

AERB SAFETY GUIDENO. AERB/SG/QA-1

**QUALITY ASSURANCE IN THE DESIGN
OF
NUCLEAR POWER PLANTS**

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**This document is subject to review, after a period of one
year from the date of issue, based on the feedback received**

**Atomic Energy Regulatory Board
Mumbai 400 094**

Price:

Orders for this Guide should be addressed to:

**Administrative Officer
Atomic Energy Regulatory Board
Niyamak Bhavan
Anushaktinagar
Mumbai - 400 094.**

FOREWORD

Safety of the public, and occupational workers and the protection of environment should be assured while activities for economic and social progress are pursued. These activities include the establishment and utilisation of nuclear facilities and use of radioactive sources. They have to be carried out in accordance with relevant provisions of the Atomic Energy Act, 1962.

Assuring high safety standards has been of prime importance since the inception of the nuclear power programme in the country. Recognising this aspect, the Government of India constituted the Atomic Energy Regulatory Board (AERB) in November 1983. The Board has been entrusted with the responsibility of laying down safety standards and framing rules and regulations in respect of regulatory and safety functions envisaged under the Atomic Energy Act. Under its programme of developing safety codes and guides, AERB has issued four codes of practice in the area of nuclear safety covering the following topics:

Safety in Nuclear Power Plant Siting

Safety in Nuclear Power Plant Design

Safety in Nuclear Power Plant Operation

Quality Assurance for Safety in Nuclear Power Plants

Safety guides are issued to describe and make available methods of implementing specific parts of the relevant codes of practice, as acceptable to AERB. Methods and solutions other than those set out in the guides may be acceptable if they provide at least comparable assurance that nuclear power plants can be operated without undue risks to the health and safety of the plant personnel, the general public and the environment.

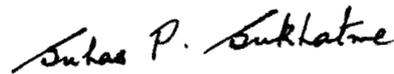
Codes and safety guides may be revised as and when necessary in the light of experience as well as relevant developments in the field. The annexures, footnotes and bibliography are not considered an integral part of the document. These are included to provide information that might be helpful to the user.

The emphasis in the codes and guides is on protection of site personnel and the public from undue radiological hazards. However, for aspects not covered in the

codes and guides, applicable and acceptable national and international codes and standards shall be followed. In particular, Industrial Safety shall be assured through good engineering practices and compliance with the Factories Act, 1948 as amended in 1987 and the Atomic Energy (Factories) Rules, 1996.

This Safety Guide is one of a series of guides which have been issued or are under preparation as a follow-up to the Code on Quality Assurance for Safety in Nuclear Power Plants (AERB/SC/QA). It prescribes guidelines on quality assurance in the design of nuclear power plants in India and is intended for the Design Organisation of nuclear power plants.

This Safety Guide has been prepared by the staff of AERB and other professionals. In drafting the guide, relevant International Atomic Energy Agency (IAEA) documents under the Nuclear Safety Standards (NUSS) programme especially Safety Guide on Quality Assurance in the Design (50-G-Q10, 1996) have been used extensively. It has been reviewed by experts and vetted by AERB Advisory Committees before issue. AERB wishes to thank all individuals and organisations who have contributed in the preparation, review and finalisation of the safety guide. The list of persons who have participated in the committee meetings, along with their affiliations, is included for information.



(Suhas P. Sukhatme)
Chairman, AERB

DEFINITIONS

Checking

As related to design, checking is the detailed technical examination of a document to make certain that it is accurate, and to ensure that all the technical design inputs, design basis and other design criteria have been correctly incorporated.

Design

The process and the results of developing the concept, detailed plans, supporting calculations and specifications for a Nuclear Power Plant.

Design Analysis

All processes which use design inputs and which result in the generation of information necessary for preparation of design output documents such as drawings, specifications and procedures. Design analyses include calculations.

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1. INTRODUCTION

1.1 General

- 1.1.1 This Safety Guide is part of the AERB programme for establishing codes, guides and other standards for assuring safety in NPPs in India. It contains recommendations to fulfill the basic requirements given in AERB Safety Code No. SC/QA, Code of Practice on Quality Assurance for Safety in Nuclear Power Plants (NPPs), hereinafter referred to as the Code.

1.2 Objective

- 1.2.1 This safety guide gives recommendations on how to fulfill the requirements of the Code in relation to the design activity of NPPs.

