GUIDE NO. AERB/NPP/SG/QA-8

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GOVERNMENT OF INDIA

AERB SAFETY GUIDE

NON-CONFORMANCE CONTROL, CORRECTIVE AND PREVENTIVE ACTIONS FOR NUCLEAR POWER PLANTS

ATOMIC ENERGY REGULATORY BOARD

AERB SAFETY GUIDE NO. AERB/NPP/SG/QA-8

NON-CONFORMANCE CONTROL, CORRECTIVE AND PREVENTIVE ACTIONS FOR NUCLEAR POWER PLANTS

Atomic Energy Regulatory Board
Mumbai-400 094
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Price

Orders for this guide should be addressed to:

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FOREWORD

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

The AERB safety codes 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 in nuclear and radiation facilities. 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. These 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 the management principles and objectives to be met during the implementation of activities in different phases of the nuclear power plants (NPPs) 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 recommends the procedures to fulfil the requirements of the Code on non-conformance control and corrective actions for items, processes and services. 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. Some of the concepts, aspects and terms in this document have not been covered by the Code. These have been introduced keeping in view the current developments/ practices in the quality assurance field foreseeing the revision of the Code in near future.

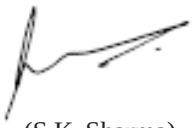
Consistent with the accepted practice, ‘shall’ and ‘should’ are used in the Guide to distinguish between a firm requirement and a desirable option, respectively. Annexures, footnotes, bibliography and lists of participants are included to provide further information on the subject that might be helpful 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, national and international standards, codes and guides applicable and acceptable to AERB should be followed. Non-radiological aspects of environmental protection and industrial safety 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 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, alongwith their affiliations is included for information.



(S.K. Sharma)
Chairman, AERB

DEFINITIONS

Assessment

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

Atomic Energy Regulatory Board (AERB)

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

Audit

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

Commencement of Operation of Nuclear Power Plant

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

Commissioning

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

Construction

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

Contractor

An individual or organisation rendering service (e.g. design, construction, inspection, review, maintenance and/or supplying items).

Decommissioning

The process by which a nuclear or radiation facility is finally taken out of operation in a manner that provides adequate protection to the health and safety of the workers, the public and the environment.

Disposition

An act to determine how a departure from a specified requirement is to be handled or settled.

Documentation

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

Grading (QA)

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

Inspection

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

Item

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

Nuclear Safety

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

Operation

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

Preventive Action

Action to eliminate the cause of a potential nonconformity (non-fulfilment of requirements) or other undesirable situation.

Quality

The totality of features and characteristics of an item or service that have the ability to satisfy stated or implied needs.

Quality Assurance (QA)

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

Quality Control (QC)

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

Responsible Organisation

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

Review

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

Services

The performance by a supplier of activities such as design, fabrication, installation, inspection, non-destructive examination, repair and/or maintenance.

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 on 'Non-conformance Control, Corrective and Preventive Actions for Nuclear Power Plants' is one of the series of the AERB safety guides on quality assurance (QA) for safety in nuclear power plants (NPPs). It gives recommendations related to the fulfillment of requirements given in Section-6 (Corrective Functions) of the Code of Practice on QA for Safety in Nuclear Power Plants (AERB Code No. SC/QA) hereinafter referred to as the Code.

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

1.1.3 Some of the concepts, aspects and terms in this document have not been covered by the Code. These have been introduced keeping in view the current developments/practices in the quality assurance field foreseeing the revision of the Code in near future.

1.2 Objective

1.2.1 This safety guide provides recommendations on how to fulfil the requirements of the Code on non-conformance[1] control and corrective[2] actions for items, processes and services. This guide also covers the recommendations on the preventive actions.

1.3 Scope

This safety guide applies to the QA programmes of the responsible organisation (RO) in all stages of a nuclear power plant and covers items, services and processes impacting nuclear safety. The guide is also applicable to any other organisation to whom RO's QA programme is delegated, such as consultants, vendors, sub-vendors, contractors, sub-contractors etc. This guide can be usefully applied to nuclear facilities other than NPPs.

