implementation of the QA programme, and its assessment and continual improvement;
- (b) reporting on the performance of the management system, including its influence on safety and safety culture, and any need for improvement; and
- (c) resolving any potential conflicts between requirements and within the processes of the QA programme.

The RO shall retain the overall responsibility for the QA programme when an external organisation is involved in the work of developing all or part of the QA programme.

2.3 Resource² Management

2.3.1 Provision of Resources

Senior management shall determine and provide the resources necessary to carry out the activities of the organisation and to establish, implement, assess and continually improve the QA programme. The information and knowledge of the organisation shall be managed as a resource.

2.3.2 Human Resources

Senior management shall determine the competence requirements for individuals at all levels and shall provide training or take other actions to achieve the required level of competence. An evaluation of the effectiveness of the actions taken shall be conducted. Suitable proficiency shall be achieved and maintained.

Senior management shall ensure that individuals are competent to perform their assigned work and that they understand the safety consequences of their activities. Individuals shall have received appropriate education and training, and shall have acquired suitable skills, knowledge and experience to ensure their competence. Training shall ensure that individuals are aware of the relevance and importance of their activities and of how their activities contribute to safety in the achievement of the organisation's objectives.

2.3.3 Training, Qualification and Certification

Plans shall be developed and implemented for timely selection and training of personnel to perform activities affecting quality. All personnel performing activities affecting quality of items shall be trained and qualified on the basis of general education, experience and proficiency required for performing the

² 'Resource' includes individuals, infrastructure, the working environment, information and knowledge and suppliers, as well as material and financial resources

assigned work and they understand the consequences of their activities on safety.

Where required by codes, standards, specifications or other special requirements, personnel performing activities affecting quality (e.g. non destructive examination personnel, welders and key operating personnel) shall be certified as per applicable codes, standards, etc. The certificate shall be valid for a stipulated period and where necessary be conditional on similar work being performed to maintain proficiency. Recertification shall be required before the individual is assigned the task after expiry of the stipulated period.

2.3.4 Infrastructure and Work Environment

Senior management shall determine, provide, maintain and re-evaluate the infrastructure and work environment necessary for work to be carried out in a safe manner and for requirements to be met.

2.4 Safety Culture

The management shall promote and support a strong safety culture by:

- (a) ensuring a common understanding of the key aspects of the safety culture within the organisation;
- (b) providing the means by which the organisation supports individuals and teams to carry out their tasks safely and successfully, taking into account the interactions between individuals, technology and organisations;
- (c) reinforcing a learning and questioning attitude at all levels of the organisation; and
- (d) providing the means by which organisation continually seeks to develop and improve its safety culture.

2.5 Grading

Nuclear Safety shall be the fundamental consideration in the identification of items, services and process to which QA programme applies. Whilst the QA principles remain the same, the extent to which QA requirements are to be applied shall be consistent with the importance to nuclear safety of the item, service, or process. A graded approach, which can satisfy the necessary requirements and ensure the required quality and safety, shall be used. The graded approach shall reflect a planned and recognised difference in the application of specific QA requirements.

Considerations for the graded approach shall include following but not limited to:

- (a) the consequences of malfunction or failure of the items,

- (b) the design and fabrication complexity or uniqueness of the items,
- (c) the need for special controls and verification over processes and equipment,
- (d) the degree to which functional compliance can be demonstrated by inspection or test,
- (e) quality history and degree of standardisation of the items, and
- (f) the difficulty of repair or replacement.

2.6 Management Commitment

The RO shall issue a written policy statement committing the organisation to implement and maintain the QA programme. The policies shall be appropriate to the activities and facilities of the organisation. The policy statement shall clearly reflect the commitment of senior management to the attainment and continuous improvement of quality. The statement shall be binding on all levels of management.

Management at all levels shall demonstrate its commitment to the establishment, implementation, assessment and continual improvement of QA programme and shall allocate adequate resources to carry out these activities.

Senior Management shall develop individual values, institutional values and behavioural expectations for the organisation to support the implementation of the QA programme and shall act as role models in the visible promulgation of these values and expectations.

