National Nuclear Regulator

Requirements Document

No.	Title	Rev.
RD-0034	**Quality and Safety Management Requirements for Nuclear Installations**	**0**

Approved:

GA Clapisson
Acting Chief Executive Officer

Date of issue: 15/09/2008

Revision Date:

APPROVAL RECORD

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REVISION HISTORY

Rev No.	Date Approved	Nature of Revision	Prepared by
0		First issue Supersedes LD-1094 rev 3	A Botha

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1 Introduction

In terms of the provisions of section 21 of the National Nuclear Regulator Act, Act No. 47 of 1999 /1/, the siting, construction, operation, decontamination or decommissioning of any nuclear installation as defined in the NNRA must be authorised by way of a nuclear installation licence granted by the National Nuclear Regulator (NNR).

The legislation also authorises the inclusion in the nuclear installation licence of any conditions deemed necessary by the Chief Executive Officer of the NNR to ensure the protection of persons, property and the environment against nuclear damage or for the rehabilitation of the site.

The principal requirements that must be met to ensure safety in any nuclear installation are presented in the Regulations on Safety Standards and Regulatory Practices published as Regulation No. R388 dated 28 April 2006 (RSRP) /2/.

The RSRP requires amongst others that:

- "*A safety culture must be fostered to encourage a questioning and learning attitude to radiation protection and nuclear safety and to discourage complacency.*"
- "*A quality management programme must be established, implemented and maintained in order to ensure compliance with the conditions of the nuclear authorization.*"

Furthermore, principle 3 of the Fundamental Safety Principles of the IAEA Safety Standards /8/ states that:

"*Effective leadership and management for safety must be established and sustained in organisations concerned with, and facilities and activities that give rise to radiation risks.*"

The publication states further that "*leadership for safety must be demonstrated at the highest levels in an organisation*" and that "*safety has to be achieved by means of an effective management system*".

The above statements highlights the importance of management systems within organisations and provides the basis for this Requirements Document (RD).

The licensee has to refer to the NNR for any interpretation or clarification of statements and requirements contained in this RD.

2 Purpose

This document details the requirements of the NNR for quality and safety management systems for licensees, applicants of a nuclear licence, as well as for designers and suppliers involved in the design, manufacturing, construction, commissioning, operation, modification and potential decommissioning for a nuclear installation in South Africa under the National Nuclear Regulator Act of 1999 (NNRA) /1/.

3 Objectives

The objectives of this document are to:

- Define the relevant quality and safety management requirements to ensure that safety is appropriately taken into account in all activities and decisions by licensees and suppliers involved in the life cycle of a nuclear installation.
- Describe the multi level concept approach for an Integrated Management System (IMS) considering the quality and safety management requirements.
- Define the principles for Safety Culture implementation in the respective organisations.

4 Scope

All parties and organisations that are in any way involved in activities important to nuclear safety related to siting, design, manufacture, construction, operation, modification, and eventual decommissioning of a nuclear installation, as defined in the NNR Safety Regulations /2/, are required to develop, introduce and maintain Management Systems that appropriately comply with the applicable requirements of this document.

The IMS requirements defined in this RD directly relate to Quality and Safety Management. Aspects such as security, economics, and environmental or health management are outside the scope of this RD but should form part of the management system of an organisation /4/.

This RD also defines the principles for Safety Culture implementation in the framework of an IMS.

4.1 Retrospective Application of Requirements

The holders of existing nuclear installation authorisations must submit to the NNR, upon issuance of these requirements to holders of existing nuclear installation licensees, within 2 months an action plan to achieve full compliance to these requirements.

5 Definitions and Abbreviations

5.1 Terms defined in the NNRA or in the RSRP

In this RD any word or expression to which a meaning has been assigned in the NNRA /1/ or RSRP /2/ shall have the meaning so assigned.

5.2 Terms not defined in the NNRA or in the RSRP

Many terms and definitions given in this RD are as defined in ISO 9001:2000 /3/ and are therefore not repeated in this section. Only additional terms, definitions and abbreviations are provided.

Term, Definition	Explanation
Acceptance Criteria	Specified limits placed on the performance, results, or other characteristics of an item, process, or service defined in codes, standards, or other requirement documents
Authorised Inspection Agency	An organisation that is empowered by the local authority or responsible body to provide inspection personnel and services as required by the regulations, standards or codes.
Certification	The act of determining, verifying, and attesting in writing to the qualifications of personnel, processes, procedures, or items in accordance with specified requirements
Conformity Assessment	Conformity assessment is any activity to determine, directly or indirectly, that a process, product, or service meets relevant standards and fulfils relevant requirements.
Construction	Those actions required to assemble components, parts, and appurtenances to functional units at site. Those actions may include forming, machining, assembling, welding, brazing, heat treating, examination, testing, inspection, and certification of manufactured products. Construction does not include design and manufacturing of products.
Configuration	The physical, functional, and operational characteristics of the structures, systems, components, or parts of the existing installation
Configuration Management	The process that controls the activities and interfaces among design, construction, operation and licensing to ensure throughout the life cycle that the configuration of the nuclear installation is established, approved and maintained
Design Change	Any revision or alteration of the technical requirements or design defined by approved and issued design documents and approved and issued changes thereto
Design Review	A critical review to provide assurance that the design is correct, satisfactory and compliant with the design specifications
Design Specifications	Documents providing the complete basis for manufacturing and construction of a product. Design specifications are part of the procurement documents of a product and specify the required characteristics of a product.
Deviation	a departure from specified requirements

