DIRECTORATE OF QUALITY ASSURANCE

NUCLEAR POWER CORPORATION
OF INDIA LIMITED

Ensuring Quality of Nuclear Components

L.K.Jain, Executive Director(QA)

POINTS FOR DISCUSSION

- Introduction
- Management functions/controls
- Performance functions/control
- Verification functions/control
- Corrective function/control
- Quality Assurance records
- Case studies
- Experience with Vendors & Lesson Learnt

INTRODUCTION

While pursuing activities for economic and social progress, safety of public, occupational workers and the protection of environment is to be assured.

Safety of facility is dependent on Quality of equipment/items over a useful service period.

Therefore Quality of products/equipments installed at any facility becomes an essential aspect for overall Safety.

These objectives are achieved by efficient and effective process management through Quality Management System.

Quality Assurance

All those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

Establishment and implementation of Quality Assurance programme is the responsibility of **each organization participating** in the manufacture of critical items including vendors, sub-vendors/material suppliers, testing agencies etc.

However overall responsibility remains with Responsible Organization (RO) i.e. NPCIL.

Quality assurance in NPCIL is based on;

1. AERB/NPP/SC/QA

   (Quality Assurance in Nuclear Power Plants)

2. ASME Codes;

   ASME Section III Rules for Construction of Nuclear Facility Components

   Subsection NCA — General Requirements for Div.- 1 and Div.-2

   Article NCA-4000: Quality Assurance which further refers to NQA-1.

   NQA-1: Quality Assurance Requirements for Nuclear facility Applications

3. IS/ ISO 9001

INTRODUCTION

Quality Assurance Program for Nuclear Components is assured by NPCIL:

1. **Corporate Management System Document of NPCIL(CMSD-NPCIL Level-1 document)**
2. **Quality Assurance Manual and other lower level QMS documents i.e Level-2 documents for Sectional Manuals, for all functions in NPCIL.**
3. **Product document such as Specification, Drawings, QAPs, Travelers/Check lists, Inspection/NDE procedures etc. are Level-3 documents.**

By Manufacturer:

1. **Quality Assurance documents of manufacturers, job specific QA document are concurred by NPCIL.**

GRADED APPROACH

On the basis of safety significance of item, service or process, a graded approach is applied for determining the extent of QA requirements. Following factor are considered for deciding the extent of QA efforts:

- **Effect of malfunction or failure of an item on safety.**
- **Complexity of the item.**
- **Degree of Standardization of the item.**
- **Need for special controls, administrative measures and surveillance over processes, methods and equipment.**
- **The degree to which compliance with design requirements can be demonstrated by inspection and testing.**
- **Quality History (experience with performance and quality)**
- **Accessibility of item, after installation in the plant, for maintenance, in-service inspection and replacement.**

GRADED APPROACH

Application of graded approach in manufacturing phase :

- **Qualification of special manufacturing process and/or personnel to carry out them.**
- **Extent and details of procedures and degree of their review.**
- **Degree of in-process controls, hold points and sample points.**
- **Requirements of material traceability.**
- **Records, their storage, preservation and retrievability**

MANAGEMENT CONTROLS

FUNCTIONS OF TOP MANAGEMENT

- **Issuance of QA "POLICY STATEMENT".**
- **Establishing, implementing, and verification of implementation of QA System.**
- **Ensuring that QA Programme of manufacturer includes controls in areas of design, purchase, manufacture, inspection, testing, handling, transportation, storage, cleaning, modifying, repair and maintenance activities.**
- **Proper/independent QA set-up containing; Structure, responsibility, authority and defined lines of communication.**

MANAGEMENT CONTROLS

- **Identification of individual by name or designation responsible for overall QA programme.**
- **Defined responsibility of task performers and verifiers and its independence.**
- **Sufficient Authority and freedom to QA personnel for identifying the problem, initiate/recommend solutions, and control of non-conforming item until disposition has been achieved.**
- **Training and certification of personnel to accomplish and maintain proficiency for activities performed.**
- **Review of Manufacturer's QA programme by NPCIL.**

PERFORMANCE CONTROLS

DOCUMENT CONTROL

Documented system for control of documents is part of QA program for activities such as preparation, review, approval, issue and subsequent changes for manufacture of critical nuclear items.

Document control system identify individuals or organizations responsible for preparing, reviewing, issuing and revising documents related to activities affecting the quality. This system ensures that:

- **Drawings, Quality plans, procedures and work instructions are reviewed and approved before the start of manufacturing.**
- **Updated documents are distributed and maintained at specified locations; all obsolete documents removed as to prevent their inadvertent use.**
- **All documents are prepared, approved, and issued by designated persons.**
- **The current status of all documents is listed and issued/made available to all concerned and record is maintained regarding issue of all documents.**

PERFORMANCE CONTROLS

DESIGN CONTROL

Quality Management System for controls during design stage is developed, maintained and verified at regular interval for its efficiency and effectiveness.

There is a separate Quality Management System for design control of Nuclear Component in NPCIL. This system is certified to ISO-9000 requirements.

