National Nuclear Regulator

Position Paper

No	Title	Rev.
PP-0008	DESIGN AUTHORISATION FRAMEWORK	0

Approved:

Date of issue: 10/12/2009

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REVISION HISTORY

Rev No.	Date Approved	Nature of Revision	Prepared by

Contents

1 Introduction

Section 2 (1) (a) of the NNR Act [1] provides that the NNR Act applies to the siting, *design*, construction, operation, decontamination, decommissioning and closure of any nuclear installation.

Section 5 (b) of the NNR Act provides that the National Nuclear Regulator (NNR), amongst others, exercise regulatory control related to safety over the siting, *design*, construction, operation, manufacture of component parts, and decontamination, decommissioning and closure of nuclear installations, through the granting of nuclear authorisations.

The NNR interpretation of the NNR Act is that in order to operate a nuclear installation, the siting, design, manufacturing and construction activities (as well as the operation and decommissioning) must fall under the regulatory control of the NNR. For this purpose the applicant has two options:

(a) Separate applications may be made for nuclear authorisations for the various stages or combinations of stages. For each application a safety assessment is required to address the aspects which would have an impact on the safety of the proposed installation. (Separate safety assessments on the impact on existing installations in the vicinity must be provided by the respective holders as required).

(b) Application for a nuclear authorisation for combined siting, construction and operation stages may be made. In this case the safety assessment submitted in support of the application must cover the design, siting, construction, manufacturing, operation and decommissioning stages. The NNR assessment and inspection processes cover the design, siting, construction and manufacturing aspects as well as operation and decommissioning.

Having regard to section 5 (b) of the NNR Act, the NNR recognizes that, in the exercise of its regulatory control over nuclear installations, there may be circumstances where the NNR may be required to issue a nuclear authorisation to design a nuclear installation.

The design authorisation framework consists of a two-stage process as follows:

1. Stage 1: Nuclear Authorisation Process - The NNR accepts the application and issues a nuclear installation licence to design that prescribes the conditions for

regulatory engagement during the design process of a particular nuclear installation.

2. Stage 2: Design Assessment Process – The NNR performs an assessment of the safety case for the *Reference Design* of a nuclear installation and issues a Safety Evaluation Report.

Stage 1 entails the assessment of the applicant's organisational and management processes and the evaluation of the applicant's ability to perform the envisaged design development and control processes.

Stage 2 entails the assessment of the *Reference Design* against supporting information provided by the licence applicant at a level of detail allowing for assessment of the safety criteria and the safety issues associated with the design. This includes an assessment of the extent of the identification of phenomena and innovative Systems, Structures or Components (SSC) that may require specific test and qualification as well as demonstration of systems response of the proposed design during process disturbances and fault conditions. This stage provides for a systematic phased design assessment process and ensures that a minimum set of information is available before proceeding to the next phase of the design assessment.

Note: The applicant may, depending on the maturity of the design and the documentation, combine the various phases of Stage 2 on condition that the information submitted for the specific phase in question allows for the assessment of issues and aspects required to be covered in the previous phase/s.

The design assessment as a self-standing licensing stage is optional and independent of other licensing stage applications and may be followed – if successful - by a construction license application. Issues resolved during this process will be recorded and given due consideration in subsequent licensing stages involving the specific *Reference Design* of the nuclear installation.

2 Purpose

The purpose of this document is to:

(a) Define the legal framework for a nuclear authorisation to design a nuclear installation,

(b) Outline the relevant processes to be followed by an applicant, and

(c) Specify the NNR requirements and deliverables associated with this process.

3 Scope

This document is applicable to applicants for a nuclear installation licence to design a nuclear installation, and to regulatory assessments of the design of a proposed nuclear installation.

This process is applicable where an application for a nuclear installation licence to design a nuclear installation is submitted to the NNR separate from and not concurrent with other applications for Nuclear Installation Licenses such as for the construction or operation of the same nuclear installation.

4 Terms, Definitions and Abbreviations

4.1 Terms & Definitions

Concept Design - The concept design information provides preliminary process and system description of the proposed nuclear installation as well as the operational capabilities, maximum radioactive material inventory, and the method(s) to accomplish the required safety functions of the nuclear installation. Preliminary systems architecture and functioning with major structural elements and components is defined and technical risks and mitigation strategies outlined. In addition to the presentation of rules for classification of SSC's, and the corresponding establishment of specific design and safety criteria linked to the classification scheme, the rules for the application of codes and standards would also be presented.

