GUIDE NO. AERB/NPP/SG/QA-7

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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

ASSESSMENT OF IMPLEMENTATION OF QUALITY ASSURANCE PROGRAMME IN NUCLEAR POWER PLANTS

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/NPP/SG/QA-7

ASSESSMENT OF IMPLEMENTATION OF QUALITY ASSURANCE PROGRAMME IN NUCLEAR POWER PLANTS

Atomic Energy Regulatory Board
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FOREWORD

Activities concerning establishment and utilisation of nuclear facilities and use of radioactive sources are to be carried out in India in accordance with the provisions of the Atomic Energy Act 1962. In pursuance of the objective to ensure safety of members of the public and occupational workers as well as protection of environment, the Atomic Energy Regulatory Board has been entrusted with the responsibility of laying down safety standards and framing rules and regulations for such activities. The Board has, therefore, undertaken a programme of developing safety standards, codes of practice and related guides and manuals for the purpose. While some of these documents cover aspects such as siting, design, construction, operation, quality assurance, and decommissioning of nuclear and radiation facilities, other documents cover regulation aspects of these facilities.

Codes of practice and safety standards are formulated on the basis of internationally accepted safety criteria for design, construction and operation of specific equipment, systems, structures and components of nuclear and radiation facilities. Safety codes establish the objectives and set minimum requirements that shall be fulfilled to provide adequate assurance for safety. Safety guides elaborate various requirements and furnish approaches for their implementation. Safety manuals deal with specific topics and contain detailed scientific and technical information on the subject. These documents are prepared by experts in the relevant fields and are extensively reviewed by advisory committees of the Board before they are published. The documents are revised when necessary, in the light of experience and feedback from users as well as new developments in the field.

The code of practice on 'Quality Assurance for Safety in Nuclear Power Plants (AERB/SC/QA, 1988)' provides management principles and objectives to be met during the implementation of activities in different phases of Nuclear Power Plants for assuring safety. This safety guide is one of a series of guides, which have been issued or are under preparation, to describe and elaborate the specific parts of the code.

This safety guide on "Assessment of Implementation of Quality Assurance Programme in Nuclear Power Plants" recommends the procedures for the assessment of implementation of the quality assurance programme. In drafting it, extensive use has been made of the information contained in the relevant documents of the International Atomic Energy Agency issued under its Nuclear Safety Standards Programme, especially, the safety guide, Assessement of the Implementation of the Quality Assurance Programme, safety guide No. 50-C/SG-Q, Q5, (1996)

Consistent with the accepted practice, 'shall', 'should' and 'may' are used in the guide to distinguish between a firm requirement, a recommendation and a desirable option, respectively. Annexures, footnotes, references/bibliography and list of participants are included to provide information that might be helpful to the user. Approaches for

implementation different to those set out in the guide may be acceptable, if they provide comparable assurance against undue risk to the health and safety of the occupational workers and the general public and protection of the environment.

For aspects not covered in this guide, applicable and acceptable national and international standards, codes and guides should be followed. Non-radiological aspects of industrial safety and environmental protection are not explicitly considered. Industrial safety is to be ensured through compliance with the applicable provisions of the Factories Act, 1948 and the Atomic Energy (Factories) Rules, 1996.

This guide has been prepared by specialists in the field drawn from Atomic Energy Regulatory Board, Bhabha Atomic Research Centre, Indira Gandhi Centre for Atomic Research and Nuclear Power Corporation of India Limited and other consultants. It has been reviewed by the relevant AERB Advisory Committee on Codes and Guides and the Advisory Committee on Nuclear Safety.

AERB wishes to thank all individuals and organisations who have prepared and reviewed the draft and helped in its finalisation. The list of persons, who have participated in this task, along with their affiliations, is included for information.

(S. K. Sharma)
Chairman AERB

DEFINITIONS

Assessment

Systematic evaluation of the arrangements, processes, activities and related results for their adequacy and effectiveness in comparison with set criteria.

