

GUIDE NO. AERB/NPP/SG/QA-6



GOVERNMENT OF INDIA

GUIDE NO. AERB/NPP/SG/QA-6

AERB SAFETY GUIDE

**ESTABLISHING AND IMPLEMENTING
QUALITY ASSURANCE PROGRAMME
FOR NUCLEAR POWER PLANTS**



ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/NPP/SG/QA-6

**ESTABLISHING AND IMPLEMENTING
QUALITY ASSURANCE PROGRAMME
FOR NUCLEAR POWER PLANTS**

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

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Price

Orders for this guide 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. 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, codes of practice 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.

Codes of practice and safety 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.

The Code of Practice on 'Quality Assurance for Safety in Nuclear Power Plants, AERB Code No. SC/QA' provides the management principles and objectives to be met during the implementation of activities in different phases of a nuclear power plant 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 guide recommends the methodology for the establishment and implementation of the quality assurance programme. In drafting it, extensive use has been made of the information contained in the relevant documents of the International Atomic Energy Agency issued under its Nuclear Safety Standards Programme.

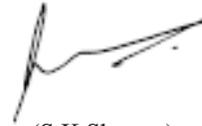
Consistent with the accepted practice, 'shall', 'should' and 'may' are used in the guide to distinguish between a firm requirement, a recommendation and a desirable option, respectively. Appendices are an integral part of the document, whereas annexures, footnotes, bibliography and list of participants are included to provide information 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 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, 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.

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.

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.

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

- 1.1.1 This safety guide is part of the AERB's set of Code and Guides for assurance of safety in Nuclear Power Plants. It gives recommendations related to the fulfilment of basic requirements given in the Code on Quality Assurance for Safety in Nuclear Power Plants (AERB Code No. SC/QA, 1988), 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 safety guides may be acceptable provided they result in at least the same level of nuclear safety.
- 1.1.3 This safety guide should be used by the responsible organisation as well as by other organisations participating in the nuclear power plant.
- 1.1.4 The quality assurance (QA) programme provides a systematic and disciplined approach to achieve correct work performance with an aim to prevent problems. Should problems occur, they are detected and corrected, improvements are made and corrective actions taken to prevent recurrence.
- 1.1.5 Participant organisations should implement QA programmes to the extent of requirements specified by the responsible organisation.
- 1.1.6 The extent to which a QA programme is applied shall be determined by a graded approach, with nuclear safety as the fundamental consideration.

1.2 Objective

The objective of the safety guide is to recommend acceptable ways to establish and implement a QA programme that is in accordance with the Code and the details contained in other relevant safety guides.

1.3 Scope

This safety guide is applicable to the establishment and implementation of a QA programme by the responsible organisation as well as other separate programmes at all stages of a nuclear power plant. It covers items, services and processes important to nuclear safety. It may, with appropriate modifications, also be usefully applied to items, services and processes at nuclear installations other than nuclear power plants.

2. ESTABLISHING THE QUALITY ASSURANCE PROGRAMME

2.1 General

- 2.1.1 The responsible organisation shall establish QA programmes as an integral part of the management system. Other organisations involved in the nuclear power plant shall establish their QA programmes as an integral part of their management system.
- 2.1.2 The person at the highest level of management within the organisation is responsible for establishing the QA programme which shall be binding on all its constituent units and personnel.
- 2.1.3 To establish a QA programme, an organisation should:
- (a) Provide necessary resources, including trained and qualified manpower.
 - (b) Identify the activities that have to be carried out.
 - (c) Review the organisation's management and technical practices with respect to applicable regulations and standards to determine whether the work activities are adequately addressed.
 - (d) Review the organisation's practices with respect to the QA code and other relevant AERB safety codes and guides to identify shortcomings and assign priorities to those areas requiring improvement or development.
 - (e) Establish time-scales within which the required changes should be implemented.
 - (f) Prepare necessary documents for defining implementation of QA programme.
- 2.1.4 The responsible organisation shall develop QA programmes for all stages of nuclear power plant (siting, design, construction, commissioning, operation and decommissioning) at a time consistent with the schedule for accomplishing stage-related activities. The responsible organisation should submit QA programme description documents of its own and various constituent organisations managing all the stages of nuclear power plant to the regulatory body for review.
- 2.1.5 Guidance on details to be addressed in the QA programmes for the different stages of the nuclear power plant are given in the various QA safety guides (list is annexed).

