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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

QUALITY ASSURANCE
IN THE
MANUFACTURE OF ITEMS
FOR
NUCLEAR POWER PLANTS



ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO: AERB/SG/QA - 3

**QUALITY ASSURANCE
IN THE
MANUFACTURE OF ITEMS FOR
NUCLEAR POWER PLANTS**

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Mumbai-400 094**

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Orders for this Guide should be addressed to:

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FOREWARD

Safety of public, occupational worker and the protection of environment should be assured while activities for economic and social progress are pursued. These activities included the establishment and utilisation of nuclear facilities and use of radioactive sources. They have to be carried out in accordance with relevant provision in the Atomic Energy Act 1962 (33 of 1962).

Assuring high safety standards has been of prime importance since the inception of the nuclear power programme in the country. Recognising this aspect Government of India constituted the Atomic Energy Regulatory Board (AERB) in November 1988 vide standing order No. 477 notified in Gazette of India dated 31.12.1983. The Board has been entrusted with the responsibility of laying down safety standards and to frame rules and regulations in respect of regulatory and safety functions envisaged under the Atomic Energy Act of 1962. Under its programme of developing safety code an guides AERB had issued four codes of practice 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 method of implementing specific part 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 risk to the health an safety of general public and plant personnel.

The codes and safety guides may be revised as and when necessary in the light of experience as well as relevant development in the field. The annexures, foot-notes, and references are not to be considered integral part of the document. They are included only to provide information that might be helpful to the user.

The emphasis in the codes and guides is on the protection of site personnel and public from undue radiological hazard. However, for aspects not covered in the codes and guides, applicable and acceptable national and international codes and standards shall be followed. Industrial safety shall be assured through good engineering practices and through compliance with the Factories Act 1948 as amended in 1987 and the Atomic Energy (Factories) Rules, 1996.

The Code of Practice of Quality Assurance for safety in Nuclear Power Plants states the minimum QA requirement to be met during the manufacture of items for land-based thermal neutron reactor power plants in India. This safety guide provides the necessary information to assist managers in the establishment of the QA programme for manufacture of items important to nuclear power plant safety.

This safety guide has been prepared by the staff of AERB and other professionals. In drafting this guide, they have used extensively the relevant International Atomic Energy Agency (IAEA) documents developed under the Nuclear Safety Standards (NUSS) programme, especially the Safety Guide on Quality Assurance in the Manufacture of Items for Nuclear Power Plants (50-SG-QA8).

This safety guide has been reviewed by experts and vetted by the AERB Advisory Committees before issue. AERB wishes to thank all individuals and organisations who reviewed the draft and finalised this safety guide. The list of persons, who have participated in the committee meeting, along with their affiliations, is included for information.

(P. Rama Rao)
Chairman, AERB

DEFINITIONS

The following definitions apply to this Guide and may not necessarily conform to definitions adopted elsewhere for notification for national or international use.

Documentation

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

Examination

A element of inspection consisting of investigation of materials, components, supplies or services, to determine conformance with those specified requirements which can be determined by such investigation.

Inspection

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

Item

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

Non-conformance

A deficiency in characteristics, documentation or procedure which renders the quality of an item unacceptable or indeterminate.

Quality Assurance

Planned and systematic actions necessary to provide adequate confidence that an item or facility will perform satisfactorily in service as per design specifications.

Quality Control

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

Records

Documents which furnish objective evidence of the quality of items and of activities affecting quality. It also includes logging of events and other measurements.

Specification

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

Surveillance

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

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.

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1. INTRODUCTION

1.1 General

1.1.1 The need for establishing and implementing effective quality assurance (QA) Programmes in the manufacture of Nuclear Power Plant items important to safety has been determined in the AERB Code of Practice (AERB/SC/QA) on Quality Assurance for Safety in Nuclear Power Plants (called the Code).

1.1.2 Many manufacturers and a wide range of sizes and complexity of items are involved in the manufacturing phase of Nuclear Power Plant. The depth and extent of the quality assurance programme will vary according to the safety significance of the item.

1.2 Scope

This Safety Guide provides recommendations on how to fulfill the requirements of the Code in relation to the manufacture of items important to safety of nuclear power plants.

This Safety Guide applies to the quality assurance (QA) programmes of the Responsible Organisation (RO) as well as to that of the manufacturing organisations in all stages of a nuclear power plant project and covers items and processes impacting nuclear safety. It may also be usefully applied at nuclear facilities other than NPPs.

1.3 Responsibility

It shall be the responsibility of each organization participating in the manufacture of items important to safety to provide for the establishment and implementation of a quality assurance programme, as specified in procurement documents. Such a programme shall be established at the earliest time consistent with the schedule for accomplishing the activities.

This responsibility should be imposed on the manufacturer through a contractual arrangement. The overall responsibility for the effectiveness of the quality assurance programme remains with the RO without prejudice to the manufacturer's obligations and the legal requirements imposed on the manufacturer.

Methods for ensuring effectiveness of Quality Assurance Programme (QAP) of the manufacturer could be surveillance and audit.

1.4 Grading

Importance to safety should be the fundamental consideration in determining the QA requirement. However in determining the extent of the QA requirements to be applied, a graded approach may be used relevant to the safety significance of each item, service or process.

1.4.1 The most important factor in determining the extent of QA efforts is the effect of the malfunction or failure of an item on safety when put in service. Other factors for consideration include the following:

- a) the complexity or uniqueness of the item;
- b) the degree of standardization of the item;
- c) the need for special controls, administrative measures and surveillance over processes, methods and equipment;
- d) the degree to which compliance with design requirements can be demonstrated by inspection and test;
- e) the quality history (experience with the performance and quality); and
- f) the accessibility of the item, after installation in the plant, for maintenance, in-service inspection & replacement.

A typical graded classification of Quality Assurance Levels is given in Annexure-I.

1.4.2 The aspects in manufacturing phase that could be graded are:

- Qualification of special manufacturing process and/or personnel to carry them out;

- Extent and details of procedures and the degree of their review;
- Degree of in process controls, hold points and sample points;
- Requirements of material traceability;
- Records, their storage, preservation and retrievability; and
- Archive samples.

2. MANAGEMENT FUNCTIONS

2.1 Policy Statement

RO shall ensure that the manufacturing organisation issues written policy statement committing the organisation to implement and maintain the QA programme. The statement shall be binding on all heads of management of the manufacturing organisation including those having the responsibility of meeting objectives such as schedules and costs.

2.2 Programme Responsibility

2.2.1 The manufacturing organisation should be responsible for the following:

- setting up of the QA programme;
- ensuring proper and effective implementation of the QA programme; and
- verifying activity such as by inspection and audit to establish that the work has been performed in accordance with the document and pre-established procedures

2.2.2 Manufacturer's functions may include activities such as designing, purchase, manufacture, inspection, testing, handling, transportation, storage, cleaning, modifying, repair and maintenance. All such activities should be covered by this QA programme.

2.3 Organisation

2.3.1 The manufacturing organisation shall have a proper QA set-up and an organisational plan.

The organisational plan should contain :

1. organisational structure;
2. functional responsibility ;
3. level of authority; and
4. lines of communication.