Atomic Energy Regulatory Board (AERB)

A national authority designated by the Government of India having the legal authority for issuing regulatory consent for various activities related to the nuclear and radiation facility and to perform safety and regulatory functions, including their enforcement for the protection of the site personnel, the public and the environment from undue radiation hazards.

Audit

A documented activity performed to determine by investigation, examination and evaluation of objective evidence, the adequacy of, and adherence to, applicable codes, standards, specifications, established procedures, instructions, administrative or operational programmes and other applicable documents, and the effectiveness of their implementation.

Commencement of Operation of Nuclear Power Plant

The specific activity/activities in the commissioning phase of a nuclear power plant towards first approach to criticality, starting from fuel loading.

Commissioning

The process during which structures, systems and components of a nuclear or radiation facility, on being constructed, are made functional and verified in accordance with design specifications and found to have met the performance criteria.

Construction

The process of manufacturing, testing and assembling the components of a nuclear or radiation facility, the erection of civil works and structures, the installation of components and equipment and the performance of associated tests.

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation in

a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Grading (QA)

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

Inspection

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

Item

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

Nuclear Safety

The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of site personnel, the public and the environment from undue radiation hazards.

Operation

All activities following and prior to commissioning performed to achieve, in a safe manner, the purpose for which a nuclear/radiation facility is constructed, including maintenance.

Quality Assurance (QA)

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

Quality Control

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

Responsible Organisation

The organisation having overall responsibility for siting, design, construction, commissioning, operation and decommissioning of a facility.

Review

Documented, comprehensive and systematic evaluation of the fulfilment of requirements, identification of issues, if any.

Safety

(See ‘Nuclear Safety’)

Site

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

Siting

The process of selecting a suitable site for a facility including appropriate assessment and definition of the related design bases.

Validation

The process of determining whether a product or service is adequate to perform its intended function satisfactorily.

Verification

The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services or documents conform to specified requirements.

CONTENTS

1. INTRODUCTION

1.1 Background

1.1.1 This safety guide gives recommendations for assessing the effectiveness of the quality assurance programme of any organisation engaged in activities related to nuclear power plants (NPPs) which may effect safety. The basic requirements for assessment of quality assurance (QA) programmes are given in Section 5 " Verification Functions" in AERB Code of practice on Quality Assurance for Safety in Nuclear Power Plants - AERB/SC/QA, issued in June1988 (hereinafter known as the Code). Assessment activities include reviewing, checking, inspecting, testing, surveillance and audits.

1.1.2 Methods and solutions for fulfilling the basic requirements of the Code, other than those set out in this safety guide, would be acceptable provided they result in at least the same level of nuclear safety.

1.2 Objective

1.2.1 This safety guide provides recommendations on how to fulfil the requirements of the Code, given in Section 5 "Verification Functions", as a part of quality assurance programme.

1.3 Scope

1.3.1 This safety guide applies to the quality assurance programmes of the responsible organisation, i.e. the organisation having overall responsibility for the nuclear power plant, as well as to any other separate programmes in each stage of a nuclear power plant, and covers items, services and processes having impact on nuclear safety. It may, with appropriate modifications, if required, also be usefully applied at nuclear installations other than nuclear power plants.

2. GENERAL CONSIDERATIONS

2.1 General

2.1.1 Assessments are carried out to determine that requirements are met and that processes are adequate and effective, and also to encourage managers to implement improvements, including safety improvements.

2.1.2 The assessment activity covers two broad categories:

- Management self-assessment, which is an on-going process conducted by the management in order to evaluate the adequacy and the effectiveness of performance in all areas of their responsibility.
- Independent assessment, which is usually conducted by an independent organisational unit in order to determine the effectiveness of management processes, the adequacy of work performance and the quality of items and services.

2.1.3 Both categories of assessment are inter-related in that the output from independent assessment assists management in their task of self-assessment. Annexure-I shows these inter-relationships.

2.1.4 Management, at all levels, shall conduct self-assessments on those key management processes for which they are responsible. Managers shall determine the effectiveness of their performance in achieving and improving nuclear safety objectives. Weakness in the management process and organisational barriers, that hinder the achievement of nuclear safety objectives and good performance, shall be identified and corrected.