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[1] Non-conformance: A deficiency in characteristics, documentation or procedure which renders the quality of an item unacceptable or indeterminate.

[2] Corrective Actions: Action to eliminate the cause of a detected non-conformance (non-fulfillment of requirements) or other undesirable situation.

2. GENERAL CONSIDERATIONS

2.1 Management Responsibilities

2.1.1 The management should empower personnel in the organisation with the authority and responsibility to report non-conformances at any stage of a process in order to ensure timely detection and disposition of non-conformances. Authority should be clearly defined to ensure appropriate disposition of non-conformance to meet item/process requirements.

Management shall establish and maintain a process or processes that provide for identifying, reporting, reviewing and physically controlling items, services or processes that do not conform to specified requirements. It is possible to develop several different processes to control non-conforming items, services or processes such as work defects, event reporting, operating rule breaches, technical specification violations, assessment findings, etc. Each process should make provisions to prevent inadvertent use or installation of items, services or processes that do not conform and ensure that effective corrective action is taken. Non-conformances should be recorded, together with their disposition, to facilitate learning and to provide data for analysis and improvement. A typical flow chart for control of non-conformances in manufacturing/construction/installation phase is given in Annexure-I.

2.1.2 Management should ensure that individuals performing work are aware of and use the process for prompt notification and reporting of non-conformances.

2.1.3 Management at all levels should encourage personnel to discover and report non-conformances. The responsible personnel after ensuring verified completion of the agreed corrective action shall provide feedback to all concerned including those personnel who notified the non-conformance.

2.1.4 The management should utilise the feedback arising out of corrective actions of reported non-conformances as well as normal course of work to aid in improving the effectiveness and efficiency of process.

2.1.5 Management should establish a QA procedure for identification, control and disposition of non-conformances and implementation of corrective and preventive actions.

2.2 Grading [3]

2.2.1 Nuclear safety shall be the fundamental consideration in the identification of the items, services and processes to which the QA programme applies. A

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[3] For guidance on grading see 'IAEA Technical Reports Series No.328'.

graded approach, based on the relative importance to nuclear safety of each item, service or process, should be used. The graded approach shall reflect a planned and recognised difference in the applications of specific QA requirements.

2.2.2 Annexure-II provides an example of the application of the graded approach in the non-conformance control process. Grading will be decided by the relative importance to safety with reference to specific non-conformance, grade-1 being the highest level.

3. NON-CONFORMANCE CONTROL

3.1 Non-conformance Identification

3.1.1 Any authorised person who finds or is informed of items, services or processes which do not meet specified requirements, or who observes abnormality, shall notify and formally report the matter to the appropriate level of management.

3.1.2 Conditions and events to be handled by the non-conformance control process could include:

- Physical characteristics outside specified limits, such as dimensional and/or material parameters, installation errors and item/system performance deficiencies
- Deviations from approved process parameters or procedures
- Failure of personnel to implement work, inspection or test instructions
- Inadequate documentation containing incorrect or incomplete information
- Inadequate training/qualification of personnel to perform assigned tasks
- In-service Inspection
- Malfunctions and failures.

3.1.3 Non-conformances may be discovered during:

- Performance of work
- Inspection and testing for acceptance
- Surveillance including process monitoring
- Procurement
- Assessments (for example audits)
- Regulatory inspections.

3.2 Reporting

3.2.1 A formal report of non-conformance should for example:

- Identify who is reporting the non-conformance, when it was found and to whom it was reported.
- Identify the non-conforming item, service or process and state the location, the method used to physically mark, label, segregate or otherwise control the item, the service or process to prevent their inadvertent use;

- Include a description of the non-conformance and applicable specified requirement.

Describe the immediate action taken by the originator, or known to be taken by others, to minimise adverse effects of the non-conformance.

The non-conformances should be reported in sufficient detail to allow proper review. Unique identification should be given to each report to allow effective tracking. Examples of information, which could be included in a non-conformance report, are shown in Annexure-III.