Term, Definition	Explanation
Equipment	An all-inclusive term used in place of any of the following: appurtenances, assemblies, components, instrumentation and control devices (including software), supporting structures, subassemblies, subsystems
Fundamental Safety Functions	The Fundamental Safety Functions to be ensured for a nuclear reactor are defined as - Reactivity Control - Heat Removal - Confinement of Radioactivity The FSF are provided by single or combinations of the Safety Functions.
Inspection	Examination, measurement, testing or gauging to verify whether an item or activity conforms to specified requirements
In-Service Inspections	Are inspections of SSC of a nuclear installation which are performed in specified time intervals or in dependence of specific occurrences during operation or outages.
Integrated Management System	A single coherent management system in which all the organisational processes are integrated to enable the organisation's goals, strategies, plans and objectives to be achieved.
Intelligent Customer	The capability of the organisation to have a clear understanding and knowledge of the product or service being supplied
Item	an all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, sub-assembly, subsystem, system, or unit
Licensee	Any organization or person applying for authorization or authorized in terms of the NNR Act /1/ for a nuclear installation licence.
Licensing document(s)	Documents to be submitted to the NNR in support of licence application, or variations to the licence, or modifications of operating nuclear installations.
Life cycle (of a nuclear installation)	Includes all the stages of a nuclear installation where regulatory control related to safety must be exercised as defined in section 5) of the NNRA, viz: • siting, • design • construction, • manufacture of component parts • operation, • decontamination or decommissioning of any nuclear installation as defined of the NNRA
Manufacturing	Those actions required to manufacture source material, components, parts and appurtenances. These actions may include forming, machining, assembling, welding, brazing, heat treating, examination, testing, inspection, and certification. Manufacturing does not include design and on site construction.
Measuring And Test Equipment	Devices or systems used to calibrate, measure, gauge, test, or inspect in order to control or acquire data to verify conformance to specified requirements

Term, Definition	Explanation
Non-Conformance	a deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate
Objective Evidence	data supporting the existence or verity of something;
Procurement Documents	A set of documents specifying the necessary technical information and data, process and functional requirements, environmental conditions, loads, codes and standards as well as the QA-measures for the products to be purchased. Procurement documents include Design Specifications.
Product	A product is the result of a material or non-material process including services.
Products of High Importance to Nuclear Safety	Products whose failure can compromise the Fundamental Safety Functions of a nuclear installation and / or violate the Dose and Risk Limits as defined in the RSRP /2/.
Products important to nuclear safety	Provide or support safety functions to ensure nuclear safety in terms of the Fundamental Safety Functions. Products important to nuclear safety (SSC) are safety classified.
Qualified Procedure	an approved procedure that has been demonstrated to meet the specified requirements for its intended purpose
Quality Plan	document specifying which qualified procedures and associated resources will be applied by whom and when to a specific project, product, process or contract
Resources	'Resources' includes personnel, infrastructure, the working environment, information and knowledge, and suppliers, as well as material and financial resources.
Repair	The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired, even though that item still does not conform to the original requirement.
Rework	The process by which an item is made to conform to original requirements by completion or correction.
Safety Classification System	A grading system that classifies SSC commensurate with their importance to nuclear safety.
Safety Culture	Characteristics and attitudes of organisations and individuals which ensure that, as an overriding priority, nuclear safety issues receive the attention warranted by their significance.
Safety Functions	Specific SSC functions that must be accomplished for nuclear safety at SSC level to support the achievement of a Fundamental Safety Function
Senior Management	The person who, or group of people which directs, controls and assesses an organisation at the highest level.
Special Process	A process, the results of which are highly dependent on the control of the process or the skills of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Term, Definition	Explanation
(Approved) Supplier	Organisation or person that provides a product. This definition also covers sub-suppliers. "Supplier" includes in principal designers and/or architect engineer. An approved supplier has been evaluated and approved by the licensee in accordance with the requirements of this RD and with the licensee requirements.
Supporting Processes	These are processes supporting the main management processes during the life cycle of the nuclear installation such as failure analysis, optimisation and licensing, engineering, security, infrastructure, radiation protection.
Testing	An element of verification for the determination of the capability of an item or SSC to meet specified requirements by subjecting the item / SSC to a set of physical, chemical, environmental, accidental or operating conditions

5.3 Abbreviations

Abbreviation	Explanation
AIA	Authorised Inspection Agency
IMS	Integrated Management System
ISI	In-Service Inspection
QA	Quality Assurance
QMS	Quality Management System
RSRP	Regulations in terms of section 36, read with section 47 of the NNR Act no. 47 of 1999 on Safety Standards and Regulatory Practises
SC	Safety Culture
SCEP	Safety Culture Enhancement Programme
SM	Safety Management
SSC	Structures, System and Components (include items and equipment)
RSA	Republic of South Africa

6 The Integrated Management System Approach

6.1 Structure of an Integrated Management System (IMS)

The multi level IMS concept described in this section is illustrated in Figure 1 below. The application of the requirements and deployment of the appropriate resources need to be determined for an organisation on the basis of the safety importance and complexity of the organisation's products. The safety importance is derived considering the following aspects:

- The hazards and the potential impact on nuclear and radiation safety associated with attributes of the product;
- The possible nuclear consequences in terms of the Fundamental Safety Functions if any Structures, Systems and Components (SSC) fail or a service is carried out incorrectly.

The scope of the management system has to be appropriate to the safety importance of the products provided by the respective organisation.

For application of the multi level concept under consideration of the requirements of this RD, a safety and quality classification system of the SSC of the nuclear installation is a prerequisite (see requirement (1.) in 7.1). The holder of a nuclear installation licence is responsible for the implementation of such a classification system. In this RD, services are considered as products and have to be classified.

The IMS-structure of this RD consists of three levels:

Level 1 (Direct influence on the safety performance of the nuclear installation):
The licensee as well as suppliers assigned responsible for products of high importance to nuclear safety must additional to the Quality Management System (QMS) implement a Safety Management System as part of an Integrated Management System (see section 6.3). These organisations with a direct influence on the safety performance of the nuclear installation are additionally required to consider Safety Culture aspects as part of their IMS.

Level 2 (Products important to nuclear safety):
A QMS is required for organisations providing products important to nuclear safety which is compliant with /3/ or any equivalent international accepted QM standard. Accreditations according to accepted nuclear QM standards (e.g. /5/) would be considered as a basis if provided for the organisation. In addition QM processes, design codes and standards have to be applied that are specific to nuclear installations. The safety and quality classification of the SSC and the application of the nuclear codes and standards require additional QM and SSC related QA measures which need to be implemented in the QMS of the respective organisations.

Level 3 (All products of the Nuclear Installation):
The implementation of an appropriate QMS is mandatory as a basis for all organisations involved in the products related to an application for or operation of a nuclear installation. The QMS requirements of the applied QM standard should include the consideration of the Quality Assurance (QA) measures specified for the particular products of the organisation. The determination of QM/QA requirements

and the associated QM/QA system for products with no importance to nuclear safety rests with the licensee.