Design – The process and the result of developing a concept, detailed plans, supporting calculations and specifications for a nuclear installation and its components and parts.

Nuclear Installation Licence to Design – It is a nuclear authorisation issued by the NNR in terms of Section 5 of the NNR Act and is an authorisation that prescribes the conditions for regulatory engagement during the design process of a particular nuclear installation.

Reference Design - The design information submitted in support of the safety case for the design assessment must be sufficiently developed based on conservative system design analysis and at a level of detail allowing for the assessment of the extent of compliance to all the safety criteria set forth by the NNR as well as for the development of procurement, construction and installation specifications.

4.2 Abbreviations

ALARA – As Low As Reasonably Achievable

BoP - Balance of Plant

C&I - Control and instrumentation

DiD – Defense in Depth

FMECA – Failure Modes, Effects and Criticality Analysis

FSF – Fundamental Safety Functions

HAZOP – Hazard and Operability Analysis

NNR - National Nuclear Regulator

PIRT – Phenomena Identification and Ranking Table

SER - Safety Evaluation Report

SSCs - Systems, Structures and Components

V&V – Verification and Validation

5 Legal Framework

5.1 Basis for the Nuclear Authorisation to design a nuclear installation

Section 2, read with section 5 (b), of the NNR Act provides the legal basis for the NNR to exercise regulatory control related to safety over the design of nuclear installations and to issue a nuclear authorisation for the design of a nuclear installation to applicants who wish to design a nuclear installation.

The NNR Act and current international practice, such as the design certification process in the USA, and the generic design assessment process in the UK, have been considered in developing the process to be followed by applicants for a nuclear installation licence to design a nuclear installation.

5.2 Nature of the Application

Any person wishing to engage the NNR on the design of a nuclear installation may apply to the NNR for a nuclear installation licence to design a nuclear installation within the defined regulatory framework. The required format and content of the application is provided in Appendix A.

5.3 Application of Section 21 of NNR Act

The application of section 21 of the NNR Act [1] is not applicable to applications of this nature.

5.4 Authorisation Fee

The NNR will recover costs incurred as a result of the design authorisation process in the initial financial year on an hourly basis consistent with the Notice issued in terms of Section 28 of the NNR Act [1] as may be amended from time to time. Authorisation fees for subsequent financial years will be gazetted in the Notice on Fees for Nuclear Authorisations in accordance with the normal process.

The NNR will also recover all operational costs on a monthly basis incurred as a result of the process. Operational costs may include, but are not limited to, services rendered by consultants, holding of meetings (consultants or bilateral partners) and workshops, participation at audits, international conferences, procurement activities, development of NNR assessment tools, and relevant NNR capacity building initiatives.

5.5 Process and NNR deliverables

The overall design authorisation process flow and description are graphically depicted in Appendix B.

The process will be initiated by an application to the NNR for a nuclear installation licence to design a nuclear installation within the legal framework defined by the NNR Act and the associated NNR requirements and in the format provided in Appendix A. The NNR will perform a legal review of the application. Should the application be rejected, a record of decision will be provided to the applicant.

If the application is accepted the NNR will request the submittal of the Project Management documentation and the Initial Design Information for the Nuclear Installation in accordance with the scope of Section 6.3 as well as a schedule for the submittal of the documentation.

Depending on the outcome of the review of the information as well as following an inspection and assessment phase and the evaluation of the applicant's ability to perform the proposed design and safety analyses, the NNR will make a decision on whether (or

not) to issue a nuclear installation licence to design i.e. an authorisation to proceed with the design engagement process on the proposed *Reference Design* of the nuclear installation.

The conditions of the authorisation will require meeting the relevant NNR requirements or standards such as RD-0034, conformance to submitted processes, including commitment to provide a safety case within a specific timeframe (e.g. five years).

The second stage would be for NNR assessment and acceptance of the nuclear installation safety case for a *Reference Design*. The NNR assessment could include conditional acceptance of the submissions, and will include evaluation reports for the interim phases in accordance with the design assessment process as described in Section 7 of this framework document.