2.1.5 Independent assessment shall be conducted for and on behalf of senior management by an organisational unit or an assigned outside agency which is independent of the work to be assessed. Managers should not regard the independent assessment as an opportunity to avoid carrying out their self-assessment. The assessment unit should devote itself to assisting management for improving effectiveness and work performance.

2.2 Grading

2.2.1 Nuclear safety shall be the fundamental consideration in determining the extent of application of the QA requirements. A graded approach, reflecting a planned and recognised difference in specific QA requirements for each identified item, service or process, shall be used.

2.2.2 The graded approach should take into account factors, such as safety significance, complexity and operational importance, to determine the extent and degree of assessment.

2.2.3 The allocation of resources for assessment should be flexible and allow for their re-allocation into areas of inadequate performance without any impact on assessment in areas of acceptable performance.

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

- Qualifications of special processes
- The extent of inspection, testing (including individual component testing), verification and validation
- Review of non-conformances
- Degree of phased and integrated testing of systems of the NPP
- Equipment to be included in plant status control
- Type and content of training, and certification
- Extent of details and degree of review, and approval of instructions
- Need for and details of inspection plans
- Degree of in-process reviews and controls
- Requirements for traceability of items
- Type of assessment
- Records to be generated and retained.

2.2.5 The QA programme should provide for review of grading consequent to significant modifications to items, processes and services. When these are modified, the assigned grade of QA requirements could become more or less stringent depending upon change in importance to safety of the affected items, processes or service.

2.3 Performance Indicators for Assessment of QA Programme

2.3.1 Performance indicators should be developed to measure whether performance is satisfactory or not, with particular emphasis on safety.

2.3.2 Performance indicators should be monitored so that variations can be recorded and trends determined.

2.3.3 Trends in performance indicators should be analysed to identify both beneficial and adverse factors. Beneficial factors should be used to encourage improvement. The causes of adverse factors should be determined and minimised.

2.4 Training and Qualification

2.4.1 Managers should make arrangements to ensure that all personnel performing assessment activities, including themselves, have appropriate qualification, training and expertise.

2.4.2 Personnel performing assessment activities should be trained in following aspects and records of training should be maintained:

- QA principles
- Methodology of assessment.

2.4.3 Criteria for qualification of assessment personnel should be established and these should include technical knowledge, professional competence and experience. The assessment personnel should also have the ability to effectively observe, evaluate and report. Communication skills, integrity and the ability to maintain confidentiality and objectivity are desirable attributes, which should be taken into account.

2.4.4 The assessment personnel should maintain their proficiency and technical knowledge by, for example:

- regular participation in assessments;
- study of codes, standards, procedures, practices and other related documents;
- participation in training courses, refresher courses and seminars; and
- spending an appropriate amount of time in the area of his technical expertise.

2.4.5 Experienced technical personnel and managers should be assigned to the assessment unit as part of professional development on a rotational basis.

3. RESPONSIBILITIES

3.1 Responsible Organisation

3.1.1 The responsible organisation shall be responsible for assessment of the effectiveness of the overall QA programme and shall identify an individual for performing the task. The responsible organisation may delegate to other organisations the work of assessing all or a part of the programme, but shall retain responsibility for the effectiveness of the assessment. The responsible organisation should define and document the extent to which the assessment activities are delegated.

3.2 Management Responsibilities

3.2.1 Management has a responsibility for setting performance expectations and for ensuring that they are met.

3.2.2 Senior management should have the overall responsibility for the process of management self-assessment at all levels. Senior management should review/ identify the resources provided/needed for effective implementation of QA programme and its continuous improvement. It is essential that senior management directly participate in the process of management self-assessment.

3.2.3 Senior management should establish an organisational unit, or appoint an outside agency when appropriate, to conduct independent assessments in order to inform line management of the degree that performance expectations are being met. The assessment unit should be given sufficient authority and organisational freedom to carry out its responsibilities.