1.3 Scope

- 1.3.1 This safety guide applies to the quality assurance (QA) programme of the responsible organisation (RO) as well as to any other constituent programme in each phase of NPP and covers items, services and processes impacting nuclear safety. It may also be usefully applied by nuclear facilities other than NPPs.
- 1.3.2 This safety guide relates to the design phase of NPP. The design phase overlaps with other NPP phases such as construction and commissioning. The RO may choose to separate these phases or combine them under one organisation. Whichever organisational arrangement is utilised, the responsibilities and interfaces must be clearly defined and understood and the status of the plant established at all times. This guide is also applicable to design activities in other phases.

2. MANAGEMENT

2.1 Quality Assurance Programme

- 2.1.1 The RO shall develop and implement a QA programme which describes the overall arrangements for management, performance and assessment of the NPP design. This programme shall also provide the means to ensure that all work is suitably planned, correctly performed and properly assessed.
- 2.1.2 The RO shall submit the QA programme manual to the regulatory body for review. Any check or hold points of regulatory intervention should be incorporated in the relevant quality plans if so desired.
- 2.1.3 Procedures should be defined by RO for control of design activities to ensure that the design of NPP fulfils specified requirements. Arrangements should be made to ensure that these procedures are reviewed and approved before issue, and their subsequent amendment controlled. A list of typical examples of design activities which require procedures is outlined in Annexure-I.
- 2.1.4 The RO may delegate and/or require suppliers or other organisational units to develop and implement all or part of the QA programme, but shall retain overall responsibility for the implementation and effectiveness of the programme.
- In such cases, the supplier(s) or other organisational units should prepare QA programme for the work for which they will be responsible and submit them to RO for approval before undertaking work in their areas of responsibility.
- 2.1.5 The QA programme defines the organisation, responsibilities, levels of authority and the internal and external interface arrangements of personnel and organisations involved in design.

2.2 Grading¹

2.2.1 Safety shall be the fundamental consideration in identifying items, services and processes to which the QA programme applies. A graded approach based on relative importance to nuclear safety of each item, service or process shall be used. The graded approach shall also consider the design complexity and already proven design of items. The graded approach shall reflect a planned and recognised difference in the applications of specific QA requirements.

2.2.2 The design activities which could be graded include:

- the level and detail of analysis of design;
- the need for and level of design review and approval;
- the degree of verification of design;
- the controls applied to design change;
- the detail of design records and their retention times;
- the need for alternative calculations to be carried out;
- the need for qualification test for design; and
- the need for validation of design.

2.2.3 In general, the highest grade should require the most stringent application of the QA requirements and the lowest grade the least stringent. The following are examples of typical areas where grading should be applied:

- type and content of training;
- extent of detail and degree of review and approval of instructions;
- degree of in-process reviews and controls;
- type of assessment; and
- records to be generated and retained.

¹ for more information on grading see IAEA Safety Series No. 328

2.3 Design Authority

2.3.1 The RO should identify the design authority which will be responsible for specifying the system requirements and for approving the design output on its behalf. The design authority could also be responsible for the detailed design.

2.3.2 The design authority's responsibilities also include:

- defining the base requirement/specification;
- involvement in design review;
- involvement in design verification;
- approval of detailed design;
- review, verification and approval of design changes;
- control of interfaces;
- reviewing relevant concession/non-conformance applications; and
- review and approval of its QA programme, as well as that of its design contractor.

2.4 Interfaces

2.4.1 Interface arrangements should be agreed between organisations performing design activities. The following interfaces should be addressed:

- interfaces between technical disciplines within an organisation;
- interfaces of design authority with:
 - siting organisation;
 - construction organisation;
 - commissioning organisation;
 - operating organisation;
 - decommissioning agency;
 - regulatory body; and
 - external organisations.

2.4.2 Each organisational unit performing design work shall identify and document all its interfaces for managing the flow of information. Responsibilities shall also be defined and documented to cover the preparation, review, verification, approval, issue, distribution and revision of associated information across the interface. The flow of design information and the mechanism for resolution of any problems should also be defined.

2.4.3 A mechanism should be established for communication and feedback between the design organisation and other organisations involved in other phases of NPP project such as siting, construction, commissioning and operation, to ensure that their requirements are taken into account.

2.5 Training and Qualification

Personnel shall be trained and qualified so that they are competent to perform their assigned work and they understand the safety consequences of their activities.

Training and development for technical personnel should supplement previous training, education and experience to prepare individuals to perform their work.