- 2.1.6 Management of the organisation shall express, in issued statements of policy, their commitment to quality, safety and implementation of the QA programme. This will facilitate the effective implementation of the programme. The quality policy should be reviewed periodically to ensure that it accurately reflects current organisational objectives and priorities.
- 2.1.7 Management should demonstrate its commitment to the quality policy through its actions and provide firm and unambiguous support for its implementation. The actions should foster a corresponding commitment to high levels of performance by all personnel, who in turn should be expected to demonstrate their commitment to the policy. Annexure-1 provides an example of the key points of the quality policy. Generally it is envisaged that the quality policy statement is brief and concise for better impact. A visible demonstration of this commitment would be by way of displaying the quality policy statement at prominent locations and bringing awareness among all levels of personnel to the quality policy.
- 2.2 Grading¹**
- 2.2.1 Whilst the QA principles remain the same, the extent to which the 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.
- 2.2.2 In general the highest grade should require the most stringent application of the QA requirements; and as appropriate for other grades. Grading should be applied in areas such as,
- Qualification of process
 - Type and content of training
 - Amount of detail and degree of review and approval of instructions
 - Need for and detail of inspection plans
 - Degree of in-process reviews and controls
 - Requirements for material traceability
 - Type of assessment
 - Records to be generated and retained
 - Requirement of Certification of Personnel
- 2.2.3 When items, processes or services are modified, the original grade of QA requirements may be appropriately modified depending upon the change in nuclear safety significance.

¹ For more information on Grading, see IAEA Technical Reports Series No.328.

3. DOCUMENTATION OF THE QUALITY ASSURANCE PROGRAMME

3.1 Strategy

- 3.1.1 The documentation of the QA programme consists of the QA programme description (QA Manual), the management documents and detailed working documents necessary to ensure that work is properly performed.
- 3.1.2 Documentation of the QA programme should be structured so that it is appropriate to the organisation and the work it performs, and is readily understood by users. Its structure and format should also be flexible enough to accommodate changes in policy, strategic aims, quality standards, regulatory requirements and other statutes, as well as feedback from implementation and lessons learnt from other plants and facilities.
- 3.1.3 The QA programme should adopt a vocabulary that is coherent, clear, unambiguous and readily understandable. As such, it is necessary that each document is written in a manner appropriate to the level of expertise of the persons using it and in a user-friendly manner that reflects the normal ways of working.
- 3.1.4 The content of documents should be determined with the participation of people who will use them to do their work, and other people who are affected by them. Such individuals should also provide an input into subsequent revisions. In the case of detailed working documents, trial use and validation using mock-ups, simulators and walk-through, or pre-production runs and testing are some of the ways of determining proper preparation of the documents.
- 3.1.5 The QA programme should take into account the guidance provided in the corresponding AERB safety guides and should also recognise that:
- time scales for implementing the stage related QA programmes overlap significantly;
 - there are significant transfers of responsibility and of hardware and software between the organisations responsible for the consecutive stage (Annexure II provides guidance on interface arrangements);
 - the planning and development of any stage QA programmes commences during the previous stages of a plant, for example design review requires consideration of inspectability, constructability, operability, maintainability and ALARA requirements before finalisation of the design. To do this effectively, the advice of

construction and operating organisations should be sought early in the design stage.

- 3.1.6 The requirements and needs of the QA programme for a particular stage should be considered during earlier stages so that they are fully established prior to the commencement of the stage. For example, establishing the QA programme for operations includes: providing transfer documents from commissioning to operation, providing fully documented detailed working documents; having a trained and qualified workforce; and ensuring that workshops, facilities, tools and suitable working environments are in place.