3.2.4 Line management of the organisation to be assessed should make arrangements for:

- appointing a responsible person to contact and accompany assessors;
- informing concerned units on the objectives and scope of assessment;
- co-operating with and providing necessary information to the assessment team to achieve the objectives of the assessment;
- reviewing and discussing the results of the assessment and communicating those to relevant staff;
- implementing and reporting corrective actions as well as preventive actions and/or improvement plans that address the root causes (corrective actions and preventive actions are explained in Annexure-II); and
- assessing the effectiveness of the corrective actions, preventive actions or the improvement plan.

3.3 Assessment Unit

3.3.1 The assessment unit should be responsible for monitoring and evaluating the effectiveness of management at all levels in implementing the QA programme.

3.3.2 The assessment unit should be responsible for assessing as a minimum whether activities are being performed in accordance with specified requirements and should, where possible, identify improvement opportunities. The assessment unit, for example :

- defines the assessment techniques;
- identifies the resources needed to achieve an effective assessment;
- obtains access for assessment teams to the levels of management having the responsibility and authority to ensure corrective actions and preventive actions;
- makes arrangements for temporary assignment of specialists to assessment teams;
- defines the methods and schedules for initiating, conducting and reporting assessments;
- determines the distribution list for the assessment reports; and
- makes provisions for follow-up activities.

3.3.3 In order to focus their assessment properly on performance, the assessment unit should have information about daily work schedule and long term planning. They should also have access to information such as:

- what and where the major safety and performance concerns are;
- whether deficiencies are increasing or decreasing;
- whether timely corrective actions are taken; and
- whether preventive measures are adequate.

3.3.4 The independent assessment need not necessarily be carried out always by the assessment unit. It may be beneficial for independent assessment to be carried out by other staff brought together for a specific assessment or by a joint team, including members of the assessment unit. Such other staff should have an understanding of the work area being assessed and be conversant with the type and methodology of assessment.

3.3.5 Personnel conducting independent assessment should not have responsibility for the work performance being assessed. Assessment personnel should exercise objectivity in examining evidence and in forming conclusions.

3.3.6 A team leader should be appointed to manage all phases of a specific assessment. The team members should follow the direction and guidance of the team leader. The team leader should be responsible for:

- selection of team members,
- planning,
- representing the team,
- managing the team during the assessment,
- preparing and submitting the report,
- checking the effectiveness of corrective actions, and
- ensuring that efforts are made to identify and implement preventive action.

3.3.7 Trainee members in the team should be adequately monitored and supervised until they are considered proficient in the type of assessment being carried out.

3.3.8 The attitude of assessors can also have an impact on the value of the assessment. Assessors should be capable of looking for improvement opportunities and providing recommendations to management. Problems should be reported in a way that will help management to understand what actions are needed.

4. PERFORMANCE OF ASSESSMENTS

4.1 General

4.1.1 Assessment activities include one or more of the following:

- Reviewing
- Checking
- Inspecting
- Testing
- Surveillance
- Auditing.

4.1.2 Some types of assessment, such as checking, inspecting and testing are normally objective. Results will be verified in accordance with written criteria. Similarly, surveillance and audits can be objectively evaluated against standards and/or specified requirements.

4.1.3 Other types of assessment such as peer evaluation could be mostly subjective, based on comparison with good practices and judgements against expert opinions. Senior management should evaluate the results of such activities before proposed actions are adopted.

4.2 Planning

4.2.1 An assessment plan should be established, taking into account the activities of the organisation, which may affect safety and the frequency and results of previous assessments. Assessments may be conducted on a limited scope of activity across a number of organisational units, or on all activities in a single organisational unit, or a combination of both.

4.2.2 Planning for an assessment should begin with the selection of areas, activities and requirements to be assessed. Assessment activities should be conducted in a manner so as not to cause any impact on plant safety. The assessment activities should be planned to have minimal impact on normal plant activities.