2.6 Planning

Design planning should take place at the earliest opportunity before beginning the design activities. Plans should define the activities to be performed in manageable units (work breakdown and structure).

2.6.1 Plans used in design should include the following, where appropriate:

- scope of work (to include work carried out by outside organisations);
- resource requirements;
- schedule of activities;
- inputs from other disciplines such as safety, reliability, maintainability, human factors and standardisation;

- software requirements (software to be developed or software codes to be validated for use);
- test requirements (qualification tests, prototype, seismic, etc.);
- design, verification and validation requirements;
- points at which checks and audits of the process will take place and the frequency of such checks and audits;
- interactions with regulatory body for clearances; and
- special training requirements.

2.7 Non-Conformance Control

2.7.1 Management Responsibilities

Management shall establish and maintain a system that provides for identifying, reporting and reviewing non-conformances in design process. Non-conformance can occur in any of these stages like design input, design planning, design process, design verification and QA programme audit. The system should provide for early detection, reporting, reviewing and disposition of non-conformances. Management should assign sufficient resources for this purpose.

Management should ensure that those performing the work are aware of and use the system for prompt notification and reporting of non-conformances. Management at all levels should encourage personnel to discover non-conformances. Management should allocate responsibilities so that handling of non-conformances is monitored from the time they are identified to verified completion of corrective action, including feedback to those personnel who discovered the non-conformance and measures to prevent future occurrence of non-conformances.

2.7.2 Non-Conformance Identification

2.7.2.1 Non-conformances can be in the design process in the form of inadequacies in documentation or non compliance with QA programme such as:

- design assumptions;
- applicable codes and standards;
- design outputs like drawings and specifications;
- results of model testing and validation to specified requirements;
- functional requirements;
- performance requirements; and
- regulatory requirements.

2.7.2.2 Any person who finds non-conformance at any stage of design should be required to notify and formally report the matter to the management.

2.7.2.3 A formal report of non-conformance should, for example, identify name of the person reporting the non-conformance, when it was found, to whom it was reported and the description of the non-conformance.

2.7.3 Review of Non-Conformances

2.7.3.1 Non-conformances should be reviewed as soon as practicable by appropriate designated personnel depending on the QA grade or classification of the item or the process involved. The review should determine the cause of the identified non-conformance, any safety implication of non-conformance and the corrective actions to be agreed and approved to correct non-conformance. The results of review should refer to non-conformance report. During review, additional information about the nature of non-conformance and restrictions to be imposed on further progress of design should be made available to the organisations involved. Information about non-conformance and its implication to safety should then be used to determine the impact on affected activities until the agreed and approved corrective action is verified as having been satisfactorily completed. Typical non-conformance report format is given in Annexure-VI.

2.7.3.2 When programmatic non-conformance is observed in an area, all completed design activities of that area shall be reviewed for similar possible non-conformance.

2.7.3.3 Non-conformance identified in the design process and design outputs which had regulatory approval or clearances shall be informed to the regulatory body along with corrective actions proposed/carried out and restrictions, if any, imposed on subsequent use of the design.

2.8 Corrective Actions

2.8.1 Disposition

If non-conformance in design is due to non-compliance with QA programme, the design output should be subjected to the specified QA procedures and the design accepted if QA requirements are satisfied and the design still meets specified design requirements. If non-conformance in design is due to not adopting an appropriate design process, the design output should be rejected.

Non-conformances may be accepted with conditions if design output is considered fit for use after review under special specified conditions.

2.8.2 Completion of Corrective Actions

Corrective actions should not be considered complete until all affected documents have been amended, modifications implemented and evidence of verification of completion obtained. Management should allocate responsibilities for monitoring non-conformances, from reporting stage to the verified completion of the agreed corrective action including feedback to those personnel who discovered non-conformance.

2.8.3 Preventive Actions

Preventive actions may be implemented to avoid recurrence of non-conformances. Preventions may include:

- feedback to organisations involved;
- special reviews;
- modification of current procedures;
- improvement in QA programme; and
- retraining and requalification of personnel involved.

2.9 Document Control and Records

2.9.1 Procedures for preparation, review, approval, issue, modification, control, security and storage of design documents including non-conformance reports shall be established.

2.9.2 Document Control Centre

In order to exercise proper control on the above activities the design authority and other agencies connected with design activity or those utilising design output documents shall establish a document control centre for dissemination and receipt of all design-related information.