Management at all levels shall communicate to individuals the need to adhere to these individual values, institutional values and behavioural expectations as well as to comply with the requirements of the QA programme.

Management at all levels shall foster the involvement of all individuals in the implementation and continual improvement of the QA programme. Senior Management shall ensure that it is clear when, how and by whom decisions are to be made within the programme.

2.7 Communication

Information relevant to safety, health, environment, security, quality and economic goals shall be communicated to individuals within the organisation and where necessary, to other interested parties.

Internal communication shall take place between the various levels and functions of the organisation regarding the implementation and effectiveness of the QA programme.

2.8 Managing Organisational Change

Organisational changes shall be evaluated and classified according to their importance to safety and each change shall be justified.

The implementation of such changes shall be planned, controlled, communicated, monitored, tracked and recorded to ensure that the safety is not compromised.

2.9 Satisfaction of Interested Parties³

The expectations of the interested parties shall be considered by senior management in the activities and interactions in the processes of organisation, with the aim of enhancing satisfaction of interested parties, while at the same time ensuring that safety is not compromised.

2.10 Configuration Management

Management shall have arrangement for configuration management⁴.

³ Interested parties, Concerned parties, Stakeholders are individuals or groups having an interest in the performance of an organisation. They typically include customers, owners, operators, employees, suppliers, partners, trade unions, the regulated industry or professionals, scientific bodies, governmental agencies or regulators (local, regional and national) whose responsibilities may include nuclear energy, the media, the public (individuals, community groups and interest groups) and other states, especially neighboring states that have entered into agreements providing for an exchange of information concerning possible cross boundary impacts or States involved in the export of certain technologies or materials or energy.

⁴ The process of identifying and documenting the characteristics of a facility's structures, systems and components (including computer systems and software), and of ensuring that changes to these characteristics are properly developed, assessed, approved, issued, implemented, verified, recorded and incorporated into the facility documentation. 'Configuration' is used in the sense of the physical, functional and operational characteristics of the structures, systems and components and parts of a facility.

3. PROCESS IMPLEMENTATION

3.1 Developing Process

Work is a process that can be planned, performed, assessed and improved. All processes that are needed to achieve the goals of the organisation shall be identified and their development planned, implemented, assessed and continually improved.

The sequence and interaction of the processes shall be determined.

The methods necessary to ensure the effectiveness of both implementation and control of the processes shall be determined and implemented.

The development of each process shall ensure that the following are achieved:

- (a) Process requirements, such as applicable regulatory, statutory, legal, safety, health, environmental, security and quality requirements are identified and addressed.
- (b) Hazards and risks are identified, together with any necessary mitigating actions.
- (c) Interactions with interfacing processes are identified.
- (d) Process inputs are identified.
- (e) The process flow is described.
- (f) Process outputs (products) are identified.
- (g) Process measurement criteria are established.

The activities of, and interfaces between, different individuals or groups involved in the process shall be planned, controlled and managed in a manner that ensures effective communication and clear assignment of responsibilities.

3.2 Process Management

An organisation has to manage many processes in various stages of the plant, viz., siting, design, construction, commissioning, operation and decommissioning. Some of these could be generic, i.e. common to all stages, and some, specific to a stage.

Each process shall have a designated individual who has the authority and responsibility for:

- (a) developing and documenting the process and maintaining necessary supporting documentation,
- (b) ensuring that there is effective interactions between interfacing processes,

- (c) ensuring that process documentation is coherent with any existing documents,
- (d) ensuring that the records required to demonstrate that the process results have been achieved are specified within the process documentation,
- (e) monitoring and reporting on the performance of the process,
- (f) promoting improvements in the process, and
- (g) ensuring that the process, and any subsequent change to it, is aligned with the goals, strategies, plans and objectives of the organisation.

For each process, any activities for inspection, testing, verification and validation; their acceptance criteria, and the responsibilities for carrying out these activities, shall be specified. For each process, it shall be specified, if and when these activities are to be performed by designated individuals or groups, other than those who originally performed the work.

Each process shall be evaluated to ensure that it remains effective. The work performed in each process shall be carried out under controlled conditions, by using approved current procedures, instructions, drawings or other appropriate means that are periodically reviewed to ensure their adequacy and effectiveness. Results shall be compared with expected values.