4.2.3 The assessor should maximise the effectiveness of the planning by using all available information and resources.

4.2.4 A plan for each assessment should be established to identify the topics and grade their priority. Such a plan is not intended to be a procedure or checklist,

but an aid to the assessor in keeping the assessment objectives clearly in mind. Assessment plans should be agreed with the management of the organisation.

4.2.5 The assessment schedule should allow adequate time for preparation, which includes familiarisation of the areas to be assessed, conduct of the assessment, evaluation of identified concerns and reporting of results.

4.3 Conduct

4.3.1 Some activities can only be properly evaluated after a thorough in-process observation has taken place. Assessment should concentrate on observations of activities that have been performed. Assessors should also interview personnel and examine completed work activities. Where activities are not being performed at the time of assessment, a decision should be made on whether they should be observed at a later date.

4.3.2 While assessing an activity, the assessor should observe the sequence of operations and investigate in more detail if a problem is suspected.

4.3.3 If, during the course of the assessment, a deficiency is found, the assessor should observe other similar activities to determine the nature and extent of the problem (for example, whether it exists throughout the organisation).

4.3.4 In an assessment, information on equipment, personnel qualification and training should be examined. The assessor may need to ask personnel specific questions to determine, for example, their experience or knowledge of procedures. The assessor may also check the conformance with, and the adequacy of, the procedures.

4.3.5 Although the planning and conduct of an assessment may follow an organised plan, circumstances may arise that require flexibility. The assessor should pursue any questionable area after consultation with the team leader. This consultation will ensure that the investigation is worthwhile.

4.3.6 When the potential non-conformances are encountered, the assessor should check to determine if these have already been identified by management and if actions are being implemented to correct them. (Potential non-conformity is explained in Annexure-II). Conditions found during the assessment, which require prompt attention, should be immediately brought to the attention of management.

4.3.7 When potential non-conformances are detected, they should be discussed with the responsible persons to avoid misunderstandings.

4.4 Evaluation

4.4.1 The assessor should analyse and consider the cause of potential non-conformances in order to evaluate the proposed corrective actions.

4.4.2 Findings should describe the non-conformance and not just provide an indication of the non-conformance. The assessor should also highlight good performance and identify any areas where improvement could be made.

4.4.3 Findings should be discussed among the assessment team members so that they can be sure of the applicability, improve consistency and look for generic problems.

4.5 Reporting

4.5.1 Assessment results should be reported clearly and promptly. The assessment report should communicate findings in a way that makes their significance readily apparent. For reports to be effective, they must be submitted in their final form as quickly as possible, emphasising particular items, if necessary. The report should include:

- a list of findings,
- a list of personnel contacted and procedures reviewed,
- a description of assessment methods adopted by the assessors,
- references to the assessment plan indicating areas assessed and their importance,
- a summary statement on whether the activities were satisfactory or not, and
- opportunities for improvement.

4.6 Follow-up Activities

4.6.1 The assessed organisation should review and investigate assessment findings to determine corrective actions, and prepare an implementation schedule and a written response to the report within a given time. The corrective actions and implementation schedule should be discussed between management and the team leader to help ensure that the corrective actions are adequate.

4.6.2 The assessed organisation should review and report on the progress achieved in completing corrective actions, so that senior management are aware of the status of corrective actions in their organisation.

4.6.3 The assessment unit of the organisation should verify the implementation of the corrective actions.

4.6.4 The assessment unit of the organisation should also verify that the assessed unit has identified preventive measures and prepared a plan for implementation of the same. The preventive measures should be subject of verification in the next assessment if it is a long-term measure.

4.6.5 On completion of all corrective actions and preventive actions, the assessment could be closed.

5. MANAGEMENT SELF-ASSESSMENT

5.1 General

5.1.1 The purpose of management self-assessment should be to evaluate the effectiveness of the QA programme, assess known performance issues, identify contributing management aspects and make improvements in management performance in all areas.

5.1.2 Management self-assessment should be regarded as an on-going process that determines how the QA programme is implemented and how well leadership is being provided to meet requirements and expectations. Management self-assessment should result in an improvement in nuclear safety and should be part of the organisation's quality improvement process.