3.2 Documentation Structure

A three-level system of documentation is recommended to promote clarity and to avoid repetition by establishing the amount of information and detail contained in each type of document and by using cross-references between specific documents at the different levels. What follows is the description of a typical three-level system, shown in the Appendix-I, which consists of:

- (a) QA programme description
- (b) Management documents
- (c) Detailed working documents.

3.2.1 Quality Assurance Programme Description

- 3.2.1.1 The QA programme description defines the programme established to meet the basic requirements of the Code. The QA programme description shall address those requirements of the Code that apply to the organisation's work.

- 3.2.1.2 The QA programme description should be management's primary means of communicating to personnel its expectations and strategy for success and methods for achieving them.

3.2.1.3. The following should be included in the QA programme description:

- Management's quality policy statement
- The mission and objective of the organisation
- The organisational structure
- Outline of the management procedures
- The level of authority and the responsibilities of persons and organisational units involved in the work
- The lines of internal and external communications and interface arrangements
- Requirements for training, facilities and working environment

- Requirements for the development of detailed working documents for the performance and assessment of work
 - The arrangements for establishing a graded approach to nuclear safety
 - The agency to facilitate and monitor implementation of the QA programme
 - The arrangements for measuring effectiveness and management self-assessment of the QA programme
- 3.2.1.4 The person at the highest level of management in the organisation shall approve the QA programme description and shall ensure that controlled copies are distributed to appropriate personnel for implementation. He shall also ensure its effective implementation.
- 3.2.2 Management Documents
- 3.2.2.1 Management documents identify the required controls to implement the policies and objectives presented in the QA programme by providing specific performance methodology. These documents should:
- (a) Detail the functions, authority and responsibilities of units and individuals within the organisation. For individuals this should be in the form of job descriptions/assignments and for units in the form of departmental (i.e. station manuals, project manual) manuals.
 - (b) Define the responsibilities and lines of communication internal and external to the organisation in each area of activity, for example management procedures and interface arrangements.
 - (c) Specify which activities are to be carried out and controlled, and who is responsible and accountable and, where appropriate, refer to detailed working documents.
 - (d) Identify and plan activities to ensure work is dealt with in a systematic and expeditious manner.
- 3.2.2.2 Management procedures are used to define the processes which are identified in the QA programme description and which usually involve more than one organisational unit. Such procedures describe what is to be done to manage a specific process by identifying inputs, key activities, necessary resources, outputs, records and associated responsibilities and are used as inputs to the development of interface arrangements and job descriptions (see Annexures II, III). Management procedure should also cover sequence and interaction of the processes, criteria and method needed to ensure that both the operation and control of the processes are effective. To avoid unnecessary detail, cross-reference should be made to working instructions. Annexure IV describes a typical format for management procedures.

3.2.3 Detailed Working Documents

- 3.2.3.1 Detailed working documents consist of a wide range of documents developed by the line organisations to prescribe the specific details for the performance of tasks by individuals, or functional groups or teams. In an operational nuclear power plant, they include work instructions and technical instructions. They typically cover components and systems operation, and their maintenance and tests, modifications, calibrations, radiation protection and chemistry activities.
- 3.2.3.2 The type and format of working documents can vary considerably depending on the application involved. Annexure V describes an example of the format of a instruction.
- 3.2.3.3 Irrespective of the format the primary consideration should be to ensure that the documents are suitable for use by the appropriate personnel and that the contents are clear, concise and unambiguous.

4. IMPLEMENTING THE QUALITY ASSURANCE PROGRAMME

4.1 General

The person at the highest level of management in the organisation shall be responsible for ensuring that the QA programme is implemented. Implementing the QA programme requires the collaborative effort of management, those performing the work and those assessing the work. Towards this, a person of sufficiently senior level with the sole responsibility for managing the implementation of the QA programme should be identified and should be of such seniority and experience, which will enable him to interact directly and effectively with heads of the participating units. Satisfactory implementation requires good planning and deployment of adequate resources. All participants should be trained to achieve proficiency and to ensure they understand the management processes, which apply to the performance of their work.