3.3 Initial Actions

3.3.1 On being informed of a non-conformance, the authorised person should promptly:

- Ensure that a report has been raised, verify the details contained in it and acknowledge notification.
- Confirm that the item, service or process has been identified (i.e. physically marked, labeled, segregated or otherwise controlled) as non-conforming.
- Initiate immediate, necessary action to minimise/eliminate the effect of the non-conformance.
- Determine what restrictions on further use of the item, service or process should be put in place.
- Refer for a more detailed review of the non-conformance, taking into account the guidance in subsection 3.6.
- Inform AERB, in case of significant safety implication and other nuclear power plants, if necessary.

3.4 Labeling and Identification

3.4.1 As soon as an item, process or service is recognised as being non-conforming, it should be physically marked, labeled, segregated or otherwise controlled. The labeling and identification system should include arrangements to ensure that:

- Marking, labeling and other information is consistent with the content of the non-conformance report (see 3.2.1 sub-section)
- The inspection, test or operational status of the item, service or process is clear
- The non-conforming status is clear, both on the item and at any remote operation or indication points connected to it
- It is clear who is authorised to change the status of an item, service or process
- Any restrictions on the use of the item or service are identified

3.5 Segregation

3.5.1 Consideration should be given to physically segregating a non-conforming item or process to ensure that it is not used before any agreed and approved corrective action has been taken. Segregation may be achieved by removal to a secured area, placing behind barriers, isolating the non-conforming item, or stopping the service or process, or by administrative control.

3.6 Review of Non-conformances

3.6.1 Non-conformances should be reviewed as soon as practicable by appropriate personnel taking the following into account.

- The QA grade or classification of the affected item, service or process.
- The safety implications of the non-conformance.
- The need to involve the design organisation or other persons who have access to the original design information, including any subsequent modifications.
- The need to involve the operating organisation.
- The need to involve the original supplier.
- The need to involve AERB.
- The need to address issues related to similar non-conformances.

The review should determine

(a) The cause of the identified non-conformance, which could include failures, material degradation, malfunctions, incorrect materials, tools, equipment, procedures, information, training or human error. Root cause analysis techniques should be used.

(b) The corrective actions (see Section 4) to be agreed and approved to correct the non-conformance and prevent repetition of similar non-conformances which may also include:

(i) identification of any other affected items,

(ii) reverification to demonstrate conformity to the requirements,

(iii) the amendment of relevant/approved documentation, and

(iv) any restrictions or requirements for the implementation of corrective action.

3.6.2 The results of the review should refer to the non-conformance report.

3.6.3 During the review additional information about the nature of the non-conformance and restrictions to be imposed on further processing or operation should be made available to concerned organisations, AERB (in case of significant safety implications) and other nuclear power plants if required.

3.7 Actions Subsequent to Review of Non-conformances

3.7.1 Information about the non-conformance and implications to safety should be used to determine the impact on affected activities until the agreed and approved corrective action is verified as having been satisfactorily completed. The following are typical effects that should be considered:

- Requirements to carry out additional inspection or testing, in order to obtain higher levels of confidence in items.
- Restrictions on further processing of items or services during manufacture or construction.
- Restriction on the use of other components from the same supplier
- Restriction on use of documents.
- Restrictions on operating regimes through changes in operating limits and conditions or amendments to maintenance schedules.
- Stoppage of the work if it is determined that its continuation would lead to an unsafe condition.
- Retraining of personnel.
- Relevance of specifications of non-conforming items, services or process.

3.7.2 Following review, disposition of non - conformances could be effected in one of the following ways:

(a) Reject (also sometimes referred to as scrap) - The non-conforming item, service or process is not fit for the intended use. Such non-conformances should be marked and segregated as soon as the action is agreed and approved.

(b) Repair - The non-conforming item, when repaired (or in the case of documents when revised) is capable of functioning in accordance with the design requirements, although it does not fully conform to the original design specification. Temporary repair should have a prescribed period of validity.