5.1.3 Management at all levels, senior, line and supervisory managers, perform these self-assessments with an emphasis on the allocation of human and financial resources to achieve organisational goals and objectives.

5.1.4 At the senior management level, it is appropriate to perform a self-assessment to determine if the overall performance effectively focuses on meeting strategic goals, including safety goals. Reports from line management, summaries of both categories of assessment and regulatory feedback are useful sources of information on the overall performance of the organisation. It also assists in targeting improvement actions.

5.1.5 Line management is more likely to rely on surveillance and review of work performance. This would include, but not be limited to, surveillance of items, services and processes, review of design documents and validation, review of procedures and records, observation of independent assessments and regular visit of facilities.

5.1.6 At the supervisory level, direct observation of work, supported by inspection and testing, should be routinely carried out. Annexure-III gives an example of a hierarchy of management self-assessment.

5.2 Self-assessment Criteria

5.2.1 The following are examples of the criteria used to perform self-assessments:

(a) Leadership:

Senior management's personal leadership and involvement in following activities:

- Creating and sustaining continuous improvement
- Setting clear values and expectations
- Establishing a system that promotes performance excellence
- Integrating into the QA programme the fulfilment by the responsible organisation of its public responsibilities.

(b) Information and analysis:

- Management and effectiveness of the use of data and information to support performance excellence.

(c) Strategic planning:

- Setting strategic directions
- Determining key plan requirements
- Translation of plan requirements into effective performance.

(d) Human resources development and management:

- Enabling the workforce to develop and utilise its full potential, aligned with the responsible organisation's performance objectives
- Responsible organisation efforts to build and maintain an environment conducive to performance excellence, full participation of work force in various activities and personnel and organisational growth.

(e) Process management:

- Designing, managing and improving key processes to achieve higher performance.

(f) Measuring results:

- Responsible organisation's performance and improvement in the key areas
- Safety and quality
- Productivity and operational effectiveness
- Performance indicators linked to these areas.

(g) External focus:

- Responsible organisation's systems of learning

- Building and maintaining relationships
- Levels and trends in key measures of success
- Service availability and responsiveness to changing requirements.

5.3 Inputs

5.3.1 Input to management self-assessment should include information on:

- Safety results/trends and performance indicators
- Current performance analysis, such as peer evaluation feedback, surveillance and technical review results
- Adequacy of the QA programme of the responsible organisation
- Effectiveness of management procedures/work instructions
- Organisational issues, such as levels of authority and responsibility, interfaces, communications, recruitment, training and promotion policies
- Effect of regulatory and statutory requirements and any changes to them
- Overall performance including safety and reliability considerations
- Strategic planning, mission of the organisation and nuclear safety objective
- Feedback from experience.

5.4 Reporting

5.4.1 Existing reporting mechanisms should be used.

6. INDEPENDENT ASSESSMENT

6.1 General

6.1.1 Independent assessment, such as internal audits, external audits, surveillance, peer evaluation and technical review, should be carried out with special emphasis on safety aspects and areas where problems have been found. Assessment objectives should be reviewed periodically to reflect current management concerns and performance activities. Appropriate combinations of various types of assessment should be used to provide the evaluation of performance which will be most balanced.

6.2 Internal Audits

6.2.1 A system for internal audits should be established by the assessment unit and agreed with the management of the organisation.

6.2.2 Internal audits are conducted on behalf of management by the independent assessment unit to determine whether activities and related results comply with the basic requirements of the Code and whether the established QA programme is adequate and being implemented effectively to achieve nuclear safety objectives.

6.2.3 Internal audits should not be conducted with the sole purpose of determining compliance with requirements. They should be conducted to evaluate the need for corrective actions, with the emphasis on seeking opportunities for improvement and enhancing safety standards.

6.2.4 Internal audits should be conducted on an on-going basis, but they should also be prompted by significant changes in the QA programme or the associated processes or by performance and nuclear safety weaknesses.