- 2.3.2** The organisation responsible for the overall QA Programme shall identify the individual by name or by designation.
- 2.3.3** Functional responsibilities shall be clearly defined distinguishing task performance from task verification and shall be delineated in writing. Involvement of both performers and verifiers of the task(s) in achieving quality requires consideration of independent and integrated functions.
- 2.3.4** The persons performing verification functions shall report at a level within the manufacturing organisation that will ensure independent and objective execution of the QA programme.
- 2.3.5** QA personnel shall have sufficient authority and freedom to :
- a) identify quality problems;
 - b) initiate and where feasible, recommend or provide solutions; and
 - c) initiate actions to control further processing, delivery or installation of non-conforming items until proper disposition has been achieved.

2.3.6 Manufacturing Functions

Functions such as purchase, planning, production and production control performed by the manufacturing organisation, shall be identified and their relationship with the quality assurance function defined.

2.4 **Staffing, Training And Certification**

2.4.1 Personnel qualifications

Persons performing the work as well as those inspecting or otherwise verifying that work, including those who audit the quality assurance programme shall be qualified on the basis of general education, experience and proficiency.

The accomplishment and maintenance of proficiency should be documented. The manufacturing organisation should establish a system for periodic review and requalification where necessary.

2.4.2 Personnel training

A programme of training shall be established, maintained and documented to the extent necessary.

This programme should provide for training of personnel in order that they can achieve and maintain proficiency in the tasks involved. In specialised areas, such as stress/structural analysis, welding, heat treatment and non-destructive examination (NDE), trained and qualified people as required should be available. The training should also cover product familiarity, special equipment, familiarization with the requirements and procedures of the QA programme.

Documented evidence of the training and proficiency achieved by the personnel shall be mandatory where certification is required.

2.5 QA Programme

2.5.1 The manufacturing organisation shall prepare, approve and maintain a QA manual, describing the overall QA programme in sufficient detail to demonstrate that the programme is consistent with the requirements of the procurement documents of RO. All such QA programmes shall be approved by RO before any manufacture is commenced.

2.5.2 In case detailed procedures, instructions and drawings are too numerous and bulky, these may be separated from the QA manual and grouped as manual of procedures, instructions and drawings. Wherever felt necessary by the RO, such procedures, instructions and drawing will be approved by RO.

2.6 Programme Reviews

The manufacturing organisation's QA programmes shall be reviewed by RO as and when necessary. However, this review shall be carried out at least once in 3 years.

3. PERFORMANCE FUNCTIONS

3.1 Document Control

3.1.1 The preparation, review, approval, issue and subsequent changes of documents essential for performance and verification of work, such as instructions, procedures, design calculations, drawings and test reports shall be subject to control. The manufacturer shall have a documented system for this control activity.

3.1.2 The control system should identify all individuals or organizations responsible for preparing, reviewing, issuing and revising documents related to activities affecting quality. The system shall ensure that:

- a) Quality plans, procedures and work instructions are reviewed and approved before the start of manufacturing and changes to these documents shall be reviewed and approved by the organizations responsible for the review and approval of the original documents;
- b) Updated documents are distributed and maintained at specified locations; all obsolete documents removed or marked in such a way as to prevent their inadvertent use;
- c) All documents and records are prepared, approved and issued by designated persons; and
- d) The current status of all documents should be listed and should be issued/available to all concerned and a record should be maintained regarding issue of all documents.

3.2 Design Control

Where the scope includes design responsibility, appropriate design control procedures as outlined in the Code shall be implemented.

3.3 Procurement Control

For control of the procurement of items and services required in the course of manufacturing processes, the recommendations contained in the Safety Guide on Quality Assurance in the Procurement of Items and Services for Nuclear Power Plants (AERB/SG/QA-2) will apply. The QA programme shall provide for review of procurement documents for the product to be manufactured to determine the regulations, codes, standards and other requirements that are applicable during manufacture. Regulatory, technical and other requirements set forth in these documents shall be included, as appropriate, in drawings, specifications, quality plans, procedures and work instructions.

3.4 Planning and Control of the Manufacturing Process

3.4.1 Introduction

The product to be manufactured should be clearly defined by drawings and specifications to the extent necessary before the manufacturing plan is commenced.

3.4.2 Pre-planning

During the initial planning phase for product manufacture, consideration shall be given to such factors as:

- a) procurement of long term delivery items;
- b) aspects of manufacturing such as forming, heat treating, partially machining or fabricating sub-assemblies, to be done by suppliers/sub-contractors;
- c) provisions or facilities required for tests and inspections specified by the designers and also those deemed necessary by the manufacturer to control product quality;
- d) provisions or facilities required for clean conditions and other environmental controls to meet requirements and to achieve product quality. These controls may include dust-free or inert atmospheres, humidity controls, temperature controls, special water chemistry;

- e) assembly of the equipment and shipment to the installation site, activities which can adversely affect the quality; and
- f) application of new techniques in manufacturing, inspection and testing.

3.4.3 Process qualification

3.4.3.1 With certain processes used in the manufacture of mechanical and electrical equipments, such as welding, heat treatment, non destructive examination, electrical termination (e.g. crimping, wire wrapping) and impregnation of electrical insulation, the quality of the product requires heavy reliance on the skills of the process operator; the process and operator shall be qualified and records be kept for verification to give confidence in the conformance to the requirements.

3.4.3.2 Where prescribed by applicable codes, standards, specifications, criteria or other special requirements, processes shall be a performed by qualified personnel using qualified procedures and equipment.

3.4.3.3 For processes not covered by available standards, or where the quality requirements exceed the requirements of the existing standards, the necessary qualification of personnel, procedures or equipment shall be defined and demonstrated before the actual work is taken up. RO and the manufacturer should establish a mutually agreeable procedure for qualification.

3.4.3.4 Manufacturing equipment control

Procedures shall be prepared and implemented to verify that manufacturing equipment is maintained as necessary to achieve the required product quality. The frequency and extent of the periodic maintenance applied to the equipment shall be such that its performance characteristics are held within specified limits.

3.4.4 Process control planning

Planning of production operations should ensure that these proceed under controlled conditions in the specified manner and sequence. Controlled conditions include appropriate controls for materials, production equipment, processes and procedures, personnel and associated supplies, utilities and environments.

Production operations should be specified to the necessary extent by documented work instructions.

Process capability studies should be conducted to determine the potential effectiveness of a process.

Verification of the quality status of a product, process, material or environment should be considered at important points in the production sequence to minimize effects of errors and to maximize yields. Control charts and statistical sampling techniques are examples of methods employed to facilitate production/process control.

3.4.5 Quality planning

Measures shall be established and implemented for documenting inspection and test procedures to ensure conformance with requirements.

A desirable method of meeting this requirement is to develop a quality plan for components and products. This plan shall be prepared at the earliest time consistent with the schedule for accomplishing the activities. The quality plan should incorporate, as appropriate, a flow chart or sequential narrative listing of all processes, procedures, work instructions, tests and inspections to be performed in the manufacture and acceptance of components and products. Quality plans shall indicate the manufacturer's, and/or the purchaser's hold points; work shall not proceed beyond this point or points until the required action has been taken and the confirmatory documentation generated and accepted. Such plans should also show witness points, if any, for which advance notification is mandatory.