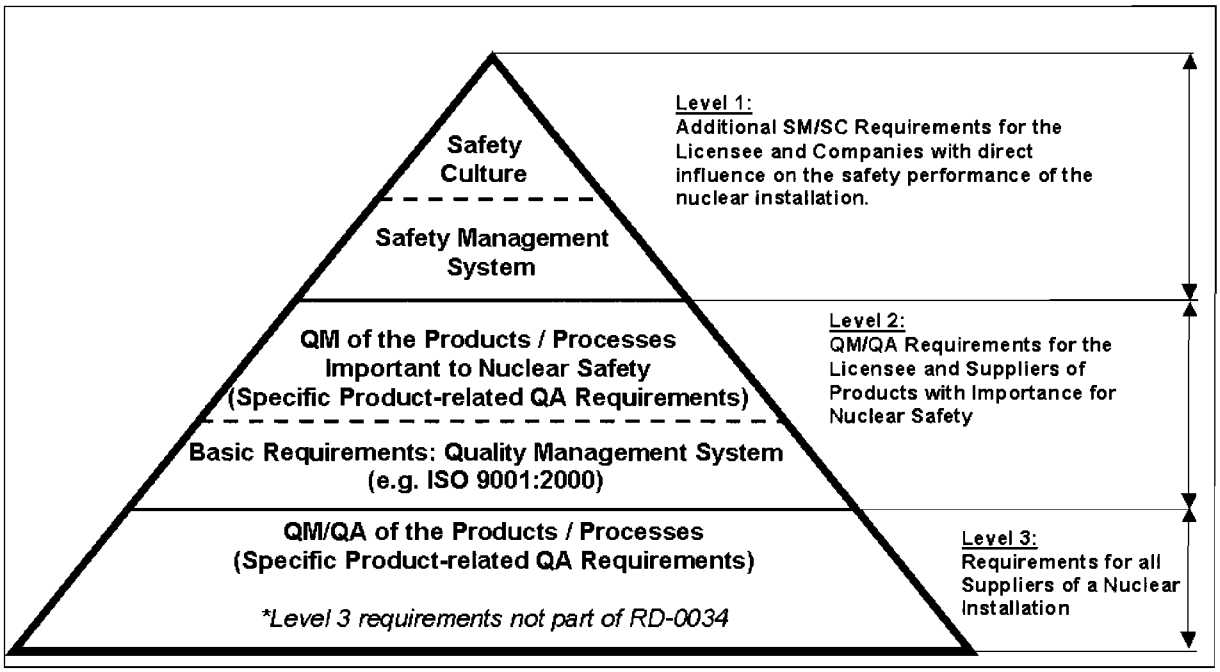

Figure 1: Structure of the Integrated Management System

6.2 Safety Management System and Safety Culture Implementation (Level 1)

Safety Management (SM) is concerned with the safety of the entire process, including the reliability of the products with respect to their nuclear safety functions. As reliability can only be achieved through adequate performance (quality), in this sense the quality of the products is a supporting attribute for safety.

- The introduction of SM provides for organisational structures and performance measures which, together with the QMS, ensure that the processes related to the life cycle of the nuclear installation and its SSC's are governed by safety aspects including consequences of failures and other occurrences.

According to INSAG-13 /5/ the term 'Safety Management System' (SMS) does not suggest that safety is managed separately from other activities. Neither should it be seen as an optional extra. Safety is an integral component of the way a whole organisation is managed and must have the involvement and active participation of all staff.

Definition:
"The SMS comprises those arrangements made by the organisation for the management of safety in order to promote a strong safety culture and achieve good safety performance." (INSAG-13 /6/)

The SMS provides the framework for promoting, establishing and maintaining a strong SC by:

- Ensuring a common understanding of the key aspects of safety culture within the organization;
- Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, taking into account the interaction between individuals, technology and the organization;
- Reinforcing a learning and questioning attitude at all levels of the organization;
- Providing the means by which the organization continually seeks to develop and improve its safety culture.

Safety Management focuses on organisational structures and processes and procedures. SC relates to the characteristics and attitudes of organisations and individuals which ensure that, as an overriding priority, nuclear safety issues receive the attention warranted by their significance.

The NNR requires that an appropriate level of SC be adopted within each organisation involved in processes with high nuclear safety importance. The NNR considers the following aspects as important to reach an appropriate Safety Culture within all level 1 organisations:

- Individual Awareness / Questioning Attitude
- Knowledge, Authority and Competence
- Example Function of Management (Safety Leadership)
- Commitment to Safety
- Acceptance of Authorities
- Acceptance of Rules
- Motivation to reach goals
- Safety Promoting Work Environment (Including Housekeeping)
- Open Communication (Including with Authorities)
- Monitoring of safety culture performance
- Operational Experience Feedback (see /9/, /10/)

The performance of individuals and teams is strongly influenced by their working environment and atmosphere, particularly the behaviour of leaders.
Senior management is responsible for developing the values and behavioural expectations for the organisation, and for modelling these through their words and actions (see requirement no. 31).

6.3 Quality Management System (Level 1 and 2)

QM is concerned with the quality of processes which should be implemented and controlled to produce a product which fulfils all internal and external (customer) requirements.

ISO 9001:2000 /3/ is considered as a basis for the QMS requirements specified in this RD. The licensee and all suppliers of products important to nuclear safety must therefore comply with all requirements specified in /3/ or equivalent QM standards. QMS based on equivalent QM standards may need adjustment to ensure compliance with the requirements of this RD.

Sections 7 – 11 of this RD are structured to reflect the equivalent sections of /3/. Although the requirements of /3/ are not repeated, they are required to be fulfilled as a basis. The QMS of the organisations involved in the activities of a nuclear installation need to consider additional QM requirements specific for nuclear installations. These additional requirements have been taken from existing international nuclear standards /4/ and /5/ and are incorporated in this RD considering the structure of /3/. With respect to the scope and level of detail of the QM requirements this RD is therefore compatible with the QM requirements defined in /5/ (NQA-1 Part 1) and /4/.

7 General Requirements on Organisation and Documentation

(1) The licensee must ensure for its own organisation and for all suppliers of products important to nuclear safety that a QMS is implemented during all stages of the life cycle of the nuclear installation considering the respective requirements as specified in this RD.

(2) The licensee must ensure for its own organisation and for all suppliers of products with high importance to nuclear safety and with a direct influence in the design of the product that a SM system, including SC aspects, is implemented as part of an IMS during all stages of the life cycle of the nuclear installation considering the respective requirements as specified in this RD.