(c) Rework - The item is capable of being fully restored to the original specification requirements, i.e. some additional rework carried out under suitable conditions will correct the non-conformance.

(d) Accept with conditions[4] - In this instance it is likely that the non-conforming item, service or process will be fit for use under special, specified conditions.

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[4] This is not a specified mode of disposition in the code. However, this is included being a prevailing practice and in line with IAEA/SG/Q-2 (1996).

(e) Accept without modification (also sometimes referred to as use-as-is) - In this instance it is likely that the non-conforming item, service or process deviates marginally from specified requirements but is still declared fit for use.

3.7.3 Relevant information on the status of non-conformances should be documented and reported to management and AERB, as required.

4. CORRECTIVE ACTIONS

4.1 Methodology for Corrective Actions

4.1.1 Sources of information for considering corrective actions include following:

(a) Non-conformance reports

(b) Audit reports

(c) Data analysis reports

(d) Record of process parameters

(e) In-service inspection reports

(f) Station log books

(g) Incident reports

(h) Test & maintenance reports

4.1.2 A document elaborating the corrective action based on the review of non-conformance should be prepared, reviewed and approved by designated authority. Wherever required, the corrective action should be validated prior to implementation by analysis/mock-up.

4.1.3 Corrective action should be commensurate with grading of non-conformance.

4.2 Completion of Corrective Actions

4.2.1 Corrective actions should not be considered complete until all affected documents have been amended, modifications implemented and evidence of verification of completion obtained.

4.2.2 Management should allocate responsibilities for monitoring non-conformances from the reporting stage to verified completion of the agreed corrective action and providing feedback to those personnel who discovered the non-conformance.

4.2.3 After implementation of the corrective action of the non-conforming item, service or process, conformance to requirement should be verified, certified and documented.

5. PREVENTIVE ACTIONS

5.1 The purpose of preventive actions is to preclude the recurrence of non-conformances and or potential non-conformances from occurring and to improve plant safety and performance. Preventive actions may include, but need not be limited to the following:

- Changes in designs, specifications, procedures.
- Enforcement of the requirements of procedures, work instructions.
- Issue of new procedures.
- Withdrawal of defective equipment for maintenance or calibration.
- Training and qualification of personnel involved.
- Improvements in the QA programme/management system[5] .

5.2 Designated personnel in the organisation should periodically analyse available information, such as non-conformance reports, audit reports, maintenance reports, operating logs, significant event records and plant safety reviews. This analysis should seek out trends in order to identify problematic areas requiring root cause analysis, to confirm that appropriate actions have been taken to prevent repetition of the non-conformances and to enhance plant safety and performance. Information on incidents, events or quality related problems available from other nuclear power plants/organisations (operational experience feedback) should be assessed in order that suitable preventive measures can be developed and implemented. Such data should be reported to management for implementation.

Implementation of preventive actions may proceed in stages. In such cases each stage should be clearly defined and the means of verification specified to assure that the actions have been effective. Prior to implementation, all proposed actions should have been agreed, documented and authorised by appropriate personnel and AERB, if required.