There are several types of format for a quality plan e.g.

- a) Flow chart indicating inspection activities and their location in the production cycle;
- b) Tabulated schedule indicating requirements for manufacture and inspection activities and quality records; and
- c) Tabulated schedule indicating requirements for manufacture and inspection activities and quality records with provision for noting stage acceptance.

An example of a list of information to be presented in a quality plan is given in Annex. II-A and an example of a quality plan in Annex. II-B.

3.4.6 Procedures and work instructions shall be prepared for activities affecting the quality of a manufactured component or product.

These documents shall be written such that their contents can be understood and properly applied by all relevant personnel, and shall include such controls as shop travelers, welding procedures, heat-treatment procedures, NDE procedures, clean condition and environmental control procedures.

Where special equipment such as tooling, jigs, fixtures or specific inspection tools are required to aid the manufacturing process controls, these shall be properly qualified for use, and their application recognized in the relevant procedures or work instructions.

3.5 Control of Items

3.5.1 Identification and control of materials, parts and Components

3.5.1.1 The manufacturer shall establish and implement a system for controlling identification of materials, parts and components. When such items are subjected to fabrication, processing or assembly operations, they shall be identified and controlled from receipt throughout the manufacturing process either by marking the items or by using related records traceable to the items as required. Particular care should be taken for small items manufactured in large amounts where physical identification is difficult or where assemblies or an operation/activity is sub-contracted.

3.5.1.2 When parts are stored as sub-components or sub-assemblies awaiting final assembly, care shall be taken to maintain identification.

3.5.1.3 Items that deteriorate rapidly with age shall be marked to indicate useful life limits to enable proper control of their induction for use.

3.5.2 Handling, storage and transportation

3.5.2.1 Handling

General procedures shall be established to ensure adequate safeguards in handling of items during receipt, manufacture, assembly and shipping. Where special precautions are required for reasons of, for example, weight, size, cleanliness, extreme temperature conditions or other environmental conditions, detailed procedures shall be established and implemented. All handling procedures shall take into account suppliers' instructions. Handling equipment shall be inspected and tested periodically.

Cartons, containers, hoists, manipulators and transport vehicles, or other protective devices and handling equipment, shall be considered for use where normal handling operations are likely to cause damage. Operators/users of such equipment shall be qualified in their use either by experience or by training.

3.5.2.2 Storage

Procedures shall be prepared as necessary to cover the storage of items throughout the manufacturing processes in order to control the conditions for formal issue, use and return of these items in accordance with quality requirements.

Procedures shall also be prepared, as necessary, to cover the preservation and packaging to be applied before, during and after manufacture, and to cover the inspection during storage of those items subject to deterioration in storage through exposure to air, moisture or other environmental conditions.

3.5.2.3 Transportation

Items being prepared for transportation shall be preserved and packaged adequately to prevent damage or deterioration. Packaging requirements shall cater to the conditions that could affect the item in transit or upon arrival and storage at destination. The manufacturer shall, before transportation, ensure that :

- a) items to be transported have met all specified quality assurance requirements, and the necessary documents such as quality assurance records and shipping clearances are available;
- b) items have been preserved and packaged in accordance with applicable specifications and procedures;
- c) items and packaging have been properly identified as to content;
- d) devices, as specified by the designer, have been provided to record conditions during shipment; and
- e) provisions including instructions for handling and storage during transit and after receipt at destination, and for the installation and use of items at the destination, are available as appropriate and their location is indicated.

An example of control measures for the shipment of items is provided in Annexure-III. (refer also AERB/SG/QA-2)

4. VERIFICATION FUNCTIONS

4.1 Calibration and Control of Measuring and Test Equipment

- 4.1.1** Procedures shall be prepared and implemented for the selection, identification and use of all measuring and test equipment used in determining conformance of the product to the acceptance criteria. These procedures shall include calibration requirements and recalibration frequency.

Calibration shall be in accordance with specified limits of accuracy, and the calibration shall be traceable to well recognized national or international standards. When this is not possible, acceptable technical support for the use of the chosen standard measuring and test equipments shall be provided.

Measures shall be established and implemented for the review and disposition of suspect items when measuring and test equipment used are found to be out of calibration.

- 4.1.2** Control measures shall include provisions for identifying test equipment and for determining calibration status by equipment marking or by records traceable to the equipment, with measures to ensure that only calibrated equipment is used.

4.2 Inspection and Test Control

- 4.2.1** Throughout the manufacturing cycle, inspections and tests shall be performed in accordance with written procedures or work instructions, in sequential order, as set forth in a quality plan.

The procedures or work instructions shall identify, as appropriate, the organization performing inspection and test, the inspection and test pre-requisites, the characteristics to be inspected or tested, the instruments or gauges to be used, the inspection or test sequence, any special environmental conditions required, and the acceptance or rejection criteria to be applied.

Indirect methods of control by monitoring the processing methods, equipment and personnel shall be provided if the inspection of processed items is impossible or if additional monitoring of processes is required. Both inspections and process monitoring shall be provided when controls are inadequate other wise.

4.2.2 The results of inspections and tests shall be recorded on suitable documents such as data sheets and traceable to the individual, who carried out the inspection or test.

4.2.3 Inspection and test results shall be evaluated by designated persons to confirm compliance with inspection or test requirements and acceptance criteria.

4.2.4 The manufacturer shall establish and implement a system whereby markings, travelers, stamps or other means are used to indicate the status of inspections and tests. The system shall ensure that only accepted materials and items are used.

4.2.5 For special examinations like non-destructive examination, the manufacturer shall ensure that only certified personnel carry out, evaluate and approve examination results.

4.3 Audits

4.3.1 Internal Audits

Measures shall be established for planned and documented internal audits to be carried out by the manufacturer to verify compliance with all aspects of the quality assurance programme and to determine the programme effectiveness.

4.3.2 External Audits

The programme of internal audits of manufacturer would be supplemented by periodic external audit by the purchaser and RO to assure continued effectiveness of the QA programme of the manufacturer.

Regulatory audit of the QA Programme may also be carried out by prior arrangement with purchaser/supplier.

4.3.3 Frequency and Timing of Audits

Auditing time and frequency shall be mutually agreed between RO and the manufacturer.

5. CORRECTIVE FUNCTIONS

5.1 Non-Conformance Control

5.1.1 The manufacturer shall establish, implement and maintain procedures for control of materials, parts, components, systems or processes that do not conform to the specified requirements. The procedures shall provide for prompt recording, technical review and final disposition of the non-conforming items. These procedures shall include identification of the non-conforming items (e.g. physical segregation and tagging) to prevent inadvertent use.

5.1.2 A disposition of non-conforming items i.e. accept as is, reject, rework or repair, shall be performed and documented in accordance with written procedures. The responsibility for review and authority for disposition of non-conforming items shall be defined. Non-conforming items involving a deviation from procurement document requirements shall be reported to the purchaser for review and acceptance. These documents should form a part of the final delivery document as a History docket.

5.1.3 The manufacturer's QA system shall provide for recording details of the non-conformance and its disposition. Repaired and reworked items shall be reinspected and retested to the original levels. A typical example of a non-conformance report format is provided in Annexure IV-A, while that of non-conformance of more serious nature involving a design concession, and Design Concession Request (DCR) is provided in Annexure IV-B.