7.1 General Requirements on Organisation (Level 1, 2)

(3) All products related to the installation must be classified with respect to the importance of the products to nuclear safety to allow for the identification of the applicable requirements of this RD. The safety classification must consider the possible nuclear consequences in terms of the FSF if a SSC fails to provide its safety function or if a service is carried out incorrectly. On subcomponent level the quality classification must consider the relative importance of the subcomponent for the performance of the safety functions of the SSC.

(4) In case important to nuclear safety activities are outsourced by the licensee or suppliers to other suppliers / sub-suppliers, the delegating organisation must implement oversight measures for these activities to retain intelligent customer capabilities.

(5) Where there is collaboration between different organisations involved in the performance of design, manufacturing and/or construction tasks responsibilities and tasks must be defined and documented. The licensee must ensure that interfaces between these organisations are clearly specified and described.

(6) If the licensee or a supplier intends to introduce or accept different QM standards to those specified in this RD, a clear structure or framework must be provided in the QM manual to indicate the intended use of the standards as well as their compliance with the requirements of this RD. In such a case, the QM manual must be submitted to the NNR for acceptance prior to implementation.

(7) The licensee and the suppliers of products important to nuclear safety must develop documents describing their management system. This set of

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(7) The licensee and the suppliers of products important to nuclear safety must develop documents describing their management system. This set of

documents must include a management system manual supported by additional documents describing the management policy, priorities, objectives and processes.

(8) The organisational structure, functional responsibilities, levels of authority and interactions of departments and persons responsible for managing, performing and assessing work must be described in the QM/SM documentation of the organisation.

(9) The organisation must provide a description of the processes and supporting information that reflects how work is prepared, reviewed, carried out, recorded, assessed and improved.

7.2 General Requirements on Organisation (Level 1)

(10) The licensee is overall responsible for the safety of the nuclear installation during the entire life cycle. .

(11) The licensee must submit to the NNR for acceptance a detailed description of its organisational structure, the applied management systems including processes, supporting processes and related human resources for the respective stages of the life cycle of the nuclear installation.

(12) An IMS must be established by the licensee and the suppliers of products of high importance to nuclear safety during all stages of the life cycle of the nuclear installation considering the specific life cycle stage requirements and constraints. The IMS must integrate QM and SM and must consider SC aspects.

(13) The following fundamental aspects must be considered for the implementation of an IMS:

- Nuclear safety has to be the primary objective of the IMS overriding all other demands.
- An effective SMS have to be integrated into the framework of existing management systems to ensure that the organisation and the individuals achieve high standards of nuclear safety.
- The SMS has to ensure compliance with all the processes important to nuclear safety.
- The effectiveness of implementing and improving the SMS has to be assessed routinely. The guidance provided in documents such as the appendix of INSAG-13, including the sets of questions (safety management indicators), should be used as a basis for the assessment.

(14) The licensee must develop and introduce a Safety Culture Enhancement Programme (SCEP) which must provide the framework for implementation of the aspects of SC within the licensee organisation.

(15) A safety culture enhancement plan must be developed and implemented by the licensee to document the specific activities that will be carried out under the SCEP. The plan must be developed in consultation with, and communicated to, staff at all levels of the organisation. The plan must be regularly reviewed and updated.

(16) The licensee must ensure that its suppliers of products of high nuclear safety importance also introduce a SCEP. The SCEP must be based on appropriate international standards and guidance e.g. IAEA, INPO/WANO and should consider the aspects defined in section 6.2 of this RD. The SCEP can be included as part of other QM or SM documents.

(17) The licensee is responsible to ensure that the safety culture within its level 1 suppliers is monitored. The type and frequency of monitoring of safety culture within these supplier organisations must be commensurate with the schedule for design, manufacturing and delivery / construction of products with high importance to nuclear safety.

7.3 General Requirements on Documentation

7.3.1 Overall Requirements (Level 1, 2)

(18) Control measures must be established within the organisations to ensure that all documents are complete considering relevant requirements before release. All individuals involved in preparing, revising, reviewing or approving documents must be specifically assigned this work, must be competent to carry it out and must be given access to appropriate information on which to base their input or decisions.

(19) The organisations are responsible to ensure that all documents must be unambiguously marked for identification. The identification code must also contain reference to the revision status of the document. Documents of external origin must also be identified and their distribution controlled. The identification code must allow an unambiguous coordination between areas, parts, items etc. and the respective documents throughout the planning, design, procurement, manufacturing, assembly, construction, operation and maintenance phases.

(20) The organisations must ensure that procedures, specifications, instructions or drawings include quantitative and/or qualitative acceptance criteria where appropriate.

(21) All organisations involved must be informed of any revisions of procedures, specifications, instructions or drawings without delay. The involved organisations must ensure that the use of incorrect or invalid documents is prevented within their own organisation and that the tasks are performed only in accordance with valid documents.

(22) The organisations must ensure that records are retained to furnish evidence of activities affecting quality and safety. These records must be readable, complete, identifiable, classified, stored and easily retrievable. Retention times of records must be defined.

7.3.2 IMS Requirements (Level 1)

(23) Within the IMS system of the licensee a documented procedure must be established to control the generation and management of all documents required for the different stages of the life cycle of the nuclear installation.

(24) The type and the scope of the documentation required for the different stages of the life cycle of the nuclear installation must be determined in the planning phase of the life cycle stage of the nuclear installation by the licensee.

(25) The licensee is responsible for the definition and introduction of the licensing documentation for the nuclear installation. This includes any design, manufacturing and construction documents which are determined to be part of the supporting documents for the licence.

(26) Licensing documents must be identifiable within the scope of all documents produced. Licensing documents must be submitted by the licensee to the NNR for review and acceptance. Licensing documents must be periodically reviewed to confirm their continued suitability.

(27) The licensee must ensure that licensing documents, including changes, are independently reviewed by themselves and approved for release by authorised personnel. It must be ensured that these documents are available at the location where the relevant activity is carried out.

(28) The licensee must ensure that lifetime documentation for SSCs are securely retained until the SSC is replaced or dismantled.

(29) All level 1 organisations must ensure that revisions to documents are reviewed and authorized in a controlled way based on written procedures. All revised parts of the documents must be clearly identified. The reasons for the revisions must be presented to the organisations involved in the document review.

8 Management Responsibility

8.1 Management Commitment

8.1.1 Overall Requirements (Level 1, 2)

(30) Senior management must ensure that management systems are established, implemented, assessed and continually improved and must demonstrate its commitment to do so.