4.2 Planning

- 4.2.1 Management should prepare a plan to achieve full implementation of the QA programme. The implementation plan should be approved and monitored by the appropriate management level.
- 4.2.2 Staffing plans should include provisions for selecting, training and assigning adequate numbers of personnel consistent with schedules for implementation and work loading. Consideration should be given to the need for special skills and training.
- 4.2.3 Work plans, schedules, instructions, technical instructions and drawings etc. which are needed to define the specific actions to perform work should be developed and used in accordance with the management processes described in the QA programme description. Their preparation should be planned and scheduled, so that performance personnel have clear instructions on how to correctly perform and sequence the work.
- 4.2.4 Plans for assessing the effectiveness of instructions, their implementation relative to the performance of work as well as the results achieved with respect to quality and safety should be specified. The implementation of such plans should commence as soon as possible. Frequent early assessments may be necessary to ensure the adequacy of instructions and to prevent the endorsement of poor practices. Plan should provide for, wherever required, intervention of verifying agencies at review point, witness point and hold points.
- 4.2.5 Plans should also provide for any regulatory body interaction in the implementation of QA programme to meet regulatory requirements.

4.3 Training

- 4.3.1 The organisation's overall objectives regarding quality, safety of members of public and occupation workers as well as protection of environment and their direct relation to the quality policy and the QA programme shall be explained in the initial and continuing training of all personnel including contractor's personnel, who are managing, performing and assessing work.
- 4.3.2 The success of the QA programme in bringing about continuous quality improvement depends on universal acceptance within the organisation. Senior managers, line managers, supervisors, designers, engineers, technicians, craftsmen and supporting staff should be informed about the importance of their roles.
- 4.3.3 The correct completion of work should be emphasised, focusing on 'doing it right the first time' and on the safety consequences of improper, inadequate or incorrect work.
- 4.3.4 Training in the application of work instructions or major instruction revisions should be given by the department responsible for the work to those who have to apply the procedure to do the work. This is an opportunity for management to explain the importance of adherence to instructions. Feedback on their application should be sought and revisions made to correct identified difficulties.
- 4.3.5 The importance of stimulating professional development should be recognised. Training shall provide for the progressive improvement of personnel, and should not be limited to initial job qualification and proficiency.
- 4.3.6 Organisation should evaluate the effectiveness of training imparted.

4.4 Implementation

- 4.4.1 Management should implement the Quality Assurance Programme at the beginning of the project. Following tasks have to be performed by the management.
- Formulation of policy and objectives of the overall programme.
 - Preparation of QA Programme Description Document.
 - Assignment of responsibility and authority for establishing and implementing QA activities.
 - Defining management procedures describing interaction of the participating organisation.
 - Establishing the graded approach of QA programme on items and service based on their safety significance.