The risks of proceeding at early stages of design on the basis of incomplete knowledge or assumptions regarding safety issues and the opportunities that may arise during preliminary or final design to reduce costs through alternative or refined design concepts or better knowledge regarding the uncertainties are recognised. The conditions would relate to assumptions, data, testing or alternatives in the design (e.g. relating to balance of plant, containment, site, external hazards, etc), which would have to be eventually confirmed to obtain a construction licence.

5.6 Timelines

The timelines associated with the process are dependent on a number of factors including but not limited to the:

- Content and quality of submissions
- Complexity of the design of the nuclear installation
- Novelty of the design
- Availability of supporting information and documentation
- Adherence to agreed schedules

6 Design Authorisation Process - Acceptance of the Application and Authorisation to proceed with the design and engagement process (Stage 1)

6.1 Acceptance/rejection of the application

The NNR will perform a legal review of the application and either accept or reject the application. Should the application be rejected, a record of decision will be provided to the applicant that will state the reasons for non acceptance. If the application is accepted the NNR will request the submittal of the project management documentation and the Initial Design Information for the Nuclear Installation as indicated in Section 6.3 as well as a schedule for the submittal of the documentation.

6.2 Qualification of the Applicant's Management System processes

The NNR will perform an assessment of the documentation to be submitted as listed in Section 6.3 and on documents requested. The evaluation of the Quality and Safety Management processes of the applicant will be based on the applicable NNR Regulations [2] and Standards [4]. The NNR will assess the applicant's processes and its ability to perform the intended design and safety analyses as well as perform audits to verify the implementation of the relevant processes.

The evaluation of the applicant's Quality and Safety Management processes is an ongoing activity, and will overlap with the Stage 2 phases, and will be considered in the decision whether to accept the safety case for the *Reference Design* of the nuclear installation.

Design and operational experience, internationally accepted practice, standards and system qualification processes should be applied in the design process where applicable. The applicant will have to demonstrate its ability to perform the nuclear installation design and associated engineering and safety analysis as per applicable NNR Regulations [2] and Standards [4].

6.2.1 Evaluation of the Initial Design Information

The initial design information must be of sufficient detail to provide context of the technical issues that will be reviewed in Stage 2 prior to the submission of the concept design information, specification of plant processes and basic SSC design information and to evaluate the ability of the applicant to perform the design and safety analysis of the nuclear installation.

6.3 Submissions

6.3.1 Project Management Documentation

The application must be supported by relevant project management documentation that must address the relevant NNR standards and must include as a minimum:

- Quality and Safety Management Manual
- Licensing schedule
- Licensing Manual
- Independent review process
- Configuration management process
- System engineering process

6.3.2 Initial Design Information

The application must be supported by a description of the proposed nuclear installation and should include the following detail as a minimum:

- Type of nuclear installation
- Potential source term, expected range of power levels (if applicable) and nuclear and radiation safety hazards associated with the nuclear installation
- Barrier concept(s) with respect to confinement of fission, activation and/or radioactive products
- Heat Removal Concept if applicable
- Reactivity Control Concept if applicable
- Concepts addressing fundamental safety issues imposed by specifics of the design (e.g. chemical attack).

6.4 NNR Deliverables

Depending on the outcome of the review of the submitted documentation the NNR will make a decision on whether to issue (or not) a nuclear installation licence to design, to proceed with the design engagement process.

7 Design Assessment Process - Assessment of the safety case for a design of a nuclear installation (Stage 2)

The principal nuclear and radiation safety requirements formulated in the Regulations in terms of Section 36, read with Section 47 of the NNR Act, on Safety Standards and Regulatory Practices [2] form the basis for the stipulation of the Licensing Requirements for Nuclear Installations which are detailed in a number of regulatory documents. The relevant requirements relating and/or applicable to design assessment of nuclear installations will be applicable to the safety case for the design of a nuclear installation. It is accepted that, consistent with the principle of a graded approach, the application of the concepts, principles and requirements contained in this document and other NNR documents will be commensurate with the safety significance and radiological hazards of the nuclear installation.