6.3 External Audits

6.3.1 External audits should be managed by the assessment unit on behalf of management, who agree to the schedule of audits to be performed. The frequency of audits should be determined by the performance of the unit concerned.

6.3.2 As a typical example, in the manufacture or supply of an item, external audit should be carried out when,

- it is necessary to determine the capability of a supplier and the adequacy of its QA programme before awarding a contract or placing a purchase order;

- after award of a contract, it is necessary to determine whether the supplier is appropriately performing the functions as defined in the QA programme, applicable codes and standards and other contract documents;
- significant changes are made in the supplier's QA programme, such as significant re-organisation or significant revisions of procedures; and
- it is suspected that the quality of an item or service is in jeopardy owing to a deficiency, either in the requirements or in the QA programme.

6.3.3 External audits should be carried out by responsible organisation on subordinate units.

6.4 Surveillance

6.4.1 Surveillance of work performance is considered to be the best technique for assessing and reporting on a specific area, or an on-going activity. It is flexible and less formal than audits and can be performed in a relatively short period of time with limited preparation. However, advance notice should usually be given. Surveillance is normally carried out to:

- provide information and data in a specific performance area;
- provide information and data on an individual activity;
- provide immediate feedback of results; and
- follow up on previous assessment observations.

6.4.2 Surveillance may show product deficiencies or indications of localised weakness in the QA programme. When the work is intellectual, selective analyses and random checks of results are considered to be more appropriate.

6.4.3 Surveillance is more suited where:

- flexibility of timing, method, personnel and reporting is desirable;
- additional information is required to develop conclusions regarding previous assessments; and
- there is a need to respond to opportunities that arise at short notice.

6.4.4 Several surveillance visits are required over a period of time for activities, which occur frequently or for determining existence of any trend.

6.4.5 A single surveillance should not be considered to be sufficient to fully assess the overall effectiveness of the QA programme. In addition to monitoring activities and the observation of work being done, reviews of documentation and interviews are also needed.

6.5 Peer Evaluation

6.5.1 Peer evaluation is a critical examination of specific nuclear safety related subjects by senior staff from one or more other nuclear power plants to seek improvements and to promote good practices. The evaluation team should consist of experts in all areas of evaluation to share experience and also to develop relationships between the peers and the people at the nuclear power plants.

6.5.2 Senior management should consider developing, on the basis of best international practices, a set of performance indicators, objectives standards and criteria against which performance can be evaluated. For a nuclear power plant, performance objectives in areas such as operation, maintenance, chemistry, reactor engineering, radiation protection, fire protection and emergency planning should be considered and developed.

6.5.3 This type of assessment is both objective, in that it compares against the performance standards and objectives, and subjective, in that it uses the collective knowledge of the peers to identify areas for improvement and good practices.

6.5.4 During the evaluation, observation of the work should be done and a judgement made on the basis of the methods used and results achieved. A written report of problems and good practices observed should be presented to management. Management should develop an action plan to implement any improvement and ensure that information on good practices is made known to others within the organisation.

6.6 Technical Review

6.6.1 Senior management may arrange for a review of the technical content of activities and processes, with a view to improving the effectiveness of these activities or processes.

6.6.2 Different techniques can be used, such as inspection and testing as well as emergency drills and exercises.

6.6.3 Senior management should define in clear terms the scope of each technical review, what is expected, when it will be implemented and who will implement it.

6.6.4 Those who are asked to perform a technical review should be qualified and competent in the area of work being assessed.