5.1.4 The four terms used for the disposition of a non-conforming item have the following meaning:

Accept : Accept [the item] for its intended purpose when as is : it can be established that the discrepancy will result in no conditions adverse to quality;

Reject : Do not use [the item] for its intended purpose;

Rework : Process [the item] to ensure that it conforms to a prior specified requirement by completion, remachining, reassembling or other corrective means; and

Repair : Process [the item] to restore to a condition such that its capability to function reliably and safety is unimpaired, even though it may yet not conform to the prior specification.

5.2 Corrective Action

5.2.1 The programme shall provide for appropriate corrective action to be taken to ensure that conditions adverse to quality are promptly identified and corrected. For significant conditions adverse to quality, the program shall provide for the cause of such condition to be determined, and corrective action taken to preclude repetition. These corrective actions may be, typically:

- a) Changes in designs, specifications, etc;
- b) Enforcement of the requirements of procedures, work instructions, etc;
- c) Modification of current procedures or issue of new procedure;
- d) Withdrawal of defective equipment for maintenance or calibration;
- e) Retraining and requalification of personnel responsible for conditions adverse to quality; and
- f) Requalification of manufacturing equipments/tools.

- 5.2.2** The identification of the significant conditions adverse to quality, the cause of the conditions and the corrective actions taken shall be documented and reported to appropriate levels of management and to the purchaser. Measures shall include the analysis of accumulated data to determine basic causes of conditions adverse to quality and quality trends.
- 5.2.3** RO, as considered appropriate, shall bring to the notice of AERB for its review any major/significant design concessions/corrective actions on items important to safety.

6. QUALITY ASSURANCE RECORDS

6.1 Measures shall be established for generating, collection, reviewing and filing the manufacturing, inspection and test records and internal audit reports necessary to provide objective evidence of the attainment of the required quality during manufacture and to provide data that may be useful during the lifetime of the item.

6.2 Two categories of records shall be established: Permanent and Non-permanent. Annexure-V indicate examples of types of records and retention categories of safety-related items and activities.

6.2.1 Permanent records

Permanent records shall be maintained by or for the Responsible Organization for at least the life of the particular item while it remains installed in the plant or stored for future use.

The permanent records are those which are of significant value to meet one or more of the following objectives:

- a) To demonstrate capability for safe operation;
- b) To enable maintenance, rework, repair, replacement or modification of an item;
- c) To determine the cause of an abnormal occurrence of an item; and
- d) To provide required baseline data for in-service inspection and for ageing management.

6.2.2 Non-permanent records

Non-permanent records are those not needed to satisfy the requirements for permanent records, but which are necessary to demonstrate the accomplishment of activities in accordance with specified requirements. Period of storage of non-permanent records may also be specified by mutual agreement between purchaser and manufacturer.

ANNEXURE-I

TYPICAL QUALITY ASSURANCE LEVELS

Criteria in selecting QA Levels:

The criteria to be used in establishing the different QA Levels are the function of the item service in terms of safety and operational importance the complexity of manufacturing process and the maturity of the manufacturing technology.

QA Level - I : is selected when,

- (i) The manufactured item is intended for a critical application and inadequate control of the manufacturing processes could lead to a malfunctioning resulting in an undue risk to the health and safety of the operating personnel or the public; or
- (ii) The items or services require a large number of complex processes; or
- (iii) The items have a large number of close tolerances or moving parts; or
- (iv) The manufacturing processes are totally new.

QA Level - II : is used when,

- (i) The manufactured item is intended for a less critical application and inadequate control of the manufacturing process could lead to a malfunction resulting in undue risk to the health and safety of the operating personnel or the public; or
- (ii) The items or services require a few complex processes or
- (iii) The items have a few number of close tolerances or moving parts or
- (iv) The manufacturing processes are relatively new.

QA Level – III : is selected when

- (i) The application is non critical and there is no risk to the health and safety of the operating personnel or the public, should a failure or malfunction occur; or

- (ii) The items or services require only a few simple processes; or
- (iii) The items or services have few close tolerances and moving parts; or
- (iv) The technology is proven.

QA Level IV :

Applied to items of proven design or manufacture where the commercial implication of failure are negligible.

GRADING OF QA REQUIREMENTS

For each of the QA Levels mentioned above and in each area, the QA requirements are graded as under:

- Grade 1 : Requires that the defined QA requirements be implemented in full. It is the most stringent grade;
- Grade 2 : For the same QA requirements, Grade 2 is less stringent than grade 1; and
- Grade 3 : For the same QA requirements, Grade 3 is the least stringent of all;
- Grade ‘_’ : Good commercial practice is acceptable with no additional QA requirements to provide adequate confidence.

The above grading depicts varying degrees of control, verification, measurements and records and still maintain confidence that items or services satisfy given requirements for quality.

The following tables show the typical graded QA requirements for Design and Manufacturing.

GRADED QA REQUIREMENTS			
Design			
	QA Level		
	I	II	III
QA requirements	QA grade		
Personnel training and qualification	1	2	3
Specification of design input	1	2	
Checking and approval of design inputs	1	-	-
Design process planning and performance	1	1	3
Design analyses	1	1	3
Drawing preparation	1	2	-
Preparation of specifications and other design documents	1	2	-
Design interface control during design process	1	1	-
Communication between design organization and other organization (feedback)	1	1	-
Design verification Design reviews and/or	1	2	3
Alternative calculations and/or	1	2	3
Qualification testing	1	2	3
Documents control			
Document preparation, review and approval	1	1	3
Document release and distribution	1	1	3
Document change control	1	1	3
Control of design changes	1	2	-

GRADED QA REQUIREMENTS			
Procurement			
	QA Level		
	I	II	III
QA requirements	QA grade		
Personnel training and qualification	1	2	3
Planning for procurement	1	1	-
Procurement document preparation review and change control	1	2	3
Content of procurement documents	1	2	3
Procurement document control	1	1	-
Selection of procurement sources	1	2	3
Review of past performance	1	2	-
Evaluation of facilities and personnel	1	2	-
Evaluation of quality assurance programme	1	2	3
Bid evaluation and award	1	2	-
Purchaser evaluation of supplier performance			
Responsibility assignment	1	2	3
Purchaser and supplier co-ordination	1	2	3
Control of supplier generated documents	1	2	-
Control of changes in procurement documents	1	2	-
Verification activities by the purchaser			
Planning of verification activities (procedure)	1	2	-
Planning of verification activities (responsibility assignment)	1	-	-
Implementation of verification activities	1	2	-
Reporting of verification activities	1	1	-
Non-conformance review and disposition	1	2	3
Corrective action	1	2	-
Acceptance of items and services	1	2	3