2.9.3 The process for preparation, modification and control of design documents should include:

- (a) drawing office standards;
- (b) standardised symbols;
- (c) identification systems;
- (d) indication of status;
- (e) checking methods;
- (f) requirements for review and approval;
- (g) issuance, distribution and storage; and
- (h) method for controlling revisions, voiding and superceding documents.

2.9.4 Design input documents and changes thereto should be controlled to ensure that current and appropriate documents are available for use by:

- identifying individuals or organisations responsible for preparing, reviewing, verifying, approving and issuing documents and revisions thereto;

- different revisions of documents shall be clearly identified and a master list of an equivalent control programme established to identify such revisions;
- documents should be reissued after substantial changes have been made; and
- establishing procedures for revising, voiding and superceding documents.

3. PERFORMANCE

3.1 Design Process

- 3.1.1 Design activities should be carried out in a logically planned sequence (see Annexure-II) in accordance with prescribed procedures and documented in sufficient detail to permit verification and auditing.
- 3.1.2 Design activities shall be performed in a controlled manner to ensure that specified requirements are correctly translated into design outputs, such as:
- design computer codes/basic plant design;
 - design specifications;
 - functional specifications; and
 - engineering models for design.
- 3.1.3 When computer software is used for analysis and process control, appropriate measures shall be provided for its quality assurance, including verification and validation.
- 3.1.4 Control measures shall, as a minimum, be applied to all design activities important to safety in areas such as:
- radiation protection;
 - fire protection;
 - environmental qualification;
 - physics, stress, thermal, hydraulic, chemical, metallurgical, seismic and accident analysis; and
 - provision for in-service inspection, operation, maintenance and ageing management.

3.2 Design Inputs

- 3.2.1 Design inputs applicable should be identified and documented. These inputs should be subject to review and approval by the design authority.

Any changes to design inputs should be identified, documented, approved by the design authority, and controlled in a timely manner. See Annexure-III for typical design inputs.

Typical inputs should include:

- regulatory requirements;
- codes and standards;
- design basis events, their frequency, duration, combination and limits;
- performance requirements;
- functional requirements;
- standardised common parameters such as plant component life, ambient temperature etc.;
- safety and seismic classification;
- feedback of experience; and
- provision for handling, installation requirements.

3.2.2 Where incomplete, conflicting or unclear information is supplied, clarification should be obtained prior to commencement of design activities.

3.2.3 Design inputs should also consider the practical conditions such as in-service inspection, maintainability and replacement of components/systems.

3.3 Design Analysis

3.3.1 Design analysis should be performed to confirm or clarify the design basis parameters specified.

3.3.2 Analysis should address the general design criteria, as specified in AERB Safety Code, SC/D.

3.3.3 Analysis should be sufficiently detailed and recorded to enable assessment by technical personnel other than those who carried out the analysis.

3.4 Engineering Models for Design

3.4.1 An important element to be considered in the design process should be the use of models (either built to scale or computer-generated images).

3.4.2 These models should be used in design process in various circumstances:

- to enable feasibility of design principles of structures and layout of critical services to be established;
- to provide a physical and visual aid in the control and allocation of space for equipment, pipework, services, separation and segregation of safety-related plant components, protection against internal hazards and access for operation, maintenance and in-service inspection;
- to identify potential problems/interferences and interfaces between buildings and plant components.
- to co-ordinate interfaces between design contractors; and.
- to provide an aid to construction planning, and operator training.

3.4.3 Where models are used, they should be subject to formal methods of change control to ensure that they remain valid representations of the current configuration.

3.5 Design Review

3.5.1 At appropriate stages of design, formal reviews of the design process should be planned, completed and documented. Reviews may range from single person reviews to multi-organisational review. Participants in team reviews should include representatives of all organisation units from the design organisation concerned with the design stage being reviewed, and other specialist personnel as required. The design authority should ensure that in case of single person review, the reviewer was not involved in the design process.

3.5.2 The object of review is to provide assurance that output documents will be correct and will fully address the requirements (e.g. functional, safety, regulatory, industry codes and standards) of the design specification.

- 3.5.3 The scope and extent of review should be determined by the design authority. As part of the review, it should also be established that procedures have been followed, that designated personnel have participated, and that the results are adequately documented and checked prior to release of design documents.
- 3.5.4 The design review should anticipate and identify potential problem areas and inadequacies and initiate corrective actions to ensure that the final design meets the design intent.
- 3.5.5 Design review shall ensure, but not be restricted to the following:
- design information is complete;
 - design inputs are correctly selected and incorporated;
 - assumptions made are adequately described and their basis is known;
 - necessary design input and verification requirements for interfacing disciplines, organisations are specified;
 - appropriate design methodology is used and the designated design standards are followed;
 - design procedures are followed;
 - consistency and system integration in input/output parameters of inter-related systems is ensured;
 - original design requirements are met; and
 - design output is reasonable when compared with design input.