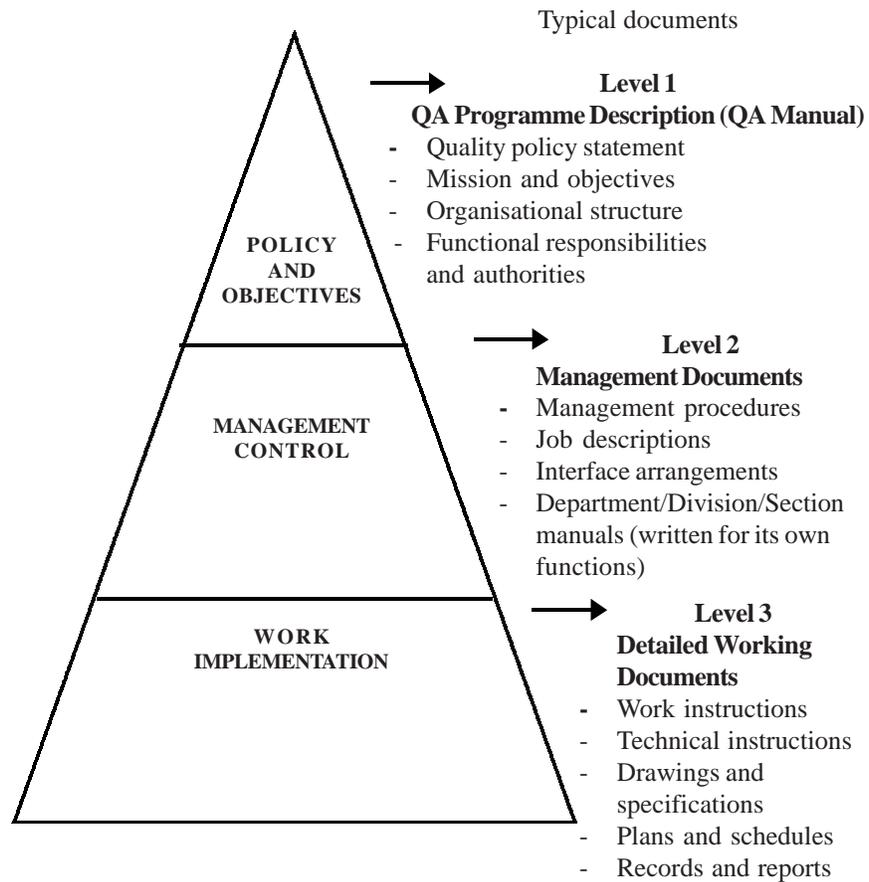
- 4.4.2 Various steps involved in implementation of QA programme are the following:
- Defining requirements for quality and quality assurance.
 - Resource planning, and responsibility assignments.
 - Defining actions to be performed to execute the programme.
 - Establishing management procedures on performance of various programme activities.
 - Planning and scheduling the verification activities for both on going work performance and quality assurance activities.
- 4.4.3 Quality Assurance programmes should be verified by auditing of all facets of the programme as well as by periodic management reviews. The focus for the reviews should as a minimum include following: -
- Status of implementation of quality assurance programme.
 - Results of programme audits.
 - Quality problems and recommendations.
 - Programme deficiencies
 - Status of corrective and preventive actions
 - Quality trends, incidents, failures
 - Adequacy of available resources.
 - Adequacy and further needs of personnel qualification, training, certification and indoctrination.
 - Need for programme revision and improvement.
- 4.4.4 The programme documents shall be controlled as required by the code and relevant safety guide AERB/NPP/SG/QA-9 on ' Document Control and Record Management for QA in Nuclear Power Plants'.

5. ASSESSMENT, ANALYSIS AND IMPROVEMENT

- (i) The effectiveness of the QA programme shall be assessed and reviewed at all stages of implementation. The information gained from assessments should be used to achieve continuous improvements in work performance. The assessment process should provide for analysis of performance. The analysis should consider, for example, failures and breakdowns, rework and frequency, delays, errors, lost time, work backlog trends, non-compliance with requirements and improvements. Use of performance indicators and other appropriate methods should be developed. For further information, refer safety guide on 'Assessment of Implementation of the Quality Assurance Programme for Nuclear Power Plants', AERB/NPP/SG/QA-7.
- (ii) When the assessment identifies the need to change management processes, such changes should be formally proposed, agreed and introduced. It may be necessary to refer recommendations for change to a more senior level of management.
- (iii) Target dates for the implementation and completion of improvements arising from these assessments should be assigned. Progress should be tracked to completion.