The Design Assessment process will consist of a number of phases. The phases include the following:

(a) Phase 1: Concept Design Assessment

(b) Phase 2: Principal Nuclear and Radiation Safety Review and identification of test and qualification issues

(c) Phase 3: Assessment of the Safety Case for the *Reference Design*

(d) Phase 4: Post Phase 3 process

The overall objective of Stage 2 is to:

- Assess the concept design and associated key safety issues that have been identified, evaluation of the resolution strategies and assessment of the safety concept and overall design strategies (ALARA, DiD, barrier concept, classification, proposed codes and standards, V&V of computer codes and models, General Design Criteria, etc.).
- Assess plant processes and the basic design of the plant and the SSC important to safety of the nuclear installation with specific consideration of the hazard and operability analyses and of the identified failure modes and associated safety challenges that may result in ionising radiation exposure to the public, environment and plant personnel.

- Evaluate the applicants approach and design solutions for the resolution of potential key safety issues identified as a result of a hazard, operability and failure and effects analyses and the application of good engineering practices.
- Evaluate the test and qualification strategy and plan for SSC requiring specific test and qualification considering the principle of proven technology and identified through the application of sound systems engineering processes. The approach to testing and qualification has to be supported by the identification of phenomena important to safety, relevant research, development and assessment processes and the establishment of uncertainties and margins..
- Evaluate the safety case for the *Reference Design* against the principal safety criteria [2] & [3] and other NNR direct or implied requirements that include the general requirements to apply good engineering practice, ALARA and the defence-in-depth principle, design principles for limitation of worker exposure, specific radiation dose limits, etc.
- Issue a Safety Evaluation Report (SER) compiled by the NNR on the Safety Case for the *Reference Design* together with conditions for the Design Assessment Process – Phase 4 - (e.g. on SSC test and qualification) and the potential subsequent applications (siting and construction).

7.1 Phase 1: Concept Design Assessment

The objective of Phase 1 is to perform an evaluation of the concept design, amended by additional information that may be requested from the applicant, against the NNR principal nuclear and radiation safety criteria. The concept design document must therefore provide the general arrangement and fundamental systems architecture information for the proposed installation. The planned operational modes of the plant must be described and the methods of achievement of the Fundamental Safety Functions must be outlined for each planned operational mode. An initial discussion on the level of technical and radiological risks typical of the type of plant proposed must be provided and the associated mitigation strategies or barrier concepts that will be provided to mitigate these risks must be outlined. The information provided must allow for the important understanding and evaluation of the:

(a) Concept design, safety concept, design philosophy and the approach to address the respective Fundamental Safety Functions.

(b) Approach for identification of initiating events and evaluation in accordance with relevant NNR requirements

(c) Preliminary identification of design basis events

(d) Approach in respect of probabilistic and deterministic safety analyses, including uncertainty management

(e) Approach for the identification of safety functions

(f) Rules for classification of SSC

(g) Approach to the application of codes and standards in accordance with RD-0034

(h) Approaches to the application of defence-in-depth, single failure criterion, redundancy, diversity and separation principles,

(i) Establishment of specific design and safety criteria linked to the classification scheme

(j) Approach to process monitoring and control and instrumentation (C&I)

(k) Approach to, plans for and application of test and qualification with specific consideration of SSC that may need research, development and test and qualification in accordance with RD-0034

7.1.1 Submissions

The following documentation has to be made available:

- Concept Design
- Safety Concept and Philosophy
- Safety Classification Method,
- Approach to the application of important Codes and Standards
- Material Selection approach and process
- Approach to DiD and ALARA
- Approach to external events
- Approach to event selection and categorisation
- Strategy on Safety Analysis;
- Approach to modelling and simulation, including the Validation and Verification of computer codes and models
- Approach to design in terms of Inspectability and Maintainability
- Approach to C&I for operational control and protection systems

- Approach to testing and qualification
- Strategies for resolution of Key Safety Issues

7.1.2 NNR Deliverables:

Having reviewed the submissions for Phase 1 on the concept design, the NNR will issue an evaluation report – based on the submissions – providing comments and conditions for the subsequent phase(s).

7.2 Phase 2: Principal Nuclear and Radiation Safety Review and Identification of Tests and Qualification Issues

7.2.1 Design Assessment, Safety Analysis and Early Intervention Process

Based on the results of Phase 1 the applicant should submit basic plant design information, specification of plant processes and basic SSC design information needed as a basis for development of the Safety Case for the design. The design documentation submitted is assessed at a level of detail allowing for assessment of the relevant safety criteria.