The control of processes contracted to external organisations shall be identified. The organisation shall retain overall responsibility when contracting any process.

3.2.1 Generic Processes

3.2.1.1 Control of Document and Records

A document control system shall be established and provide for the preparation, review, approval⁵, issuance, distribution, revision, validation and storage (for task and processes, where appropriate) of documents essential to management, performance, assessment and review.

Documents shall be controlled. All individuals involved in preparing, revising, reviewing or approving documents shall be specifically assigned this work, shall be competent to carry it out and shall be given access to appropriate information on which to base their input or decisions. It shall be ensured that document users are aware of and use appropriate and correct documents.

Changes to documents shall be reviewed and recorded and shall be subject to the same level of approval as the documents themselves.

⁵ Approval: Formal consent to a proposal.

Records shall be specified in the process documentation and shall be controlled. All records shall be readable, complete, identifiable and easily retrievable.

Retention times of records and associated test materials and specimens shall be established to be consistent with the statutory requirements and knowledge management obligations of the organisation. The media used for records shall be such as to ensure that the records are readable for the duration of the retention times specified for each record.

3.2.1.2 Control of Products⁶

Specifications and requirements for products and any subsequent changes shall be in accordance with established standards and shall incorporate applicable requirements. Product specifications interfaces shall be identified and controlled.

The organisation shall confirm that products meet the expected requirements and ensure that products perform satisfactory in service.

Products shall be provided in a form such that it can be verified that they satisfy requirements. Control shall be used to ensure products do not bypass required verification activities.

Products shall be identified to ensure their proper use. Where traceability is a requirement, the organisation shall control and record unique identification of the product.

Products shall be handled, transported, stored, maintained and used as specified, in order to prevent their damage, loss, deterioration or inadvertent use.

3.2.1.3 Procurement

Procured items and services shall meet established requirements and perform as specified. Suppliers shall be evaluated and selected on the basis of specified criteria.

Requirements necessary to ensure the quality of items and services shall be developed and specified in the procurement documents. Evidence that purchased items and services meet procurement requirements shall be available before they are used.

Requirements for reporting deviations from procurement requirements shall be specified in the procurement documents.

⁶ A product is the result or output of a process.

Procedures shall be established for control of non-conformance and initiating and implementing corrective and preventive actions.

3.2.1.4 Manufacturing

The manufacturing organisation shall establish documented procedures for its functions which apart from manufacturing include designing, purchasing, sub-contracting, handling, shipping, storing, cleaning, inspections, testing, etc., as applicable.

The management of the manufacturing organisation shall ensure the effective implementation of its QA programme acceptable to purchaser. The persons within the manufacturing organisation responsible for verification of the implementation of the QA programme shall be independent of manufacturing functions.

Persons performing work affecting quality shall be suitably qualified. Where formal qualifications and certifications are mandatory, the requirements shall be specified and complied with.

Manufacturing process shall be controlled by measures such as use of approved procedures and work instructions, tests and inspections, process and equipment qualifications, and calibration and control of measuring and test equipment.

Procedures shall be established for control of non-conformance and initiating and implementing corrective and preventive actions.

3.2.1.5 Inspection and Testing for Acceptance

Inspection and testing of specified items, services and processes shall be conducted using established acceptance and performance criteria. The level of inspection and testing and the degree of independence of personnel shall be established.

Administrative controls, such as hold points and status indicators, shall be used to preclude the bypassing of required inspections and tests. Any inadvertent use, installation or operation of items, services and processes, which have not passed the required inspections and tests, shall be prevented.

3.2.1.6 Calibration and Control of Measuring and Test Equipment

Measures shall be established to ensure that tools, gauges, instruments and other inspection, measuring and test equipment and other devices used in determining the conformance to acceptance criteria, shall be of the proper range, type, accuracy, sensitivity and precision.

Testing and measuring devices shall be controlled, calibrated and adjusted at specified intervals or before use, to maintain accuracy within prescribed limits.