APPENDIX I

DOCUMENTATION STRUCTURE OF THE QUALITY ASSURANCE PROGRAMME



ANNEXURE I

QUALITY POLICY

- (A) The following aspects should be considered in formulating the quality policy:
- (1) Specify the organisation's mission and objectives.
 - (2) Set management's expectations for organisational and individual employee performance.
 - (3) Express management's support of each employee in carrying out his/her assigned work.
 - (4) Promote an attitude of continuous improvement.
 - (5) Create an environment that promotes quality and the improvement of quality throughout the entire organisation.
 - (6) Ensure employees have the necessary responsibility and authority to carry out their work as it has the greatest effect on item, service and process quality.
 - (7) State a commitment that items, services and processes should be of the highest quality, resulting in protection of the health and safety of the workers and the public.
 - (8) Establish management's responsibility for ensuring that employees understand and accept their respective roles and obligations in carrying out the quality policy.
 - (9) Define the key documents which govern the levels of performance, such as:
 - Responsible organisation's policy statements
 - Statutes and regulations
 - QA programme description
 - National/International codes and standards.
- (B) Typical example of Quality Policy of NPCIL is given below:

STATEMENT OF POLICY AND AUTHORITY

Nuclear Power Corporation of India Limited (NPCIL) is committed to generate electricity in a safe and commercially competitive manner adopting nuclear fission process. With this in view, it builds and operates nuclear power plants at various places.

It is the policy of the corporation to adopt quality assurance programme in various phases of the plant(s) such as design, manufacture, construction, commissioning and operation so that safety of the plant(s), plant personnel and public is fully assured and that the plant(s) is (are) operated without any adverse effect on environment, flora and fauna. NPCIL also propagates the environmental benignness and the benefits of nuclear power to the public.

Towards achieving safety and reliability in its nuclear plants the corporation supports R&D, provides necessary facilities and environmental conditions for training and development of its own personnel and assists in development of others connected with the nuclear power programme among other things.

The quality assurance programme of the corporation has been evolved to meet the requirements set forth by the Atomic Energy Regulatory Board and also takes into account the intents of applicable international guidelines. The top management is committed to the quality assurance programme and enforces it in all phases of the plant(s) by creating appropriate organisational structure with requisite delegation of authority. All heads of units have the responsibility to ensure effective application of the quality assurance programme requirements at the project sites, operating nuclear plants and the supporting organisations at the headquarters. Director (QA) and heads of units have the authority to stop work in case of quality problems.

The responsibility for ensuring overall effectiveness of quality assurance programme has been entrusted to Director (QA) and who reports to the Chairman & Managing Director.

All concerned in the corporation are required to follow quality assurance programme enumerated in the topical quality assurance document.

Mumbai
23.12.97

Sd/-
(Y.S.R. Prasad)
Chairman & Managing Director

ANNEXURE II

INTERFACE ARRANGEMENTS

There needs to be a clear understanding of the division of responsibilities between all organisational units participating in a QA programme. These include centralised corporate, and technical departments providing support to architect/engineering firms, company safety committees and public services providing support.

Consistent methods of defining relative responsibilities and lines of communication should be implemented whenever two or more significant organisational units contribute to an activity that affects quality.

Interface agreements, sometimes referred to as 'memoranda of understanding', or equivalent documents should be developed to satisfy these needs. An interface agreement is a formal agreement, which defines the interface. Its acceptance by the senior managers of the interfacing organisations is obtained in writing. It should be distributed to all participants.

In the preparation of these interface documents the following points should be addressed:

- (a) The participating units should be identified and included on the circulation/control list.
- (b) The prime responsibilities and authority for the activity should be clear.
- (c) Responsibilities for review and comment, resolution of technical issues, implementation, reporting, verification and audit, and where appropriate, maintaining latest status of document should be defined.
- (d) Key positions within each unit to act as focal points for communication should be identified.
- (e) The contents of the formal documents required to implement the procedure or convey technical information across the interface (typically programmes, plans, specifications, procedures, instructions, drawings and records) should be defined.
- (f) The flow of documents among the organisational interfaces and time-scales for requisite action by the interfacing units/groups should be prescribed.

ANNEXURE III

JOB DESCRIPTIONS

The Code requires that QA programmes describe the organisational structure, functional responsibilities, levels of authority and interfaces for those managing, performing and assessing the adequacy of work. At the individual employee level, one of the primary ways this information communicated is through a job description.