PERFORMANCE CONTROLS

PLANING AND CONTROL OF MANUFACTURING PROCESS

Drawing and specification are prepared as per established QA system. These documents clearly define the product without any error. With the help of these documents pre-manufacturing planning is carried more precisely. During pre-planning consideration are given to following factors:

- **Aspects of manufacturing such as forming, heat treating, special machining.**
- **Requirement of special inspection and tests specified by designers and required for product quality.**
- **Clean and other special shop conditions requirements.**
- **Assembly and shipment to site, activities which can offset the manufacturing.**
- **Application of new techniques in manufacturing, inspection and testing.**

PERFORMANCE CONTROLS

PROCUREMENT CONTROL

Quality Management system during procurement of items is developed and followed which is based on AERB document No. AERB/SG/QA-2 (Quality Assurance in Procurement of items and services for nuclear power plants). The Quality Assurance system provides review of procurement documents for the items to be manufactured to determine that they are in line with:

- **the regulations,**
- **codes,**
- **standards,**
- **Specification and**
- **other requirements that are applicable during manufacturing.**

Regulatory, technical and other requirements are included as appropriate, in drawings, specifications, quality plans, procedures and work instructions.

There is a separate Quality Management System for procurement control of Nuclear Component in NPCIL. This system is also certified to ISO-9000 requirements.

PERFORMANCE CONTROLS

PROCESS QUALIFICATION

The of Critical Nuclear items have heavy reliance on the skills of process operator and the process. Therefore the qualification of process and operator is essential to get required confidence for getting conformance to the requirements. Following process generally are qualified before using on critical Nuclear components:

- **Welding**
- **Heat Treatment,**
- **Non destructive Examination**
- **Special machining processes etc**

- **Whenever prescribed by codes, standards, and product specification, process are performed by qualified personnel using qualified procedure and equipments.**
- **Manufacturing machine tools and measuring instruments used are maintained in good conditions and are calibrated to national standard at required intervals.**

PERFORMANCE CONTROLS

PROCESS CONTROL

The production operations are planned so that they proceed under controlled conditions in a specified manner and sequence. Controlled condition includes:

- **Control on raw material identification and traceability.**
- **Control on production equipments.**
- **Control on processes and procedures.**
- **Control on personnel working on job.**
- **Control on working environment**
- **Control on sub-suppliers**

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

Process capability studies are conducted to determine the potential effectiveness of a process, when necessary as per specification.

Quality status of product, process, material is verified regularly to minimize the errors and maximize the yields.

Control charts and statistical methods are employed to facilitate production process control.

PERFORMANCE CONTROLS

QUALITY PLANNING

Measures are established and implemented for documenting inspection and test procedures to ensure conformance with the QMS. Following are the documents which are prepared, reviewed and approved by appropriate authority:

- Quality Assurance Plan covering entire job cycle
- Procedures and work instructions for activities affecting the quality of product. These procedure includes:
  1. Shop travelers/fabrication operations process sheets.
  2. Welding Procedures
  3. Heat Treatment Procedures
  4. NDE procedures
  5. Critical dimension Inspection procedures
  6. Test procedures
- When special tooling and fixtures are required to aid manufacturing process controls, they are properly qualified for use.

PERFORMANCE CONTROLS

CONTROL OF ITEMS

Measures are established and implemented for controlling identification of materials, parts and components and maintaining their traceability during various manufacturing activities such as:

- Fabrication
- Processing and
- Assembly operations

VERIFICATION CONTROLS

CALIBRATION AND CONTROL OF MEASURING AND TEST EQUIPMENTS

Procedure are prepared and implemented for selection and use of all measuring and test equipments used for product acceptance. These procedure include identification of equipments and their calibration requirements including calibration frequency.

VERIFICATION CONTROLS

INSPECTION AND TEST CONTROL

Throughout the manufacturing cycle:

inspection and tests are performed in accordance with written procedures or work instructions, in a sequential order, as per QAP and the same is verified by planned internal checks/audits etc.

VERIFICATION CONTROLS

AUDITS

- **Internal audit**
- **External audit**

CORRECTIVE FUCTIONS/CONTROLS

Non-Conformance Control-

The procedure are established, implemented and maintained for control of material, parts, components, system or processes that do not conform to specified requirements. This procedure provides for prompt recording, technical review and final disposition of non-conforming items.

Corrective Actions- may be related to design, procedure, requalification etc

QUALITY ASSURANCE RECORDS

Measures are established for

- generating,
- collection,
- reviewing and
- Filing (documenting) the
  - ✓ manufacturing records,
  - ✓ inspection and test records and
  - ✓ audit reports

to provide objective evidence of attainment of the required quality during manufacturing and to provide data that may be useful during lifetime of item.

CASE STUDIES

- Fastener of Heat exchangers
- Hydraulic Power-Pack testing
- Cable Glands for Electrical/ C&I cables

EXPERIENCE WITH VENDORS- LESSON LEARNT

- Vendors to study specification thoroughly before submission of quotation.
- QAP submitted by Vendor to be in full conformance to P.O.
- Strengthening QAP by thorough review by QAD.
- Vendor to perform effective internal audit.
- Instituted Vendor Audit program
- Vendor QA policy to be translated from Top management to Shop floor.
- Vendor to establish strong QA org. with full authority.
- Critical shop area should be under camera surveillance.
- Organise periodic training for QA Org. and Production group on QA Management.
- Vendor should participate actively in seminar organised by INS, AERB etc


Thank you for your
kind attention