GRADED QA REQUIREMENTS			
Manufacturing			
	QA Level		
	I	II	III
QA requirements	QA grade		
Personnel training and qualification	1	2	3
Manufacturing process planning and change control			
Identification of requirements	1	1	1
Identification of process	1	1	1
Process qualification	1	1	3
Plans and procedures	1	2	3
Change control	1	2	3
Document control	1	1	3
Procurement control	1	1	3
Item identification control	1	1	3
Inspection and test control			
Procedures and instructions	1	2	3
Inspection	1	2	3
Testing	1	2	3
Results, evaluation and reporting	1	2	3
Measuring and test equipment control	1	1	3
Handling, storage and shipping			
Handling	1	1	1
Storage	1	2	3
Shipping	1	2	3
Non-conformance control			
Identification and documentation	1	1	3
Segregation	1	1	1
Review and disposition	1	2	3
<p>Note: For management of manufacturing, the graded QA requirements should be in accordance with the graded QA requirements for management.</p>			

GRADED QA REQUIREMENTS			
Management			
	QA Level		
	I	II	III
QA requirements	QA grade		
Personnel training and qualification	1	2	3
Planning and designing QA programme	1	2	-
Developing QA programme procedures	1	1	3
Documenting QA programme	1	2	3
Structuring the organization	1	1	-
Documenting the organization structure	1	1	3
Document control system	1	2	-
Preparation, review and approval	1	2	-
Issue and distribution	1	2	-
Change control	1	2	-
Audits and reviews	1	2	-
Management reviews	1	2	-
Non-conformance control	1	1	1
Corrective action	1	2	-
Trend analysis	1	-	-
Reporting quality status	1	2	3
Reporting QA programme status and adequacy	1	1	-
Record management system	1	2	-

EXAMPLES OF GRADING OF QA REQUIREMENTS

Design review

Grade 1

- (1) A formal design review shall be carried out by a competent panel/individual(s) who has (have) not contributed to the design effort under review.
- (2) The panel/individual(s) shall be representative of all disciplines (e.g. QA, mechanical, electrical, instrumentation) which could be impacted by the system under review.
- (3) In case of panel, an appointed panel president shall distribute to each panel member copies of all the design inputs (performance, functional, environmental, safety requirements), design output (design calculations, analyses, drawings) for review prior to the design review meeting.
- (4) The panel/individual(s) shall review all aspects of the design prior to the meeting and shall provide written comments.
- (5) Comments shall be discussed in detail, recorded and resolved in writing at the meeting or later if necessary.
- (6) Minutes of the meeting shall be kept & circulated, when finalised, to all members of the panel & to all personnel involved in the design.
- (7) The minutes shall form part of the permanent records.

Grade 2

- (1) A technical review shall be carried out by a competent panel/individual(s) who has (have) not contributed to the design under review.
- (2) The panel/individual(s) may be composed of personnel from the same department as the designer whose design is under review.
- (3) In case of panel, an appointed panel president shall distribute the design inputs and outputs to all panel members.
- (4) At the design review meeting, the panel members/individual(s) shall discuss and resolve any points of the design which are in question.

- (5) A record of the meeting shall be kept and placed on file as part of the permanent record.

Grade 3

The designer's supervisor, provided he has not participated in the design effort, shall review all design calculations, analyses and output documentation and shall signify approval/acceptance by signing or initialing the reviewed documentation.

EXAMPLES OF GRADING OF QA REQUIREMENTS			
Purchaser and supplier co-ordination			
Actions to be performed by Purchaser	QA requirements		
	Grade 1	Grade 2	Grade 3
Supplier evaluation		Management area 'Direct' evaluation of new suppliers of 'indirect' evaluation of usual suppliers	'Indirect' evaluation except for important technical reports
Acquisition of QA manual or equivalent document	For concurrence	For information and comments	
Review of supplier's management /administrative procedures	For concurrence, on procedures involving purchaser-supplier interface		Optional
Verification of the supplier's QA programme implementation	To be performed in conjunction with surveillance activities and, at least annually by audit	To be performed in conjunction with surveillance activities	Optional
Review of design Planning documents	For concurrence	Design area For information and comments	Optional
Review of design output documents	For concurrence on documents concerning interfaces and concurrences on selected documents		Optional
Review of change proposals	For concurrence on change proposals to technical requirements contractually established by the purchaser		

EXAMPLES OF GRADING OF QA REQUIREMENTS

Document Control

Grade 1

Procedures shall be established and implemented to control all technical and administrative documents pertaining to the QA programme.

Each document shall be reviewed and duly approved by authorised personnel before issue. The control system shall ensure that appropriate revisions of the documents are available where the related activities are performed and that obsolete documents are promptly removed. Changes to documents shall be reviewed and approved by the same organisation that performed the original review and approval unless other organisations with access to the original design information are designated. Pertinent information shall be available to the designated organisation. The nature of the change, where significant, shall be identified and documented. Different revisions of the documents shall be clearly identified and a master list or an equivalent control programme established to identify such revisions.

Documents shall be reissued after a practical number of changes has been made.

Grade 2

A documented system shall be adopted to control technical and selected administrative documents concerning the QA programme.

The system shall ensure that these documents are approved by competent persons before their issue, appropriate revisions are available to users, obsolete documents are removed and changes to the documents are approved by competent and knowledgeable persons.

Grade 3

The technical documents on the QA programme shall be approved before issue.

A control system shall ensure that appropriate revision of inspection and test procedures and other important documents is instituted.

Grade ' _ '

Good commercial practice shall be used.

EXAMPLES OF GRADING OF QA REQUIREMENTS

Measuring and test equipment control

Grade 1

- (1) A system shall be maintained for selecting, using, calibrating and controlling measuring and test equipment.
- (2) Measuring and test equipment shall be:
 - (a) Of the appropriate range and accuracy for the intended use;
 - (b) Calibrated before use when first acquired;
 - (c) Calibrated at appropriate intervals;
 - (d) Stored and calibrated in a controlled environment to the extent necessary to ensure valid measurements; and
 - (e) Calibrated according to approved procedures using reference standards traceable to national standards or those derived from accepted values of physical constants;
 - (f) Identified to indicate its calibration status and the scheduled date of its next calibration and to identify it with its calibration record.
- (3) A calibration record shall be maintained for each piece of measuring and test equipment.
- (4) A record of issue, use and return of measuring and test equipment shall be maintained.

Grade 2

- (1) A system shall be maintained for selecting and calibrating measuring and test equipment.
- (2) Measuring and test equipment shall be:
 - (a) Of the appropriate range and accuracy for intended use;
 - (b) Calibrated before each use;

- (c) Stored and calibrated in a controlled environment to the extent necessary to ensure valid measurements;
 - (d) Calibrated using reference standards traceable to national standards or those derived from accepted values of physical constants; and
 - (e) Identified to relate it to its record of issue, use and return.
- (3) A record of issue, use and return of measuring and test equipment shall be maintained.

EXAMPLES OF GRADING OF QA REQUIREMENTS

Non-conformance control

Grade 1

- (1) Identify and hold non-conformances for evaluation
- (2) Define the responsibilities and authority of those assigned to the disposition of non-conforming items and services.
- (3) Provide for a review of the non-conformance involving representatives from all relevant functions, including quality assurance.
- (4) Record each non-conformance.
- (5) Obtain concurrence of all responsible parties for dispositions.
- (6) Tag all non-conforming items and place in a segregated holding area when feasible.
- (7) Ensure that reworked and repaired items are reinspected and retested according to the original or approved modified requirements.
- (8) Maintain records of all non-conformances, dispositions, results of reinspections and retests.