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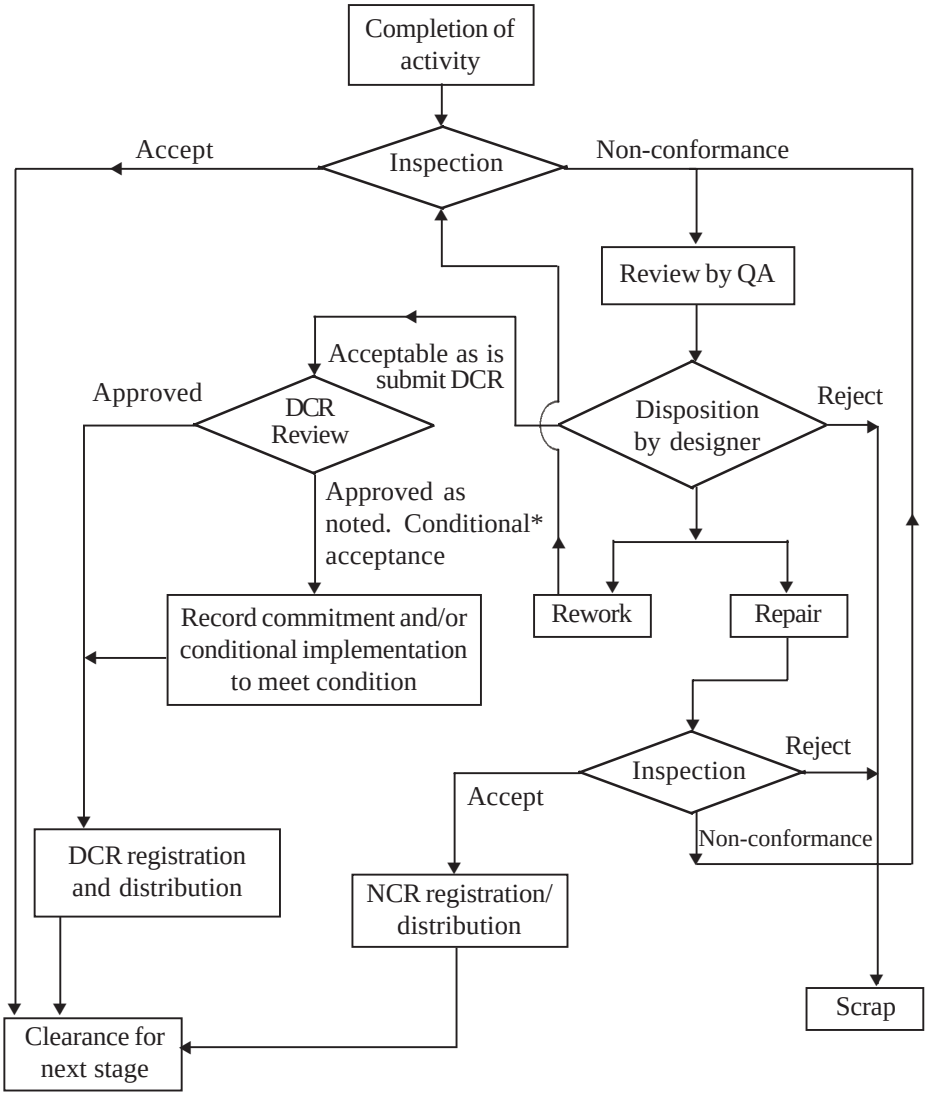
[5] Management system : Set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives.

ANNEXURE - I

TYPICAL FLOW CHART FOR CONTROL OF NON-CONFORMANCE



DCR: Design Concession Request
NCR: Non-conformance Report

* After conditional acceptance of the design concession, no rework is envisaged on the non-conforming item.

ANNEXURE - II

EXAMPLES OF GRADING IN NON-CONFORMANCE CONTROL

The grading of non-conformances should be performed by personnel of appropriate experience to the type of non-conformances. The following text provides an example of what the requirements for each grade could be:

Grade 1 (highest level)

- Identify and hold non-conformances for evaluation.
- Report non-conformances to senior management and AERB if required.
- Define the responsibilities and authority of those assigned to the disposition of non-conforming items, services and processes.
- Provide for a review of the non-conformance involving representatives from all relevant organisational units, including the assessment (or quality assurance) unit.
- Record each non-conformance.
- Obtain concurrence of all responsible parties for agreed corrective actions.
- Identify all non-conforming items, services or processes, mark them and place them in a segregated holding area when feasible.
- Ensure that reworked and repaired items are reinspected and retested according to the original or approved modified requirements.
- Verify that the agreed and approved corrective action has been properly implemented.
- Maintain records on all non-conformances, agreed corrective actions, results of reinspection and retests in the form of NCR/DCR.