A staged approach may be needed for the submissions to arrive at a stage where results feeding into subsequent activities can be accepted by the NNR in advance. Such design assessment steps would include but are not limited to:

- Specification of radiation, neutronic and thermofluid data for the processes of the facility
- Identification of sources of radioactivity
- Approach to site-independent definition of source terms and conditions for safety analysis (e.g. environmental, site envelope)
- Identification of initiating events (e.g. by using HAZOP, FMECA, etc.)
- Identification and ranking of specific phenomena (e.g. using PIRT)
- Clarification of the confinement strategy
- Application of the safety classification method (classification of SSC)
- Specification of codes, standards and additional requirements for the SSC
- Specification of the SSC, identification of uncertainties, requirements for research, development, verification and validation of design (see subsection 6.3)

- Resolution of Key Safety Issues

7.2.2 Design issue identification and resolution process

Nuclear authorisations are based on the principle of 'proven technology'. RD-0034 requirement (77) states that '*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*'

NNR acceptance of the safety case for the design of a nuclear installation will only be granted if phenomena and performance to be investigated in a testing programme, at the component level and (for integral tests) at the system level, are clearly established. Note: The safety performance must be proven to an acceptable level and interdependent effects must have been evaluated for a potential construction licence with sufficient degree of reliability[1]. Remaining uncertainties must be covered by safety and design analyses.

For this purpose the relevant phenomena have to be identified comprehensively by appropriate processes in support of evaluation model development. The testing programmes should provide requisite data to validate the evaluations models that will be used to perform transient and accident analyses. It should be demonstrated how the key phenomena expected to occur on the nuclear installation are identified by PIRT or other similar process and are evaluated as part of the validation programme.

7.2.3 Documentation

The following documentation has to be made available in advance of the submission of the safety case for the *Reference Design*:

- Basic design information (systems description and system design basis) of important to safety SSC
- Balance of Plant (BoP) information/envelope and connectivity
- Process flow diagrams
- Control and Instrument concept and design

[1] The application of the principal nuclear safety requirement of good engineering practice requires the use of appropriate standards. The proper application of a system engineering standard will ensure that systems performance is consistent with reliability, capability, performance and maintenance targets.

- Electrical Power Supply including emergency supply
- Monitoring concept during commissioning, operation and events
- Maintenance and ISI concept
- Operating Envelope
- Site Envelope (environmental and external event conditions such as seismic)
- Application of the Safety Classification, Codes and Standards and codes and standards justification
- Specification of the Material Selection for the SSC
- Implementation of DiD and ALARA
- Specification of Civil Design including protection against external and internal events
- List of initiating events (selection and categorization)
- Representative deterministic and probabilistic risk assessment reports for Postulated Initiating Events
- Specification of the sources of radioactivity and representative source term analyses
- Specification and qualification of materials specific for the installation such as fuel, graphite, etc.
- Design specification of SSC with overall safety importance concerning the FSF
- Accident Management
- Documents on Human Factors, Human Reliability Analysis, and Human interface with the plant
- Specification of the scope and the structure of the Safety Case for the design of the nuclear installation.

In addition, for SSC and phenomena bearing specific risks and uncertainties the following documents are required:

- PIRT/HAZOP (or similar process) reports and related documents
- A list of all of the test facilities proposed to be used in support of the code validation and plant performance demonstration.

- A clear description of how each of the test facilities will be utilised to support the various aspects of the software code validation programme and plant performance demonstration. This does not need to describe the justification for the individual tests used to validate each software code (this should be included in the individual code V&V plans). However, sufficient detail should be included in the master plan to allow the NNR to form a judgement as to the completeness and appropriateness of the overall programme.
- The description of the proposed tests should be based at component level and at system level, and should indicate in general terms the nature of the tests and which evaluation model they will support. For each test facility the following items should be addressed, either in the V&V master plan, or later for a **construction licence** in the individual code V&V plans:

  Test set-up quality information
  Scaling reports
  Outline test programme
  Data to be obtained from the tests
  Assessment reports
  Uncertainty analysis reports

- Documents related to V&V of computer codes and models as indicated in RD-0016 Section 5.1 [6]

7.2.4 NNR Deliverables:

Having reviewed the submissions for Phase 2 on the design, the NNR will provide an evaluation report providing comments and conditions for the subsequent phase.

7.3 Phase 3: Assessment of the Safety Case for the *Reference Design*

The objective of Phase 3 is the assessment of the Safety Case submitted to the NNR. The scope, structure and content of the safety case will have been accepted by the NNR in Phase 2 as well as the approach on key issues, design and analyses.