(31) The commitment of senior management of the organisation in terms of safety and quality of the products must be clearly defined and documented and must be communicated to the staff.

(32) The roles and responsibilities as well as the delegation of authority must be clearly defined within the management system of the organisations.

8.1.2 IMS Requirements (Level 1)

(33) Senior management is responsible for the activities and behaviours necessary to foster a strong safety culture, including:

- setting safety goals, policies and standards and ensuring that they are effectively implemented,
- visibly demonstrating their commitment to safety,
- recognising and resolving production/safety conflicts,
- encouraging involvement and challenge from staff at all levels of the organisation, particularly when making decisions affecting safety,

- ensuring that reward and recognition systems promote safe behaviour and discourage unsafe behaviour, and
- establishing an open reporting culture, where events are treated as an opportunity to improve individual and organisational performance.

8.2 Management Priorities, Policy and System Planning

8.2.1 Overall Requirements (Level 1, 2)

(34) The senior management of the organisation must ensure that goals, strategies, plans and objectives defined for the management system are achieved. The process must be defined in procedures.

(35) The validity and effectiveness of the processes affecting quality and safety of the products must be evaluated periodically by the organisations.

8.2.2 IMS Requirements (Level 1)

(36) The senior management of the licensee must define, document and implement a safety policy which demonstrates the organisation's commitment to high quality and safety performance and to a strong safety culture. The policy must be supported by the definition of accepted standards / guides and targets.

(37) The licensee must determine and classify the activities and processes of their organisations in terms of the potential impact on the quality and nuclear safety and must manage these processes accordingly.

(38) Specific safety goals must be developed for the respective organisational units based on the classification of the activities and/or processes.

(39) Each stage of the nuclear installations life cycle must be preceded by monitoring and a pre-assessment to identify the impact of the life cycle specific processes on the nuclear safety and to initiate corrective and preventive actions if required.

8.3 Management Responsibility, Authority and Communication

8.3.1 Overall Requirements (Level 1, 2)

(40) The management structures, responsibilities and accountabilities for management system must be clearly defined by the senior management of the organisation. The overall responsibility for the management system must rest with a member of the organisation's senior management.

(41) The authority and responsibilities of the persons and organisational units performing activities affecting quality and/or nuclear safety must be clearly established and defined in writing.

(42) The QM and/or SM management functions must be independent from operational and line functions. The persons assigned to be responsible for the management system must be suitably qualified and experienced.

(43) Persons and/or organisations performing QM and/or SM functions must be in a position to report to the management at such a level that the required assurance and oversight function is ensured. The persons and organisations performing QM and/or SM functions must therefore have authority and

freedom to identify and correct quality problems or safety relevant aspects and prevent repetition. They must ensure the implementation of corrective and preventive measures and verify the introduction and effectiveness of such measures.

(44) Guidelines must be defined and documented to ensure effective communication and team support allowing individuals to receive the advice, information and support they require, and to provide the necessary feedback wherever it is required.

(45) A management review process must be established within the organisations to ensure that an evaluation of the efficiency and effectiveness of the management system with respect to the requirements of this RD is done.

9 Resource Management

9.1 Overall Requirements (Level 1, 2)

(46) All organisations must determine and provide the resources needed to carry out the activities of the organisation, and to establish, implement, assess and continually improve the management system.

(47) All organisations must select their personnel and must implement training programmes to ensure and maintain the required levels of qualification and experience. It must be ensured that all staff have the competence to carry out their tasks safely and effectively.

9.2 IMS Requirements (Level 1)

(48) The senior management of the organisations must include a systematic process to establish technical and behavioural competence requirements. This process must consider the following aspects as a minimum:

- Determination of training methods to ensure awareness of the relevance and importance of their activities to the achievement of safety goals,
- Formal assessment of competence of individuals,
- Evaluation of training actions,
- Supervision and monitoring of the individuals until full competence is achieved.

(49) The licensee must ensure that changes within their own organisation and other level 1 organisations, including structure, staffing levels and resources, are evaluated to ensure that they will not adversely affect safety. Organisational changes within the licensee that could potentially impact nuclear safety must be submitted to the NNR for acceptance prior to implementation.

(50) For all functions and processes necessary for design, licensing, commissioning, operation and decommissioning, including supporting processes, the licensee must ensure that sufficient resources are available to respond to all foreseeable circumstances, including normal operations, abnormal and emergency conditions, maintenance and inspection.

(51) Human factors must be systematically considered at all stages of the life cycle of the nuclear installation. These considerations include the allocation of functions to humans and technology, the identification and analysis of tasks important to nuclear safety (including human error potential), the design of the work environment, user interface design, training and procedures.

10 Process Realisation

10.1 Planning and Management of Processes

10.1.1 Overall Requirements (Level 1, 2)

(52) All processes needed to achieve the quality and safety goals of the organization must be identified, and their development must be planned, implemented, assessed and continually improved.

(53) The interaction of the processes needed to achieve the quality and safety goals of the organization must be described and documented. The interaction between different groups of the organisation involved in a single process needs to be ensured through effective communication and clear assignment of responsibilities.

(54) The organisations management must ensure the effectiveness of the implementation and the control of the processes.

(55) For each process a responsible person (process owner) must be determined.

10.1.2 IMS Requirements (Level 1)

(56) During all stages of the life cycle of the nuclear installation the licensee must plan and develop the processes and resources required to achieve a safe installation.

10.2 Licensing related Processes

10.2.1 IMS Requirements (Level 1)

(57) A description of the purpose, objective, functional and operational behaviour of the nuclear installation must be documented by the licensee.

(58) The licensee must ensure that all relevant licensing requirements are considered during the different stages of the nuclear installation life cycle, including those specified in laws, standards, legal directives, codes and standards as well as the NNR requirement documents and licence documents. The design, construction, commissioning, operation and decommissioning processes must therefore include provisions to ensure that these licensing requirements are fulfilled and that they are correctly introduced in the documentation.

(59) Management of the licensee must ensure that the organisation has defined acceptable processes for communicating effectively with the NNR. The licensee and its suppliers must introduce and maintain such processes to ensure understanding of the requirements of the NNR, and for their translation into requirements for the organisation.

(60) A project management plan defining the licensing schedule and activities must be submitted to and agreed with the NNR. In developing the schedule the tasks of the NNR must also be considered. The project management plan must be reviewed regularly and revised as necessary to reflect any changes considering the status of licensing as well as the different licensing stages.