Grade 2

- (1) Identify and hold non-conformances for evaluation.
- (2) Contact those individuals assigned to the disposition of non-conforming items or services.
- (3) Record each non-conformance.
- (4) Tag all non-conforming items.
- (5) Maintain records of all non-conformances and dispositions.

Grade 3

- (1) Identify and hold non-conformances for evaluation.
- (2) Contact those individuals assigned to the disposition of non-conforming items or services.
- (3) Tag all non-conforming items.
- (4) Release non-conforming items for disposition when instructed.

Grade ' _ '

Use good commercial practice.

EXAMPLES OF GRADING OF QA REQUIREMENTS

Records management system (manufacturing & construction)

Grade 1

- (a) Maintain quality records as objective evidence that:
 - (i) The quality assurance programme meets the requirements;
 - (ii) The product or service and documentation meet specified requirements
 - (iii) Personnel, procedures, documentation and equipment for special processes are qualified;
 - (iv) The requirements for selection, surveillance and audit of subsuppliers are met; and
 - (v) Corrective actions are taken and are effective.
- (b) Maintain quality audit records which identify:
 - (i) Audited procedures, processes, products and services;
 - (ii) Results obtained; and
 - (iii) Analyses of audit data and resultant corrective actions taken.
- (c) Maintain records of management reviews and resultant corrective actions.
- (d) Maintain records of verifications, inspections and tests which identify:
 - (i) The item or service;
 - (ii) Applicable requirements;
 - (iii) Specific verifications, inspections, tests performed and results obtained, including the basis of acceptance
 - (iv) Non-conformances;
 - (v) Feedback or corrective actions generated;
 - (vi) Dates of inspections or tests;

- (vii) Verifiers or inspectors; and
- (viii) Data recording instruments
- (e) Make quality records available to the customer representative for analysis and review.
- (f) Identify, index and file quality records for prompt retrieval upto the time of customer acceptance of the product or service and for sure retrieval for the time specified in the contract.
- (g) Define and provide the environment needed to minimize deterioration or damage and to prevent loss of records.

Grade 2

- (a) Maintain quality records as objective evidence that:
 - (i) The quality assurance programme meets the requirements;
 - (ii) The product or service and documentation meets specified requirements;
 - (iii) Personnel, procedures, documentation and equipment for special processes are qualified; and
 - (iv) Requirements for selection, surveillance and audit of subsuppliers are met.
- (b) Maintain inspection and test records which identify:
 - (i) Item or service;
 - (ii) Basis of acceptance;
 - (iii) Non-conformances;
 - (iv) The dates of inspections or tests;
 - (v) Verifiers or inspectors; and
 - (vi) Data recording instruments.

Grade ' _ '

Use good commercial practice.

Annexure II-A

EXAMPLE OF A LIST OF INFORMATION TO BE PRESENTED IN A QUALITY PLAN

1. General information: The name of power plant, the name of component, the customer, number of the document, etc.
2. Sequential listing, enumerated point-wise of manufacturing operations, inspections and tests. All items to be manufactured and inspected should be identified and referred to in the plan.
3. The procedure, work instruction and standard (or specific part, if appropriate) to be followed in respect of each manufacturing operation, inspection or test.
4. Identification of the organization (manufacturer, purchaser, independent inspection organization or others) performing inspections, tests and documentation review points.
5. Appropriate identification of all hold points, witness points and documentation review points.
6. Type of records to be prepared for each inspection or test.
7. Extent of verification i.e. 100%, random by sampling etc.

Annexure II-B

A TYPICAL QUALITY ASSURANCE PLAN FOR FORGING

QUALITY ASSURANCE PLAN						
Name of the Manufacturer : and address				Purchaser's : details		
Project :				Component :		
No.	Operation	Interv- ention	Manufact -urer's Specific- ation rev.	Extent of verifi- cation	Agency	Remarks/ of supplier/ purchaser
1.	Submit QA plan for customer approval.	H				
2.	Produce of the ingot	H	0			
3.	Ladle analysis	R	2			
4.	Forging of the ingot	-	0			
5.	Heat-treatment	H	0			
6.	UT examination	H	1	100%		
7.	Dimensional checking	R	1	100%		
8.	Machining to delivery dimensions	W	1			
9.	LP examination	H	2	100%		
10.	Packing and preservation					
11.	Shipping release	H				
(R) Report required (W) Witness point (H) Hold point Witness code :						

Annexure-III

EXAMPLE OF CONTROL MEASURES FOR THE TRANSPORTATION OF ITEMS

I. Classification of Items

The requirements for packaging, preserving, protecting, and transporting manufactured products for nuclear power plants are divided into four levels with respect to protective measures to prevent damage, deterioration or contamination of the items, based upon the important physical characteristics and not on the important functional characteristics of the item with respect to safety, reliability and operation. It should be recognized, however, that within the scope of each levels there may be a range of controls and that the detailed requirements for an item are dependent on the importance of the item to safety or reliability. For example, even though a reactor vessel and structural steel are classified as level D, the degree of protection and control over the reactor vessel should exceed that of the structural steel. Each manufactured product should be classified into one of these four levels by the manufacturer if not pre-classified by the purchaser. Shipping procedures shall then be implemented according to the appropriate requirements.

- Level A** - Items classified as level A are those that are exceptionally sensitive to environmental conditions and require special measures for protection from one or more of the following effects: temperatures outside required limits, sudden temperature changes, humidity and vapours, gravitational (g) forces, physical damage and airborne contamination (e.g., rain, snow, dust, dirt, salt, spray, fumes).
- Level B** - Items classified to level B are those that are sensitive to environmental conditions and require measures for protection from the effects of temperature extremes, humidity and vapours, g forces, physical damage and airborne contamination and should not require special protection required for level A items.
- Level C** - Items classified to level C are those that require protection from exposure to the environment, airborne contaminations, g forces and physical damage. Protection from water vapor and condensation is not so important as that for level B items.
- Level D** - Items classified as level D are those that are less sensitive to the environment than those of level C. These items require protection against the elements, airborne contamination, and physical damage.

II. Packaging

The packaging requirements should be based on the protection that the items should receive during shipping and subsequent handling, and storage. The following packaging criteria are divided into four levels corresponding to the categories of subsection I.

Level A Items - Level A items require the highest degree of protection and should conform to the following criteria:

- (a) Package design requirements are for extraordinary environmental protection to avoid the deleterious effects of shock and vibration, to control temperature or humidity within specified limits, or for any other special requirements;
- (b) Items should have been inspected for cleanness immediately before packaging. Dirt, oil residue, metal chips or other form of contamination should have been removed by approved cleaning methods. Any trapped water should have been removed;
- (c) Items which are not immediately packaged should be protected from contamination;
- (d) All items should be packaged with a barrier so that water vapor, salt air, dust, dirt and other forms of contamination do not penetrate the package;
- (e) Items should be packaged in containers or crates;
- (f) Items that can be damaged by condensation trapped within the package should be packaged with approved desiccant inside the sealed water vapour-proof barrier or by an equivalent method;
- (g) All openings into items should be capped, plugged or sealed. Weld end preparations should be protected against corrosion and physical damage;
- (h) Items packed in containers should be blocked, anchored, braced and/or cushioned to prevent physical damage to the item or barrier; and
- (i) Items and their containers should be identified by marking.