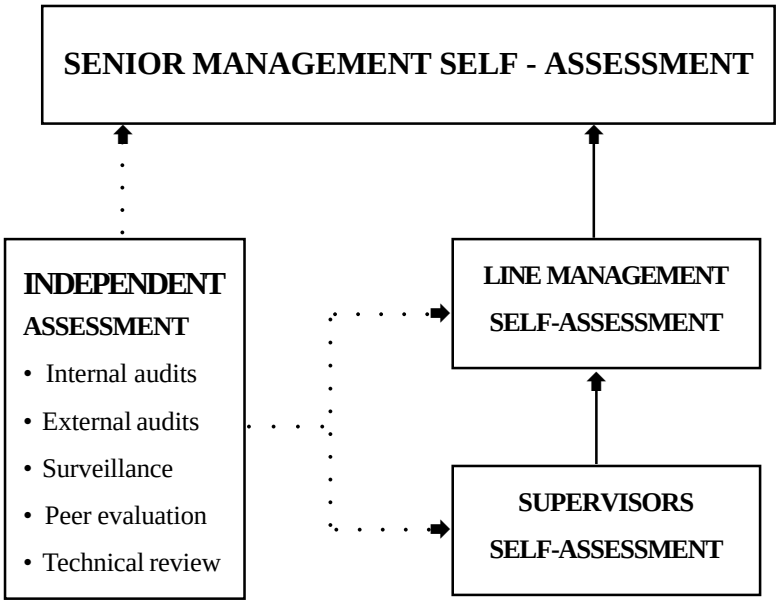
6.7 Management Review

6.7.1 Management review should be performed periodically by the senior management taking into account the outputs of the independent assessment and self assessment and take appropriate actions towards improvement of the safety and the performance of the plant, and the organisation as a whole.

ANNEXURE - I

(Refer section 2.1.3)

INTER-RELATION BETWEEN MANAGEMENT SELF-ASSESMENT AND INDEPENDENT ASSESSMENT



Legend : - - - - ➡ **INPUT** ——➡ **REPORTING**

ANNEXURE - II

(Refer section 3.2.4)

CORRECTIVE ACTION, PREVENTIVE ACTION AND POTENTIAL NON-CONFORMANCE

II.1 Preventive Action:

Action taken to eliminate the causes of a potential non-conformance or other undesirable potential situation in order to prevent occurrence (reference ISO 9000:2000) is called preventive action.

Sources of information pertaining to preventive action:

(a) Processes and work instruction which affect product quality
(b) Concessions
(c) Audit results
(d) Quality records
(e) Customer complaints/feed back

II.2 Corrective Action:

Action taken to eliminate the causes of a detected non-conformance or other undesirable situation in order to prevent recurrence (reference ISO 9000:2000) is called corrective action.

Sources of information pertaining to corrective action:

(a) Customer complaint/feed back
(b) Reports of product/service non-conformance

II.3 Potential Non-conformance vs. Detected Non-conformance:

Non-conformance which has not happened but there is a possibility that it may lead to actual non-conformance in future, if suitable action/measure is not taken is known as potential non-conformance.

II-4 Examples:

Example-1 Some audit observations may not be detected as non-conformance but if no action is taken it may lead to non-conformance at a later date.

Example-2 A non-conformance was detected in one office. Suitable corrective action is taken there to prevent it from recurrence. But, if same type of activity is being performed by other office of an organisation, and if suitable action is taken before occurrence of any non-conformance, in the second office based on corrective action of first office, then it can be called as preventive action for the second office.

Example-3 Tube to tube sheet welding:
Control chart is drawn based on average value of minimum leak path (MLP) and standard deduction obtained on sample tube to tube sheet welding procedure qualification mock up block. On control charts two lines are drawn as warning limit and action limit. Warning limit is the value of MLP which has not gone beyond tolerance limit; but if no action is taken, then the MLP in production tube to tube sheet welding may lead to non-conformance i.e. MLP will go beyond specification value. Action limit is the value beyond which non-conformance occurs.

So warning limit can be called as preventive action and action limit can be called as a corrective action.

ANNEXURE - III

(Refer section 5.1.6)

EXAMPLE OF A HIERARCHY OF MANAGEMENT SELF-ASSESSMENT

REVIEW

• 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**

SURVEILLANCE

• 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**

DISCRETE CHECK

• Checking • Inspecting • Testing	**SUPERVISORS**

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

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AERB/NPP/SG/ QA-8	Non-conformance Control and Corrective Actions for Nuclear Power Plants	Under Preparation
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