When deviations beyond prescribed limits are detected, an evaluation shall be made of the validity of previous measurements and tests and acceptance of tested items shall be reassessed. Controls shall be established to assure proper handling, storage and use of calibrated instruments. Retention period for any reference standard, which may be required for later inspections, shall be specified.

3.2.2 Stage Specific Processes

3.2.2.1 Siting

A QA programme shall be established and implemented to ensure that studies, evaluations and analyses and all siting activities important to safety, are correctly performed and provide a consistent basis for making decisions. Procedures for controlling siting activities shall be defined. These procedures shall be prepared and controlled. Interface arrangements shall be established between the RO, organisation responsible for siting, AERB and other concerned organisations.

3.2.2.2 Design

Control measures shall be established and documented to ensure the following:

- (a) Applicable design inputs such as regulatory requirements, design basis, codes and standards and specifications are identified and approved after review.
- (b) Design inputs are translated correctly into design output documents such as drawings and specifications.
- (c) As appropriate, design documents identify the codes, standards and specifications used in the design, design calculations and acceptance criteria.

Procedures shall be established for generation, review, approval, issue and retrieval of design documents.

Procedures shall be established to control design inputs, interfaces, flow of design information and changes to original design.

Design control measures shall provide for verifying the adequacy of design, such as by performance of design reviews, by use of alternative calculation methods, or by performance of a testing programme using appropriate models and test conditions. The extent of verification shall be commensurate with the importance of the item to safety. The adequacy of design, including design tools and design inputs and outputs shall be verified or validated by individuals or groups other than those who originally performed the design.

Verification, validation and approval shall be completed before implementation

of the design. Verification methods to be applied shall be identified by the organisation responsible for design and design verification results shall be documented to the extent specified.

All changes to design shall be subject to the same controls as the original design.

3.2.2.3 Site Construction

QA programme shall be established for all construction activities of the NPP such as receiving and storing components, civil construction, erection, installation, cleaning, flushing, inspection, testing, modification, repair and maintenance. Provisions shall be made for verification, review and assessment of activities affecting quality of construction. Procedures shall take into account technical requirements and any special administrative controls.

Site construction activities shall be planned and documented in adequate detail and approved by designated persons. Planning shall among other, take the following aspects into account:

- (a) the sequence of activities, when applicable,
- (b) the need for the use of special procedures for implementation, verification and acceptance,
- (c) the need for special equipment for construction, inspection and testing, and
- (d) the need for training and qualification of personnel.

Preservation of items; in stores or installed, shall be carried out in accordance with manufacturers' recommendations and good engineering practice.

3.2.2.4 Commissioning

RO is responsible to ensure that appropriate tests shall be performed during commissioning to demonstrate that design intent and regulatory and other statutory requirements are met. Satisfactory demonstrations of functional capability of items important to safety are a prerequisite for considering the NPP to be suitable for the operating phase. Measures shall be established to ensure that all commissioning activities including modification, replacement and repair of items important to safety are planned, controlled and implemented in accordance with approved documents such as procedures, instructions and checklists and results documented.

Commissioning activities shall commence only after due completion of respective construction activities supported by certified documents.

Inspection and surveillance shall be performed and documented to verify compliance with specification requirements.

Configuration of equipment or system for maintenance and modification during commissioning and their return to service shall be controlled.

Operational limits and conditions as relevant to the stage of commissioning and requirements for emergency preparedness shall be met.

Measures shall be established to identify, report, review, dispose, control and document field changes as well as non-conformance.

3.2.2.5 Operation

On transfer of system from commissioning group, the operation group shall satisfy that the system complies with specified performance, functional adequacy, design intent and safety requirements and shall formally accept responsibility for the systems.

QA programme shall be established for safe operation of the NPP in accordance with the design intent and operational limits and conditions as prescribed in technical specifications for operation of the NPP. Activities affecting safety in NPP operation shall be prescribed by written procedures or instructions. Provisions shall exist for regular verification of operational activities related to safety.

Measures shall be established to identify emergency situations and to develop and implement emergency preparedness plans and procedures for coping with emergencies. The release of equipment or systems for maintenance and modifications and their return to service shall be controlled. Inspection and testing during normal operations as well as subsequent to maintenance, modification or procedural changes shall be performed to specified requirements.