3.6 Design Verification

- 3.6.1 Design verification (often referred to as independent design verification) is the process of reviewing, confirming or substantiating the design to ensure that design requirements have been satisfied. This should include, but not be restricted to:
- design process planning and performance;
 - design input requirements; and
 - design interface controls.

- 3.6.2 Verification activities should be conducted in accordance with documented procedures.
- 3.6.3 Design verification shall be performed and documented by designated competent individuals or groups who were not involved in the original design. These individuals could be from the same organisation and should have access to all relevant information. Identification of checkers, verifiers and management approvals should be clearly indicated in the final design output document.
- 3.6.4 Design verification may be by performance of design reviews, use of alternative calculations, or suitable test programmes. While establishing a graded approach in verification process, the design organisation should consider the importance of the item to safety, the complexity of design, and any similarity with previously proven designs.
- 3.6.5 Alternative Calculations
- (a) Verification of the correctness of calculations or analysis may be achieved by comparing results with those obtained by alternative methods of calculation or analysis,
 - (b) On completion of the alternative calculation, reviews should be performed to confirm the appropriateness of assumptions, design input data, and the computer code or other methods of calculation used,
 - (c) The alternative method need not produce exactly the same result as the original calculation or analysis, but there shall be no unresolved differences which are of significance to safety.
- 3.6.6 Qualification Testing
- (a) In certain circumstances design verification may be achieved by suitable qualification testing of a model or prototype,
 - (b) Where a test programme is used to verify the adequacy of a design feature, it should include suitable testing under the most arduous design conditions for specific design features being verified,

- (c) Where testing cannot be carried out under the most arduous design conditions, testing should be under specified conditions the results of which can be extrapolated to the most arduous conditions, otherwise alternative methods of design verification should be applied,
- (d) Qualification testing should be performed at qualified testing facilities in accordance with documented procedures. These procedures should ensure that reference requirements and acceptance limits are prescribed and that test configuration of the model or prototype is defined,
- (e) Test results should be documented and reviewed by appropriate personnel to ensure that test requirements have been satisfied.

3.7 Design Validation

- 3.7.1 Design validation should be carried out to confirm by examination and provision of objective evidence that the particular requirements for a specific intended use are fulfilled, and that the item conforms to defined requirements.
- 3.7.2 Design validation follows successful design verification and should be performed on the final item under defined operating conditions, such as commissioning or pre-operational testing.
- 3.7.3 In special cases where a new design has been evolved or significant changes made to an earlier design, design validation shall be carried out.

3.8 Design Change Control

- 3.8.1 All design changes, including changes to requirements and those found necessary by construction, testing, commissioning or operational experience, shall be controlled.
- 3.8.2 When design changes are made, the reasons for change should be documented.

- 3.8.3 Consideration should be given to the impact of these changes and their consequences to other design areas.
- 3.8.4 Design changes should be reviewed and approved either:
- by the same groups or organisation responsible for the original design documents; or
 - by other design organisations which have proven competence in the specific design area and have access to original design information; or
 - by the Regulatory Body where appropriate.
- 3.8.5 Information concerning changes should be transmitted to all personnel or organisations, potentially affected by the change.

3.9 Design Documents

- 3.9.1 Design documents to be retained should typically include:
- system descriptions;
 - design specification and amendments;
 - design drawings;
 - design calculations and checking information;
 - safety evaluation;
 - technical analysis, evaluations and reports;
 - design reports;
 - design review reports;
 - design verification and validation information; and
 - approved design change requests/non-conformances.

4. ASSESSMENT

4.1 General

4.1.1 Design activities could be carried out by a single agency or multiple agencies who are a part of the RO or external to RO, under responsibility/ supervision of the RO. Therefore assessment of performance is a significant function of the RO.

4.1.2 Objective of assessment is to confirm that design and QA requirements are met and that design and QA processes are effective, as well as to encourage implementation of improvements.

4.1.3 Assessment activity falls into two broad categories:

- management self assessment; and
- independent assessment.

Both categories are inter-related as shown in Annexure-IV.