Level B Items - Level B items require a high degree of protection and the package should be designed to avoid the deleterious effects of shock, vibration, physical damage, water vapor, salt spray, condensation and weather during shipping, handling and storage. This packaging should be equivalent to that for level A except that the extremes of criteria (a), (b), (d) and (e) need not apply. Level B items such as control panels or similar special items may be shipped with a minimum of protection when transported in a fully enclosed furniture type van with special suspension, provided the shipment goes through to destination in the original vehicle and level B storage facilities are available at the site.

Level C Items - Level C items require protection from exposure to salt spray, rain, dust, dirt and other airborne and windblown contaminants. Protection from water vapour and condensation is less important than for level B items. The following criteria should apply:

- (1) Criteria (b),(c),(e),(g),(h) and (i) for level A items should apply to level C items;
- (2) Items should be packaged with a waterproof enclosure so that water, salt, spray, dust, dirt, and other forms of contamination do not penetrate to the item; and
- (3) Items subject to detrimental corrosion, either internal or external, should be suitably protected.

Level D Items - Level D items require protection from physical and mechanical damage. The following criteria shall apply:

- (a) Items, just before packaging, shall have been inspected for cleanness according to the requirements specified in the purchasing document. Dirt, oil residue, metal chips or other forms of contamination should have been removed by approved cleaning methods. Any entrapped water should have been removed;
- (b) All openings into items should be capped, plugged and sealed. Weld end preparations should be protected from corrosion and physical damage;
- (c) Items subject to detrimental corrosion, either internal or external, should be suitably protected;
- (d) Items packed in containers should be blocked, braced and/or cushioned to prevent physical damage;

- (e) Items such as aggregate and reinforcing steel should be suitably protected against detrimental contamination or corrosion; and
- (f) The identity of the item should be maintained by marking or other appropriate means.

III. Cleaning

Cleaning includes the preparation of items for preservation or packaging or both, to minimize the requirements for site cleaning. Items should be inspected for cleanness immediately before packaging according to the cleaning requirements specified in the purchase document. Any dirt, oil residue, metal, chips or other forms of contamination should be removed by documented cleaning methods. Any entrapped water should be removed. Any item which is not immediately packaged should be protected from further contamination.

IV. Methods of Preservation

Items subject to deleterious corrosion should be protected by using either contact preservatives, inert gas blankets, or vapour-proof barriers with desiccants.

- A. Contact Preservatives - Contact preservatives are compounds applied to bare metal surfaces to prevent surface corrosion during shipping and storage and generally require removal prior to installation; and
- B. Inert Gas Blankets - Purging and pressurizing the interior of an item or its container or both with a dry inert gas provides a means of preventing moisture or corrosive atmospheres from acting on sensitive bare metal surfaces or other materials. The item or its container should be either evacuated prior to filling with the inert gas or adequately purged with the same gas before to applying the gas blanket is applied.

V. Caps, Plugs, Tapes and Adhesives

These items should be of materials which enable them to perform their intended function adequately without causing deleterious effects on items or systems operation.

Caps and Plugs - Caps and plugs should be used to seal openings in items having sensitive internal surfaces, and to protect threads and weld end preparations.

Tapes and Adhesives - Pressure-sensitive, removable tape should be used in lieu of adhesives in contact with bare metal surfaces. Tapes or adhesives which could have damaging effects on the item or system should not be used. Tapes near a weld and any residual material adhesives should be removed completely immediately prior to performing a weld or closure. Tapes used for identification rather than sealing which are not near a welding operation may remain until system testing.

VI. Barrier and Wrap Materials and Desiccants

A barrier generally is a flexible material designed to withstand the penetration of water, water vapour, grease, or harmful gases. A wrap is a flexible material, formed around the item or **QUALITY** package to exclude dirt and to facilitate handling, marking or labelling. Material thickness should be selected on the basis of type, size and weight of equipment or item to be protected, such that the barrier or wrap will not easily be damaged by puncture, abrasion, weathering, cracking, temperature extremes, wind conditions, and the like. When used in direct contact with austenitic stainless steels barrier and wrap material should have halogen content within specified acceptable limits, should be non-corrosive, should not readily support combustion and should not be otherwise harmful to the item packaged. Vapour-proof barrier materials used with desiccants constitute another preservation system; it protects against potential damage by water vapour condensate.

- (A) Waterproof Barrier Material - Waterproof barrier material should be resistant to grease and water; it shall protect items from airborne and windblown soils;
- (B) Vapour-proof Barrier Material – Vapour-proof barrier materials should be sealable and the edge of the barrier which normally will be opened at destination should be of sufficient area to permit at least two subsequent sealing operations; and
- (C) Desiccants - Desiccants may be used within a vapour-proof barrier when condensation or high humidity could damage an item by corrosion, mold or mildew.

VII. Containers, Crating and Skids

- (A) Containers - Containers are used when maximum protection for the item or its barrier is required. Types used should be limited to:

- (a) cleated, sheathed boxes (1100 kg maximum net weight);
- (b) nailed wood boxes;
- (c) Wood, cleated solid fiberboard boxes;
- (d) Fiberboard boxes (260 kg maximum net weight);
- (e) Metal or fiber drums;
- (f) Crates;
- (g) Wire bound boxes (440 kg maximum net weight); and
- (h) Other specially designed containers for special equipment.

Cleated boxes in excess of 110 kg should be bound with steel strapping or equivalent around the container at not less than two places.

- (B) Crates and Skids - Crates and skids should be used for equipment in excess of 1100 kg. Skids and runners should be used on boxes with a gross weight of 100 lb or more, allowing a minimum floor clearance for forklift tines as provided by 4 inch lumber.

VIII. Cushioning, Blocking, Bracing and Anchoring

- (A) Cushioning - Cushioning should be used where protection from shock and vibration is required; the cushioning materials should have sufficient strength to perform this function.
- (B) Blocking and Bracing - Blocking and bracing used for protection of the load to be supported should be compatible with the size, shape, and strength of bearing areas of the shipment. The blocking and bracing used to prevent item movement should withstand thrust and impact applied in any direction. Blocking and bracing used in direct contact with the item being blocked should not have a corrosive effect on the item.

- (C) Anchoring - Anchoring of the item within a crate or on a skid should adequately fasten the item during shipment and protect the item from potential damage due to rough handling. To facilitate disassembly and minimize damage when removing container contents, bolting is preferred. Temporary cushioning, blocking, bracing or anchoring placed within an item for shipping protection that must be removed prior to operation of the item should be identified by warnings placed in a conspicuous manner to effect proper removal of the packing material.

IX. Marking

To maintain proper identification and instructions or both during shipping, receiving and storage and to provide for identification after removing the outside of the container, the item and the outside of containers should be marked.