Arrangements shall be established to identify, report, review, dispose, control and document items and situations that do not conform to specified requirements.

3.2.2.6 Decommissioning

Decommissioning shall be carried out as per approved QA programme. Measures shall be established for decommissioning of NPP in a safe manner. The programme shall cover all activities including surveillance that are required to ensure safety after decommissioning has been completed. Compliance with procedures shall be verified and recorded.

4. MEASUREMENT, ASSESSMENT, REVIEW AND IMPROVEMENT

4.1 Monitoring and Measurement

The QA programme effectiveness shall be monitored and measured to confirm the ability of the processes to achieve planned results and to identify improvement opportunities.

4.2 Management Self Assessment

Management at all levels shall regularly assess the processes for which it is responsible. Management shall determine its effectiveness in establishing, promoting and achieving objectives of nuclear safety. QA programme weakness and barriers that hinder the achievement of the objective of nuclear safety shall be identified and corrected.

4.3 Independent Assessment⁷

Independent assessments shall be conducted on behalf of senior management to measure the effectiveness of QA programme and the adequacy of work performance to monitor item and service quality and to promote improvement. Independent assessments consist of audits, reviews, checks and other methods.

An organisational unit shall be established, or an outside agency assigned, with the responsibility to conduct independent assessments. It shall have sufficient authority and organisational freedom to carry out its responsibilities.

Persons conducting independent assessment shall not participate directly in the work being assessed. The results of the independent assessments shall be considered by the management and where necessary actions shall be taken to implement improvements.

4.4 Review

Review of QA programme shall be conducted at planned intervals to ensure the continuing suitability and effectiveness of the QA programme and its ability to enable the accomplishment of the objectives set for the organisation.

The review shall include :

⁷ Assessments such as audits or surveillances are carried out to determine the extent to which the requirements for the QA programme are fulfilled, to evaluate the effectiveness of the QA programme and to identify opportunities for improvement. They can be conducted by or on behalf of the organisation itself for internal purposes, by interested parties such as customers and regulators (or by other persons on their behalf), or by external independent organisations.

- (a) outputs from all forms of assessment,
- (b) results delivered and objectives achieved by the organisation and its processes,
- (c) non-conformances and corrective and preventive actions,
- (d) lessons learned from other organisations, and
- (e) improvement opportunities.

Weaknesses and obstacles shall be identified, evaluated and remedied in a timely manner.

The review shall identify if there is a need to make changes or improvements to policies, strategies, plans, goals, objectives and processes.

4.5 Non-conformances and Corrective and Preventive Actions

The causes of non-conformances shall be determined and remedial actions shall be taken to prevent their recurrence.

Products and processes that do not conform to the specified requirements shall be identified, segregated, controlled, recorded and reported to an appropriate level of management within the organisation. The impact of non-conformances shall be evaluated and non conforming products or processes shall be either

- (a) rejected,
- (b) repaired,
- (c) reworked,
- (d) accepted with modifications, or
- (e) accepted as is.

Concessions granted to allow acceptance of a non-conforming product or process shall be subject to authorisation. When non-conforming products or processes are reworked or corrected, they shall be subject to inspection to demonstrate their conformity with requirements or expected results.

Corrective actions for eliminating non-conformances shall be determined and implemented. Preventive actions to eliminate the causes of potential non conformances shall be determined and taken.

The status and effectiveness of all corrective and preventive actions shall be monitored and reported to management at an appropriate level in the organisation.

Potential non-conformances that could detract from the organisation's performance shall be identified. This shall be done :

- (a) by using feedback from other organisations, both internal and external,
- (b) through the use of technical advances and research,
- (c) through the sharing of knowledge and experience, and
- (d) through the use of techniques that identify best practices.

4.6 Improvement

Opportunities for improvement of the QA programme shall be identified and actions to improve all the processes shall be selected, planned and recorded.

Improvement plans shall include plans for the provision of adequate resources. Actions for improvement shall be monitored through to their completion and effectiveness of the improvement shall be checked.

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