4.1.4 RO should define and document the extent to which assessment activities are to be performed depending on the grading and the extent to which responsibilities are delegated.

4.2 Management Self-Assessment

Design organisation should carry out self-assessment as an on going process of various levels of hierarchy of management. A typical example of hierarchy of assessment is shown in Annexure-V.

4.2.1 Typical subjects for assessment of performance by the design organisation may include:

- use of computers and software;
- personal training and qualification;
- design reviews;
- calculation control;
- use of models;

- documentation control, especially design output document;
- self assessment reports and corrective actions; and
- QA programme implementation.

4.2.2 Persons carrying out assessment should be trained in:

- quality assurance principles; and
- methodology of assessment.

4.2.3 Assessment personnel should be selected on the basis of professional expertise attributes such as technical knowledge, competence and experience. It is not necessary that only quality assurance unit personnel carry out assessment.

4.2.4 Line management could rely on the following aspects among others for assessment of performance

- surveillance;
- review of work;
- review of design documents;
- validation; and
- review of procedures.

4.2.4.1 Supervisory assessment would rely on direct observation of work supported by inspection.

4.2.4.2 Senior management self-assessment should focus on meeting strategic goals with special emphasis on safety goals. In performing self-assessments they should provide:

- leadership and involvement;
- for continuous improvement; and
- for process management for higher performance.

4.2.5 Inputs for management self-assessments in the design phase are:

- technical review results;
- adequacy of QA programme;
- effectiveness of management procedure/work instructions;
- peer evaluation feedback;
- surveillance; and
- feedback from experience.

4.3 Independent Assessment

Independent assessment could be carried out by organising:

- internal audits;
- external audits;
- peer review;
- technical review; and
- surveillance.

4.3.1 Internal audits are carried out by independent assessment units on behalf of the management. Internal audit should also be conducted to evaluate opportunities for improvements and enhancing safety standards, in addition to determining compliance with requirements. This should be an on-going process.

4.3.2 Audit is carried out by RO, if design work is carried out by an organisation external to RO.

External audits are organised:

- on appointment of the design organisation;
- if any changes are made in design organisation's QA programme; and
- during performance of design work.

4.3.3 Surveillance is carried out by selective analysis and random check of results of design work and reviews of documentation.

4.3.4 Senior management should arrange for peer evaluation and technical reviews of activities and processes with a view to improving effectiveness of work processes.

The personnel carrying out evaluation should be selected on the basis of expertise in the area of evaluation/review and demonstrably qualified/competent in the area of work being assessed.

4.3.5 Typical subjects to be addressed in independent assessments are outlined in subsection 4.2.1. above.

ANNEXURE-I

TYPICAL EXAMPLES OF DESIGN ACTIVITIES WHICH REQUIRE PROCEDURES

- Calculations,
- Safety analysis,
- Design review,
- Design analysis,
- Design models, their use and review,
- Design change control,
- Design outputs, their format and control,
- Design verification,
- Design validation,
- Design planning,
- Design inputs,
- Design source data control,
- Configuration control,
- Drawing standards, and
- Documentation control.