(61) A specification must be issued by the licensee to define the scope and content of the licensing documentation (see section 7.3.2). The sequence of submission of licensing documents must be consistent with the agreed licensing schedule.

10.3 Design and Development

10.3.1 Overall Requirements (Level 1, 2)

(62) The conditions for application of the selected codes and standards as prescribed by the authority which released the code / standard must be fulfilled by the organisations involved in the process. Any deviations must be justified and presented to the NNR for acceptance.

(63) QA measures must be defined and must be compatible with the technical requirements of the selected codes and standards. The involvement of the licensee in the QA measures must be commensurate with the safety and quality classification of the SSC.

(64) All SSC important to nuclear safety must be designed according to the latest or applicable approved standards as at the time of licensing of the nuclear installation and must be accepted by the relevant South African authorities. If no approved standards are available for a specific application, internationally recognised codes or standards must be proposed for acceptance. The licensee may also request NNR acceptance of a specific edition of a code or standard. If possible the SSC should be of a design proven in previous equivalent applications, and must be consistent with the reliability goals determined for the respective SSC.

(65) Where new or innovative design or features are used, the licensee must provide the results of the investigations on applicability of the codes and standards to the NNR. It must be demonstrated that the selected codes and standards are fully applicable to the SSC. In any other case a revised code, standard or specification must be developed and approved.

(66) Design and development outputs must contain the information necessary for verification and validation to pre-determined requirements and/or design criteria. The licensee must ensure that the outputs must be reviewed against inputs as part of a design review process to provide objective evidence that the requirements /or design criteria have been met.

(67) Validation of the output of the design and development processes must be performed in a controlled manner to ensure that the resulting product is capable of meeting the requirements for the specified use.

(68) Design control procedures must be established for verifying or checking the adequacy of design and as a basis for the performance of design reviews.

(69) The verification or checking process must be performed by individuals, departments or organizational units other than those who have performed the original design.

10.3.2 IMS Requirements (Level 1)

(70) The licensee must establish a process for the selection and acceptance of the codes and standards which must be based on the classification of the SSC and graded quality assurance measures. The selected codes and standards have to be determined and justified by the licensee. The justification of a code or standard for an intended application must be acceptable to the NNR.

(71) The licensee must show to the NNR how the deviations will be incorporated and covered during the design and licensing process in case of deviations from an existing code or standard with a potential to result in verification, validation and approval process. The requirements resulting from such deviations must be implemented in the selection and implementation process of the codes and standards and the qualification of the suppliers and the SSC.

(72) Procedures must be established at suppliers for selecting, and reviewing the suitability of materials, parts, equipment and processes that are essential to the safety functions of SSC.

(73) Provisions must be implemented to ensure that quality assurance measures are included in design specifications and that responsibilities are determined to ensure that compliance with these measures is controlled and achieved. The requirements that are essential to quality and to procedural processes must be specified prior to commencing with the activity to which they relate.

(74) The licensee must ensure that design verification procedures are implemented and measures are performed within their own organisations and level 1 suppliers if:

- New safety features for nuclear installations are considered that differ significantly from proven technology or that use simplified, inherent, passive, or other innovative means to accomplish their safety functions
- Design changes occur for components of existing nuclear installations

(75) In case of design changes the design verification measures must be commensurate with those applied to the original design and must be performed based on processes agreed with the NNR.

(76) Design changes must be controlled as part of a configuration management system. Design changes affecting the safety functions and occurring after the submission of a safety case must be submitted to and accepted by the NNR in accordance with agreed processes.

(77) A test programme must be implemented by the licensee or its suppliers to demonstrate the safe performance of new safety features. It must be ensured that the safety features will perform as predicted, to provide sufficient data to validate analytical codes, and that the effects of systems interactions are acceptable. The test program must include suitable qualification testing of a prototype simulating the most adverse design conditions. The test programme must be defined in writing and make provision for sign-offs as the test programme conditions are met.

10.4 Procurement

10.4.1 Overall Requirements (Level 1, 2)

(78) The licensee must establish a supplier qualification process based on and graded according to an accepted safety and quality classification system of the product to be delivered by the supplier.

(79) NNR involvement must be considered during the supplier qualification process for suppliers of nuclear safety important products. The licensee must therefore implement processes to ensure that the following information will be made available to the NNR as a minimum:

- The SSC to be delivered or scope of work to be performed,
- The QM documentation, facilities and production processes,
- The contractual agreements and the interface arrangements,
- The product related deliverables already provided by the supplier to the licensee and a list of those scheduled for future delivery shall be submitted.

(80) All suppliers of products important to nuclear safety must have a current quality management system appropriate to the scope of supply and must submit a product related QM confirmation issued by a certification or conformity assessment organisation, which is accepted by the NNR and the South African legal framework. The certificate / confirmation must contain a statement of the scope of application, which must be appropriate to the scope of supply, and must be within its stated period of validity. Accreditation must be provided by a relevant organisation where it is required by the selected codes and standards.

(81) Suppliers must implement procedures to ensure that product specific requirements and any other requirements affecting the achievement of quality are clearly defined.

(82) The licensee must ensure that the qualification process for suppliers must include an evaluation of their ability to comply with the requirements of this RD (compliance audits) and to perform the required tasks (technical process evaluations and/or audits). The criteria for evaluation of a supplier must be based on product related requirements and, as a minimum, the following aspects must be evaluated:

- Technical equipment
- Qualification of personnel
- Quality management system and Certification
- Internal and external surveillance
- References and product related experience.

(83) It must be ensured that the required reviews, tests and inspections are carried out where procurement documents and / or codes standards require an Authorised Inspection Agency (AIA) or an Independent Inspection company to undertake surveillance during the manufacturing and assembly of SSC or the construction of structures.

(84) The licensee must ensure that procedures are established within their own organisation or at the suppliers to ensure that purchased material, equipment and services, whether purchased directly or through suppliers, conform to the requirements specified in procurement documents. These procedures must include appropriate provisions for source evaluation and selection. Objective evidence of quality must be available covering inspections at the supplier and at the supplier's sources for accessory parts and examinations of materials, parts and equipment up to delivery.

(85) It must be ensured by the licensee and its suppliers that materials, parts and equipment must not be used until documentary evidence is available confirming that they conform to the procurement documents.

(86) The licensee and its suppliers must ensure that materials, parts and equipment are inspected before use to identify any damage occurred during transport and to determine whether the delivered products conform to the procurement documents.