Job descriptions should be developed for different categories and/or types of work. They should define the total scope of an employee's job. Job descriptions can be used effectively to establish baselines for identifying training needs. While job descriptions are usually only mandated down to supervisory levels, descriptions are an excellent way for management to communicate responsibilities, authority and interfaces to all employees.

A typical job description should contain the following information:

- (1) Job title
- (2) Purpose of job
- (3) Organisation
 - Organisational structure for that post - Position in the organisation
 - Lines of reporting
- (4) Duties
 - Key tasks and responsibilities - Authority
 - Accountability
- (5) Qualifications
 - Knowledge and expertise - Education
 - Training
 - Experience
 - Medical fitness

ANNEXURE IV

MANAGEMENT PROCEDURES

Management procedures sometimes referred to as programmatic or management control procedures provide administrative direction to management personnel. The procedures outline the actions management must take to implement the organisation's management system. Management procedures are not used to provide the details of how technical tasks are to be performed. Technical tasks are addressed in working level documents (see Annexure V). The following provides guidance regarding the content of sections typically contained in a management procedure:

- (1) **Purpose.** What is the objective of the management procedure? State clearly and concisely the specific objectives of the management procedure.
- (2) **Scope.** What management actions are addressed by the management procedure and who is supposed to use it? Define the type of work and situations to which the management procedure applies. State the boundaries of application of the management procedure.
- (3) **Responsibilities.** 'Who in management is primarily responsible for the work defined in the management procedure? Identify the persons by title and define their responsibilities.
- (4) **Definitions.** What words are used in the management procedure that are not commonly understood? Define those words that may cause confusion.
- (5) **References.** Would other documents be of use to managers who use the management procedure? If so, list the specifications, standards or other documents that are referenced in the text and which may possibly provide additional information to users. If documents are referenced in part, state the page and paragraph numbers.
- (6) **Details.** How is the work that is the subject matter of the management procedure conducted? Detail the actions required to accomplish the purpose and scope of the management procedure. Include all information that is critical to planning, scheduling and performing the work outlined in the management procedure. Write the text simply and directly. Approved numbering and nomenclature for job titles and documents should be used. The detail section of a management procedure describes what is to be done by providing the following typical information:
 - Planning and scheduling considerations to ensure work is dealt with systematically and expeditiously

- Administrative and technical information
 - Work steps to be carried out
 - Responsibilities and authorities
 - Interfaces
 - Lines of communication both within and outside the organisation
 - Cross-references between the management procedure and supporting sections of the QA programme description, other management procedures and working level documents.
- (7) **Documents and records.** Which documents and records are necessary to do the work and which ones need to be retained after the work is complete? Identify the documents that provide the applicable policies and work requirements. Identify the records required to show that the tasks required in the management procedure have been accomplished.
- (8) **Appendices (where applicable).** Is additional information required ? If so, provide it.

ANNEXURE V

WORK INSTRUCTIONS

Work instructions are used to describe specific work processes and convey administrative and technical information to personnel performing work. Work instructions include technical instructions and drawings. In an operating nuclear power plant, work instructions include, for example, instructions for equipment operations, equipment maintenance and testing, calibrations, radiological assurance processes, chemistry control and welding. The following provides guidance regarding the content of sections typically contained in work instructions.

- (1) **Purpose.** Why is the document necessary? Give a clear, concise statement explaining the specific aim(s) of the document and answer the question “why does the document exist?”.
- (2) **Scope.** What is covered by the document? Define the type of work and situations or conditions where the document applies, and delineates the boundaries of the functions, systems and areas treated in the document.

Note: The above two headings (Purpose and Scope) need not be used if the title adequately covers the content.