ANNEXURE-III

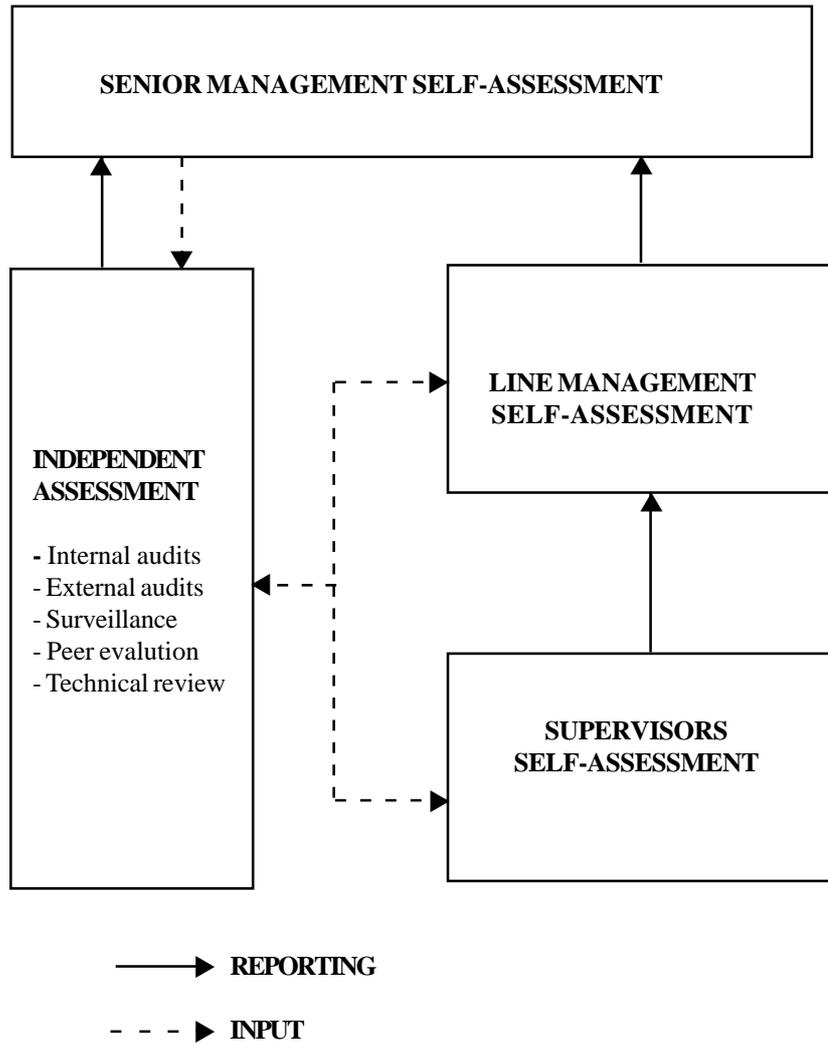
TYPICAL DESIGN INPUTS

1. Basic functional requirements of the structure, system or component.
2. Performance requirements.
3. Applicable codes, standards and regulatory requirements, including the relevant issue, revision or addenda.
4. Design conditions such as neutron flux, other radiations, pressure, temperature, fluid chemistry and voltage.
5. Loads, such as seismic, wind, thermal and dynamic.
6. Environmental conditions/effects.
7. Interface requirements including definition of the functional and physical interfaces involving structures, systems and components.
8. Material requirements.
9. Mechanical requirements.
10. Neutronic requirements.
11. Structural requirements.
12. Hydraulic requirements.
13. Chemistry requirements.
14. Electrical requirements.
15. Layout and arrangement requirements.
16. Operational requirements.
17. Instrumentation and control requirements.
18. Reliability requirements.

19. Test requirements.
20. Maintenance requirements.
21. Handling, storage and shipping requirements.
22. Safety considerations - prevention of injury to personnel.
23. Ergonomics considerations.
24. Fire protection and prevention requirements.
25. Access and requirements for plant security.
26. Other requirements to prevent undue risk to the health and safety of the public.

ANNEXURE-IV

INTERRELATION BETWEEN MANAGEMENT SELF-ASSESSMENT AND INDEPENDENT ASSESSMENT



ANNEXURE-V

EXAMPLE OF A HIERARCHY OF MANAGEMENT SELF-ASSESSMENT

Review

<ul style="list-style-type: none">- Middle management reports- Management self -assessment reports- Summary reports from independent assessment unit- Regulatory feedback- Strategic review- Peer evaluation- Technical review- Plant walkabout	Senior Management
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Surveillance

<ul style="list-style-type: none">- Surveillance of items, services and processes- Review of design documents and validation- Review of procedures and records- Observation of audits- Nuclear power plant tours	Line Management
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Discrete Check

<ul style="list-style-type: none">- Checking- Inspecting- Testing	Supervisors
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ANNEXURE-VI

TYPICAL NON-CONFORMANCE REPORT FORMAT (DESIGN)

NCR NO/DATE:		PLANT/UNIT
SYSTEM/SUB-SYSTEM	SYSTEM/SUB-SYSTEM IDENTIFICATION No.	
DESIGN DOCUMENT REF:		
DETAILS OF NON-CONFORMANCE		
NON-CONFORMANCE REPORTED BY: NAME: SIGNATURE: DATE:	NON-CONFORMANCE ADDRESSED TO: NAME: DESIGNATION:	
DISPOSITION OF NON-CONFORMANCE ACCEPT AS IS/REDESIGN/REVIEW POTENTIAL AREAS WHICH MAY BE AFFECTED BY THIS NON-CONFORMANCE NAME: SIGNATURE: DATE:		
JUSTIFICATION FOR ACCEPTANCE AS IS/CORRECTIVE ACTION PROPOSED		
DEAD LINE FOR IMPLEMENTATION DATE:	NAME: SIGNATURE : DATE :	
CORRECTIVE ACTION TAKEN		
NAME: SIGNATURE : DATE:		
THE ABOVE NON-CONFORMANCE HAS BEEN SATISFACTORILY DEALT WITH		
NAME: CHIEF DESIGN ENGINEER SIGNATURE: DATE:	NAME: CHIEF QA ENGINEER SIGNATURE: DATE:	