X. Transportation Requirements

- (A) Open Carriers - For shipment on open carriers where items may be exposed to adverse environmental conditions, the following should apply:
 - (a) Level A, B and C items should be covered for protection from environmental conditions. Tarpaulins, when used should be fire-retardant: and they should be so installed as to provide drainage and to ensure air circulation to prevent condensation; and
 - (b) Barrier and wrapping materials subject to transportation damage should be covered with waterproof shrouds such as tarpaulins, so that they are not exposed directly to the environment.
- (B) Closed Carriers - For shipment on closed carriers the following should apply:
 - (a) When level A, B and C items cannot be adequately protected from weather or environment on open carriers, closed carriers should be used; and
 - (b) Use of fully enclosed furniture vans is recommended when shipping large delicate items such as control panels.

- (C) Special Shipments - items that exceed established weight or size limitations for railroads or highways, or require special handling, should be given additional consideration in the following areas:
- (a) The type of bracing and tie-down methods to be used with the mode of transportation selected for special shipments should be specified;
 - (b) Use of impact recording meters should be specified on shipments of heavy or relatively large items incorporating delicate factory-installed instrumentation. Meters, when specified, should be installed prior to loading (to record any rough handling during loading). Procedures should be established to interpret recorded data, and to thoroughly check the integrity of an item when there is evidence of rough handling. A notice that impact recording meters are being used should be prominently displayed. Special recording meters with operating time limits greater than the expected transit time should be specified or, if the expected transit time exceeds the operating time limit of the recorders being used, provisions should be made to service the meters during transit;
 - (c) The use of "escorts" may be specified to accompany shipments, when additional surveillance is required during transit of certain items; and
 - (d) For special shipments, the conveyance used for transport should be certified to be structurally adequate to take the loads imposed during loading, while enroute, and during unloading. Prior to shipment the route should have been investigated to assure safe transit.

XI. Precautions during Loading and Transit

- (A) Loading - The weight, lifting points, or centre of gravity indicated on the crate, skid or package by the shipper should be observed to insure proper handling during loading, transfer between carriers, and unloading.

- (B) Rigging - Carbon steel rigging equipment should not come in direct contact with stainless steel except when attached to lifting lugs, eyes or pads, in order to avoid surface damage.
- (C) Handling Precautions - All austenitic stainless steel and nickel base alloy materials should be handled in such a manner that they are not in contact with lead, zinc, copper, mercury, or other low melting elements, alloys, or halogenated material.
- (D) Package/Preservative Coatings - Packages and/or preservative coatings should be visually inspected after loading, and damaged areas repaired before to shipment. Items shipped with desiccants should be inspected after loading to assure that sealed areas are intact.
- (E) Sealed Openings - Sealed openings should be visually inspected after loading to assure closure are intact. Materials used for resealing should be in accordance with Section II.
- (F) Stacking - Written instructions covering the location and stacking limits of the crates or boxes on the transport vehicle should be specified; these should be marked on the container.
- (G) Theft and Vandalism - Precautions should be taken to minimize the possibility of theft and vandalism during shipment of items.

XII. Identification and Marking

Identification and markings on the outside of all packages, skids or protective covering should be maintained.

ANNEXURE IV-A

A TYPICAL EXAMPLE OF NON-CONFORMITY REPORT

		SHOP/ PURCHASE	INSP. CENTRE	WELDING ENGG.	DPE	INSP. CENTRE
PWO NO.	PART NO.	DRG. NO.	P.O. NO. (IN CASE OF BO PARTS ONLY)		NCR NO.	
DESCRIPTION OF NON-CONFORMITY						
HOLD FURTHER WORK					INITIATOR	DATE
RECTIFICATION PROPOSED						
					SHOP SUPERVISOR/PURCHASE ENGINEER	DATE
COMMENTS FROM WELDING ENGG.						
					WELDING ENGINEER	DATE
COMMENTS FROM DESIGN & PRODUCT ENGG.						
					DESIGN & PRODUCT ENGINEER	DATE
INSPECTION REVIEW AND RULING		HOLD RELEASED - YES/NO				
AUTHORISED INSPECTOR		DATE	INSPECTION IN-CHARGE		DATE	
NON-CONFORMITY CORRECTED						
					INSPECTION IN-CHARGE	DATE
REVIEW			REVIEW			
CUSTOMER INSPECTOR		DATE	AUTHORISED INSPECTOR		DATE	

Annexure IV-B
A DESIGN CONCESSION REQUEST FORMAT

P.O.No. _____ U.S.I No. _____ Concession Request No. _____

Manufacture: _____ Component: _____

Manufacturer's Ref.No. _____ Spec/Drg. No. _____

Equipment/Tag No. _____ Detail/Item No. _____

DETAILS OF PROPOSED CONCESSION : (This could include reason for deviations and corrective action to prevent repetition.)

This request does not involve a change in contract price _____

Estimated Cost : _____

Requested by : _____

(Name and sign)

Date : _____

QUALITY SURVYOR'S COMMENTS :

Original Signed _____ Dated _____

REFERRED TO DESIGNER :

APPROVED/APPROVED AS NOTED/REJECTED/ALTERNATE DESIGN
APPROVED

NOTES :

Signed _____ Date _____

DISTRIBUTION :

ANNEXURE V

TYPES OF RECORDS AND THEIR RETENTION CATEGORIES

Type of record	Permanent	Non-Permanent #
As-constructed drawings	*	
Design calculation and records of checks	*	
Design change requests	*	
Design drawings	*	
Design review reports		*
QA audit reports		*
Reports of engineering surveillance of field activity	*	
Procurement specification	*	
Purchase order including amendments		*
Receiving records		*
Supplier's quality assurance programme manual		*
As-built drawings	*	
Certificates of inspection and test personnel qualification	*	
Certificates of compliance	*	
NDE procedures		*
NDE results	*	
Electrical control verification test results		*
Ferrite test procedure		*
Ferrite test results	*	
Heat treatment procedures		*
Heat treatment records	*	
Calibration procedures and records		*
Major defect repair records	*	
Material properties records		*
Non-conformance reports	*	
Packaging, receiving, storage procedures		*
Performance test result records		*
Pressure test procedure		*
Pressure test results	*	
Welding procedures		*
Work processing and sequencing documents		*

Retention period of non-permanent records to be kept by RO.

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1. INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Safety Guide 50-SG-QA8, 'Quality Assurance in the Manufacture of Items for Nuclear Power Plants', (working draft, 21.10.1994).
2. ATOMIC ENERGY REGULATORY BOARD, AERB Safety Code No.SC/QA, "Code of Practice on Quality Assurance for Safety in Nuclear Power Plants".
3. INTERNATIONAL ATOMIC ENERGY AGENCY, IAEA Technical Reports Series No.328; "Grading of Quality Assurance Requirements : A manual".

LIST OF PARTICIPANTS

Advisory Committee on Codes and Guides for Quality Assurance
constituted by AERB

Dates of the meetings : October 18, 1993
November 22, 1993
January 27 and 31, 1995
March 24, 1995
March 21, 1996

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Shri M. Das	:	NPC
Shri S.N.Ogale	:	Larsen & Toubro
Shri M.S. Ghate	:	BARC
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Date of Meeting : November 22, 1997

Members and alternates participating in the meeting:

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	Quality Assurance	
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AERB/SG/QA-1	Quality assurance in the design of nuclear power plants.	
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.	
AERB/SG/QA-4	Quality assurance during site construction of nuclear power plants	
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