- (3) **Responsibilities.** Which persons are responsible for the particular activities defined in the document? Define the duties of the persons implementing the document. Identify the persons (by title) and their responsibilities and specify when a required action is needed.
- (4) **Definitions.** Define those words and terms used in the document that might cause confusion and thus require clarification.
- (5) **References.** Give a bibliography of specifications, standards and other documents referenced in the document. If documents are referenced in part, state the page and paragraph numbers. (This can include reference to other work instructions.) Reference documents could include applicable design or other source documents such as vendors’ literature, engineering drawings or plant specifications.
- (6) **Prerequisites.** What independent actions need to be performed and by whom, prior to the use of the procedure or instruction? State any spare parts, special tools or instrumentation which are necessary (scaffolding, services, etc.) and the required state of the plant if relevant, plus any special conditions to be used to simulate normal or abnormal operating conditions.
- (7) **Precautions.** What precautions are necessary to protect equipment, personnel

and the public or to avoid an abnormal or emergency situation? Identify these in the relevant steps of the procedure or instruction or highlight them in a separate section.

- (8) **Limitations.** Are there any limitations on the parameters being controlled? Identify corrective measures to restore them to the normal control limits.
 - (9) **Actions.** Include a step by step description of the function or task to be performed. Give sufficient detail so that a qualified individual can perform the function or task without direct supervision. Wherever possible, a step should consist of one action.
 - (10) **Verification.** Identify any work activity which requires verification or independent verification. Highlight these points at the relevant step in the procedure.
 - (11) **Acceptance criteria.** Include criteria so that satisfactory completion of the task or function, resolution of non conformances can be determined. If tolerances in prescribed limits are allowable, they should be identified together with any requisite actions (reporting, etc.). Identify the method of verification to be used. This can be included within the procedure or on check sheets. Reference documents could be used as a source of acceptance criteria details.
 - (12) **Restoration** (normally used when plant is taken out of normal operation for routine tests). Include step by step requirements for restoring the component or system to the required operational condition following completion of the tasks or function (if relevant to the particular task).
 - (13) **Records/checksheets.** Which documents/forms are used and retained? Check sheets are recommended when complex procedures or instructions are used. Enumerate, by title, the list of reports and documents required to certify or provide that the tasks required in the document have been accomplished and verified and attach examples of the documents/forms., Identify records as permanent or non-permanent in accordance with the criteria defined in safety guide AERB/NPP/SG/QA-9, together with the retention time for non-pertinent records. Mark sample attached forms 'Specimen', record the date and the identification of those performing the work and, where appropriate, the 'as found' condition, corrective action performed and the 'as left' condition.
- Note: The following paragraphs apply to the event based instructions such as emergency procedures or receipt of alarms and should be included in the procedure when appropriate.
- (14) **Symptoms.** Include a list of symptoms such as alarms, operating conditions and probable magnitude of parameter changes to aid the identification of an abnormal situation. Where applicable, identify those parameters, which are not expected to change.

- (15) **Automatic actions.** Identify the probable automatic actions to occur during an abnormal situation.
- (16) **Immediate operator actions.** Specify the immediate operator actions required or confirmation of automatic actions which will stop the degradation of conditions or mitigate their consequences.
- (17) **Subsequent, operator actions.** Include steps that need to be taken to return the plant to normal conditions or that are needed to shut down the plant safely under abnormal or emergency conditions.

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3. INTERNATIONAL ATOMIC ENERGY AGENCY, Safety Guide, Establishing and Implementing a Quality Assurance Programme, Safety Series No. 50-C/SG-Q, Q1 (1996)

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LIST OF SAFETY CODE AND GUIDES ON QUALITY ASSURANCE FOR SAFETY IN NUCLEAR POWER PLANTS

Safety series No.	Title	Year of Publication
AERB/SC/QA	Code of Practice on Quality Assurance for Safety in Nuclear Power Plants	1988
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 Quality Assurance Programme for Nuclear Power Plants	2005
AERB/NPP/SG/QA-7	Assessment of Implementation of the Quality Assurance Programme for Nuclear Power Plants	2005
AERB/NPP/SG/QA-8	Non-Conformance Control, Corrective and Preventive Actions for Nuclear Power Plants	Under Preparation
AERB/NPP/SG/QA-9	Document Control and Record Management for Quality Assurance in Nuclear Power Plants	Under Preparation

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