BIBLIOGRAPHY

1. AERB Safety Code No. SC/QA, "Code of Practice on Quality Assurance for Safety in Nuclear Power Plants", 1988.
2. BS 5750: Part-1: 1987(ISO 9001-1987) Quality Systems Part-1 "Specification for Design/Development, Production, Installation and Servicing".
3. BS 5750: Part-4: 1981, Quality Systems Part-4 Guide to the use of 5750: Part 1 "Specification for Design, Manufacture and Installation".
4. IAEA Technical Reports Series No. 328; "Grading of Quality Assurance Requirements : A manual", 1991
5. IAEA Safety Guide 50-SG-QA6, "Quality Assurance in the Design of Nuclear Power Plants" (working draft, 21.10.1994)
6. IAEA Safety Guide Q1, "Quality Assurance in Establishing and Implementing a QA programme", 1996
7. IAEA Safety Guide Q5, " Assessment of the Implementation of the Quality Assurance Programme", 1996
8. IAEA Safety Guide Q10, "Quality Assurance in Design", 1996
9. USNRC Regulatory Guide 1.28 Revision 3, August 1985, "Quality Assurance Program Requirements (Design & Construction)"

LIST OF PARTICIPANTS

CONTRIBUTORS TO THE DRAFT

Draft prepared by :

Shri T.K. Shanmugam : Head, EPS, PPCD, IGCAR
Shri M. Venkata Ratnam : SO/Engr.'SD', EPS, PPCD, IGCAR

Draft checked by :

Shri K. Raghavan : Head, PPCD, IGCAR

Draft reviewed by :

: Director, RG, IGCAR
: Division Heads, RG, IGCAR
: Section Heads, RG, IGCAR

LIST OF PARTICIPANTS

ADVISORY COMMITTEE ON CODES AND GUIDES FOR QUALITY ASSURANCE FOR NUCLEAR POWER PLANTS (ACCGQA)

Dates of the meeting : November 27 & 28, 1995
December 18 & 19, 1995
June 30, 1997
November 30, 1997
December 21, 1999.

Members and alternates participating in the meetings:

Shri R.S. Kumar (Chairman) : Director, QA, NPCIL (Formerly)
Shri M. Das : NPCIL
Shri M.S. Ghatge : AFD, BARC (Formerly)
Shri S.P. Singh : AERB (Formerly)
Shri A.K. Asrani
(Member-Secretary till 31-10-99) : AERB (Formerly)

Shri S. Gurunathan : NPCIL
Shri K.K. Abdulla : BARC
Shri S.K. Warriar (Member-Secretary) : AERB
Smt. Usha.A. Menon(Co-opted) : AERB (Formerly)
Shri K.P. Dwivedi (Invitee) : NPCIL

ADVISORY COMMITTEE ON NUCLEAR SAFETY (ACNS)

Date of the meeting : July 22, 2000.

Members and alternates participating in the meeting:

Shri S.K. Mehta(Chairman) : Director, Reactor Group, BARC(Formerly)
Shri S.M.C. Pillai : Nagarjuna Power Corporation Ltd.,
Hyderabad
Prof U.N. Gaitonde : IIT, Bombay
Shri S.K. Goyal : BHEL
Shri Ch. Surendar : NPCIL (Formerly)
Dr. U.C. Mishra : BARC (Formerly)
Shri S.K. Sharma : BARC
Dr. V. Venkat Raj : BARC
Shri S.P. Singh : AERB (Formerly)
Shri G.K. De : AERB (Formerly)
Shri K. Srivasista : AERB
(Member-Secretary)

**PROVISIONAL LIST OF CODE AND GUIDES ON
QUALITY ASSURANCE**

Safety Series Nos.	Provisional 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/SG/QA-6	Assessment of the Implementation of Quality Assurance Programme	Under preparation
AERB/SG/QA-7	Establishing and Implementing a QA Programme	Under preparation
AERB/SG/QA-8	Document Control and Records	Under preparation

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