Grade-2

- Identify and hold non-conformances for evaluation.
- Contact those individuals assigned to the disposition of non-conforming items, services and processes.
- Record each non-conformance .
- Identify agreed and approved corrective action.
- Verify that the agreed and approved corrective action has been properly implemented.

Grade-3

- Identify and hold non-conformances for evaluation.
- Contact those individuals assigned to implement corrective action.
- Identify all non-conforming items.
- Release non-conformances for agreed and approved corrective actions when instructed.

Grade-4

- Identify and correct non-conformances as they occur.
- Record non-conformance data for trend analysis.

ANNEXURE - III

NON-CONFORMANCE REPORT - TYPICAL CONTENT

The following list of headings for a non-conformance report may be considered, but it is not necessarily a full list. On the other hand, not all its headings are applicable for every non-conformance. Responsible organisation should consider their own activities, the stage of the nuclear power plant in which the work is being undertaken and the importance of any item to safety. From these considerations they should then develop their own reporting requirements.

Example 1

Non-conformance reporting content for items/services:

- Unique number
- Description of non-conformance including its grading
- Plant item and location of non-conformance
- When discovered (time/date)
- By whom discovered (name/department/organisation)
- How discovered
- Immediate action taken
- To whom the report is addressed
- Reported at (time/date) (Note: Important and urgent items may be initially reported by verbal communication and then confirmed in writing. Both actions should be documented in the report)
- Signature to record acceptance of the form.

The status of the item under corrective action should be recorded with respect to the following:

- To whom reported (name/position/organisation)
- Verification of non-conformance details
- Initial assessment of implication with regard to safety
- Notification to management/other affected personnel and as appropriate to AERB.
- Physical marks, labels or other controls implemented on other items or systems potentially affected by the non-conformance

- Root cause
- Agreed corrective action (immediate/short term/long term)
- Agreement of designer
- Restrictions to be applied during the implementation of the agreed corrective action and if necessary in the longer term
- Documentation requiring change.
- Related instructions for implementation of the agreed actions
- Verification of completion (name/date/time)

Example 2

Non-conformance reporting content for processes:

- Report no.
- Plant
- Location or installation
- Title of occurrence of non-conforming (unusual) event
- Date and time of occurrence
- Status of installation (power, start-up, shut down, testing etc. to be ticked off)
- Category of unusual event (if relevant)
- Date of prompt notification and means thereof
- Description
- Additional useful information for assessment
- Affected system components
- Radiological information
- Cause of occurrence
- Consequences of occurrence
- Effect on site personnel (injuries, radiation exposures)
- Conditions in installation after occurrence
- Safety assessment
- Root cause
- Corrective actions
- Lessons learned
- List of supporting documents annexed
- Signatures such as: prepared by, countersigned by, and approved by

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LIST OF PARTICIPANTS

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

Safety Series No.	Title	Year of Publication
AERB/SC/QA	Code of Practice on Quality Assurance for Safety in Nuclear Power Plants	1988
AERB/SG/QA-1	Quality Assurance in the Design of Nuclear Power Plants	2001
AERB/SG/QA-2	Quality Assurance in the Procurement of Items and Services for Nuclear Power Plants	1998
AERB/SG/QA-3	Quality Assurance in the Manufacture of Items for Nuclear Power Plants	1998
AERB/SG/QA-4	Quality Assurance during Site Construction of Nuclear Power Plants	2001
AERB/SG/QA-5	Quality Assurance during Commissioning and Operation of Nuclear Power Plants	1993
AERB/NPP/SG/ QA-6	Establishing and Implementing a Quality Assurance Programme for Nuclear Power Plants	2005
AERB/NPP/SG/ QA-7	Assessment of Implementation of Quality Assurance Programme in Nuclear Power Plants	2005
AERB/NPP/SG/ QA-8	Non-conformance Control, Corrective and Preventive Actions for Nuclear Power Plants	2006
AERB/NPP/SG/ QA-9	Document Control and Records Management for Quality Assurance in Nuclear Power Plants	2006

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