(87) The licensee and its suppliers must ensure that documentary evidence is retained confirming that products conform to the design requirements specified in the procurement documents.

(88) Procurement documents for material, equipment and services must include or reference the procedures and/or standards required to be applied by the supplier.

10.4.2 IMS Requirements (Level 1)

(89) The licensee must ensure that all suppliers of products important to nuclear safety provide all the documentation and other information as required by the purchasing / procurement documents.

(90) The effectiveness of the assessment of the suppliers must be assessed by the licensee at intervals commensurate with the importance, complexity and quality of the product.

(91) All suppliers of products important to nuclear safety involved in design, manufacturing, construction, operation and decommissioning must be registered in an up to date list (database) of approved suppliers, and their qualification / certification must be traceable. This list must include at least the following information:

- Product to be delivered
- Supplier of the product and sub-supplier of components
- Safety and quality classification of the SSC
- Selected codes and standards
- Status of qualification / certification

The list must be submitted to the NNR in accordance with agreed processes whenever changes involve suppliers of products of importance to nuclear safety and must be available in general for NNR inspection, review and audit.

(92) The requirements for the products must be clearly defined in procurement documents and design specifications for the suppliers. The documentation must specify the required codes and standards, materials, duties and

capacities, operational and environmental parameters, loads, safety margins, settings, design limits, acceptable tolerances as well as QM requirements based on the classification of the SSC. These requirements must be compatible with the content of the Safety Case and the associated Safety Analysis Report (SAR). Procurement documents or design specifications produced by suppliers on behalf of the licensee must be accepted by the licensee.

(93) If it is required to undertake surveillance during the manufacturing and assembly of SSC or the construction of structures, the licensee must ensure that required reviews, tests and inspections are prescribed in the procurement documents and are followed by the their suppliers.

(94) The licensee must ensure that the procurement documents for materials, items and equipment of the nuclear installations reflect the requirements established during the respective life cycle stage. Procurement documents must provide the following minimum information:

- Intended application and operating conditions,
- Quality characteristics and safety classifications,
- Performance requirements and surveillance of in-process, final and functional tests and inspections,
- Documentation and submission requirements for design and analyses, the manufacturing and assembly of parts, components and systems and the construction of civil structures, including the associated tests and inspections,
- Requirements concerning handling, storage, conservation, transportation and packaging,
- Identification coding for documents and for procured items, and
- Product identification and traceability.

10.5 Production and Service Provision

10.5.1 Overall Requirements (Level 1, 2)

(95) Programmes must be established to ensure compliance with relevant requirements during manufacturing, construction and commissioning activities. Procedures must be used in these programmes and must incorporate the requirements and acceptance criteria contained in the applicable design documents and specifications.

(96) Special processes including welding, heat treatment, inspection and non-destructive testing must be documented and controlled at supplier level. All special processes must be performed by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications or any other specific requirements or criteria.

(97) Procedures must be established for the identification and control of materials, parts, and components, including partly fabricated assemblies of nuclear safety important SSC at supplier level. These procedures must ensure the identification of the items, either on the item or on records traceable to the item, throughout manufacturing, construction, installation and use of the item.

(98) The licensee must ensure that the identification and control procedures available at their suppliers are designed to prevent the inadvertent use of non-conforming or defective material, parts and/or components.

(99) A configuration management system must be established at suppliers to indicate by the use of markings such as stamps, tags, labels, route cards or other suitable means the status of inspections and tests performed upon individual items. Respective procedures must specify the identification of items which have satisfactorily passed required inspections and tests and the release process of those items.

(100) Procedures must be established at suppliers to control the handling, storage, shipping, cleaning and preservation of materials, components and equipment to prevent damage or deterioration. Surveillance measures must be applied to ensure that the requirements regarding marking, handling, storage, transportation and packaging are met.

(101) In-process inspections of processed material, items or products must be performed for each work step at suppliers where it is necessary to ensure quality. Where direct inspection of processed material, items or products is impossible or disadvantageous, statistical process control and/or indirect controls must be provided by monitoring processing equipment and personnel.

(102) Inspections must be performed at suppliers during manufacturing and qualification of SSC by qualified organisations and individuals, other than those who performed the activity being inspected.

(103) Mandatory hold and/or witness points, beyond which work must not proceed without the consent of the licensee, the NNR or another authority as required by the applied standards and/or design specifications, must be specified in documents. Tests and inspections must be performed at specified hold points during, and at completion of manufacturing, assembly and construction. The production and inspection steps must be coordinated (e.g. by using an inspection sequence plan or quality plan) such that the tests and inspections are performed at a stage when the required quality characteristics can still be verified without restriction. Processes need to be defined for identification of Hold and Witness Points.

(104) Qualification and test programmes must be established at suppliers to ensure the execution of all testing required to demonstrate that SSC will perform their functions satisfactorily. Procedures must be used in the test programme and must incorporate the requirements and acceptance criteria contained in the applicable design documents.

(105) Qualification and test procedures of suppliers must include provisions for assuring that all prerequisites for the given test have been met, that adequate test instrumentation is available and was used and that the test was performed under testing conditions.

(106) The qualification, test and inspection results must be documented, evaluated and accepted by the licensee or another authority as required by the applied standards and/or design specifications to provide assurance that test requirements have been satisfied.

(107) In case SSC's are sourced from the original equipment manufacturer it must be demonstrated by the licensee that the SSC conforms to the design specification, and that the relevant QA measures were implemented.

10.5.2 IMS Requirements (Level 1)

(108) The test and commissioning process must be structured so as to provide a progressive integration both in terms of the hierarchy of the SSC (bottom up approach, starting with parts and single components) as well as in terms of power / loads (bottom up approach starting with minor loads) for SSC and the entire nuclear installation. The commissioning programme must consider specific verification requirements for first of a kind SSC.

(109) Procedures and processes must be implemented to ensure that the SSC are installed at the correct location (e.g. by the application of an installation marking system) and to prevent their incorrect use in terms of qualification.

(110) Maintenance and In-Service Inspection (ISI) programmes must be defined and periodically reviewed and updated according to the design specifications and applied codes and standards to maintain the reliability of the product according to its safety classification throughout service.

(111) The licensee must ensure that design studies are performed to ensure that maintenance and ISI within the nuclear installation are carried out under allowed work and radiation conditions. The maintenance and ISI programmes must be periodically reviewed and updated if necessary considering lessons learned and operating experience.

10.6 Control of Monitoring and Measuring Devices

10.6.1 Overall Requirements (Level 1, 2)

(112) The licensee must ensure that procedures are established within its own organisations and at its suppliers to ensure that tools, gauges, instruments and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated and adjusted at specified periods to maintain specified measuring accuracy.

(113) The instruction documents relating to the inspection, measuring and testing equipment must specify when, how and by whom the necessary controls and calibrations must be performed, repeated and documented.

11 Measurement, Analysis and Improvement

11.1 Monitoring and Measurement of the Management System

11.1.1 Overall Requirements (Level 1, 2)

(114) A programme for auditing and inspection of activities affecting quality and safety must be established and executed by the organisation performing the activity to verify conformance to the relevant documented procedures, instructions and drawings.

(115) The management system of organisation's must be periodically audited to verify compliance with requirements.

(116) Senior management and management at all other levels in the organisation must perform self assessments to evaluate the effectiveness of the management system, and to identify areas for improvement.

(117) The licensee must ensure that audits / assessments are performed at level 1 and level 2 organisations in accordance with documented procedures and by appropriately trained personnel who do not have direct responsibilities in the areas being audited.

(118) The audit/ assessment results must be documented and reviewed by the management representative of the organisations responsible for the area audited. Follow-up actions, including the re-audit of deficient areas, must be taken as appropriate.

11.1.2 IMS Requirements (Level 1)

(119) A comprehensive programme of systematic audits must be planned and carried out by the licensee to verify compliance with all aspects of the QM programme, the SM programme and the product and process specific requirements and to determine the effectiveness of the QM and SM programs.

(120) The safety performance of level 1 organisations must be routinely monitored internally in order to ensure that safety goals are met and to improve the performance of work affecting the safety goals. Performance indicators must be developed for the measurement of safety performance.

(121) Auditing and review of the overall safety performance of the organisation must provide an independent assessment of the effectiveness of the safety management system and identify opportunities for improvement.

(122) A systematic process for monitoring safety culture within level 1 organisation's must be established, using suitable leading and lagging indicators, and qualitative information (for example findings from self-assessments, NNR and independent reviews).

(123) The organisation to be audited must submit at least the following documents (SC aspects only required for level 1 organisation with direct influence and responsibility on the design):

- Structure of the organisation including internal and external interfaces (Organisational structure with indication of responsibilities including SM/SC)
- Definition of the business processes
- Specifications, procedures, manuals and status reports of the introduced and applied IMS system, and including those describing the integration of all relevant aspects of SM and SC into the Management Review Specifications, manuals and status reports of the introduced and applied IMS system
- Philosophy and status reports of the SC introduction and enhancement process
- Specifications for QM and SM/SC introduction at suppliers
- Supporting SM/SC related documents, commitments, guidance etc.
- Documentation of the internal and external review and improvement process of SM / SC

- Documentation of external review and surveillance measures (if available)

11.2 Control of Non-conforming Products

11.2.1 Overall Requirements (Level 1, 2)

(124) Procedures must be established to prevent the use or installation of materials, parts or components, which are not conforming to requirements. These procedures must define the arrangements for identification, documentation, segregation, disposition and notification to affected organisations. The process for notification, release, approval and control of non-conforming products must be clearly documented.

(125) Rework and repair actions must be described in documents equivalent to those on which manufacturing of the respective parts was based. These documents must be reviewed and maintained as records in the same manner as the original documents.

11.2.2 IMS Requirements (Level 1)

(126) The NNR must be informed of non conforming products based on the safety classification as soon as such non conformances are recognized by the licensee. The licensee must implement the respective processes which must adequately reflect the NNR involvement.

11.3 Analysis of Data

11.3.1 Overall Requirements (Level 1, 2)

(127) The licensee must ensure that the sources of any data used are traceable and must be validated for the specific application. Documented records must be maintained of the source from which the data is taken and the measures introduced for its validation and verification. Data input must be part of the controlled process defined for QM and SM.

11.4 Improvement

11.4.1 Overall Requirements (Level 1, 2)

(128) A continual process for the identification of opportunities for improvement must be implemented at level 1 and level 2 organisations and an effective implementation of corrective actions must is ensured. These organisations must make arrangements to support the feed back process. Work results must be reflected and considered within this enhancement process.

(129) Procedures must be established to ensure that conditions adverse to quality, such as failures, deficiencies, defective material, system deviations and equipment non-conformity, are promptly identified and corrected.

(130) For significant conditions adverse to quality, the procedures of the organisations must ensure that the root cause of the condition is determined and that appropriate corrective action is introduced to prevent recurrence.

(131) The responsible management representatives of the organisations must ensure that appropriate corrective actions are identified and introduced. The response to non-conformities must identify the objectives for improvements.

(132) The responsible management representatives of the organisations must clearly define the measures to be adopted to prevent non-conformance of products or unsafe processes.

11.4.2 IMS Requirements (Level 1)

(133) Procedures must be established to identify conditions adverse to quality or safety. Such conditions must be investigated, causes identified and corrective actions implemented. The effectiveness of the corrective actions implemented must be monitored. The identified conditions and corrective actions must be reported to the appropriate level of management.

(134) Senior management of the licensee is responsible for ensuring that systems are in place to continuously improve organisational systems and processes. This must include implementing operating experience and lessons learned from internal and external sources, both within and outside the nuclear industry. A systematic event analysis and corrective action process, which addresses human, organisational factors and technical issues, must be established.

12 References

/1/ NNR Act No. 47 of 1999

/2/ Regulations in terms of section 36, read with section 47 of the NNR Act on Safety Standards and Regulatory Practises (RSRP)

/3/ ISO 9000:2000 Series including ISO 9001:2000

/4/ IAEA Safety Standard GS-R-3: The Management System for Facilities and Activities

/5/ ASME NQA 1:2008: Quality Assurance Requirements For Nuclear Facility Applications

/6/ INSAG-13: Management of Operational Safety in Nuclear Power Plants

/7/ IAEA - INSAG Series No. 4: Safety Culture

/8/ IAEA Safety Standard SF-1: Fundamental Safety Principles

/9/ IAEA Safety Requirements NS-R-2, Safety of NPPs Operation

/10/ IAEA Safety Guide NS-G-2.11: A System for the Feedback of Experience from Events in Nuclear Installation