Where needed, the NNR will request further information or updates from the applicant during this phase. Once the Safety Case will have been submitted all subsequent changes introduced by the applicant must be categorized and indicated to the NNR with a request for inclusion into the submitted Safety Case.

The NNR will develop a list of comments and conditions during the assessment process as appropriate that will be communicated to the applicant for consideration on a regular basis. The resolution of these comments and conditions may however delay the

finalisation of the Safety Evaluation Report or may result in pre-conditions for subsequent licensing stages such as construction and even manufacturing.

7.3.1 Submission

The following documentation has to be made available with submission of the safety case for the *Reference Design*:

- Safety Concept and Safety Philosophy Document
- *Reference Design* Safety Analysis Report (RD-SAR)
- Balance of Safety Case Documentation

7.3.2 NNR Deliverables

The NNR will issue a Safety Evaluation Report (SER) on the *Reference Design*. The SER will be structured congruent to the safety case, and will consider the assessment results of Stage 1 and Stage 2 (Phase 1, 2 and 3) and will provide detailed conclusions of the assessment results. Where needed, comments and conditions will be included that may influence subsequent licensing applications (construction).

7.4 Phase 4: Post Phase 3 process

For this phase and beyond, the applicant will have to implement a configuration and design change management process to maintain consistency among design requirements and the related documentation, even as changes are made.

Design documentation for SSC may be submitted to the NNR for assessment in this phase and the applicant may enter a process aiming at the resolution of the comments and conditions from the NNR Final SER, addressing the identified needs for test and qualification of phenomena and SSC characteristics and developing the detailed design for construction license and/or manufacturing.

8 References

[1] "Act No. 47 of 1999: National Nuclear Regulator Act, 1999", published in Republic of South Africa Government Gazette, Vol. 414, No. 20760, 23. December 1999.

[2] Regulations in Terms Of Section 36, Read With Section 47 Of The National Nuclear Regulator Act, 1999 (Act No. 47 Of 1999), On Safety Standards And Regulatory Practices (Published in Government Gazette 28755 April 2006)

[3] RD-0024: Requirements on Risk Assessment and Compliance with Principal Safety Criteria for Nuclear Installations.

[4] RD-0034: Quality and Safety Management Requirements for Nuclear Installations

[5] RD-0014: Emergency Preparedness and Response Requirements for Nuclear Installations

[6] RD-0016: Requirements for licensing submissions involving computer software and evaluation models for safety calculations

[7] INSAG-12: Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev 1

Appendix A: Format and Content of an Application for a Nuclear Authorisation to Design a Nuclear Installation

(1) The application must be made to:

The Chief Executive Officer
The National Nuclear Regulator
P O Box 7106
Centurion 0046

(2) Contents of application

(i) the full name of the applicant;

(ii) if the applicant is a juristic person, a certified copy of the certificate of incorporation or founding document or any other establishing document and physical address of its head office or its domicilium citandi and executandi;

(iii) if the applicant is a natural person, his or her identification number and date of birth;

(iv) the postal address of the applicant;

(v) a description of the nuclear installation and any other relevant information which may be required by the chief executive officer; and

(vi) a signature by the applicant or, in the case of a juristic person, the signature of a duly authorised person and a certified copy of that authorisation.

Appendix B: Process Flow & Process Description

	Design Authorisation Framework					
Stage	Stage 1: Authorisation		Stage 2: Design Assessment			
			Phase 1	Phase 2	Phase 3	Phase 4
Objective	Application	Authorisation	Concept Design Assessment	Principal Safety and test and qualification approach review	Safety Case Assessment	Post Phase 3 Process Assessment
Documentation	Application as per Appendix A	• Project Management documentation (6.3.1) • Initial Design Information (6.3.2)	• Concept Design • Safety Concept and Philosophy • Safety Classification Method, • Approach to the application of Codes and Standards • Material Selection approach and process • Approach to DiD and ALARA • Approach to external events • Approach to event selection and categorisation • Strategy on Safety Analysis; • Approach to modelling and simulation, including V&V of computer codes and models • Approach to design ito ISI and Maintainability • Approach to testing and qualification • Strategies for resolution of Key Safety Issues	• System descriptions and design basis • BoP information/envelop and connectivity • Process flow diagrams • C&I concept and design • Electrical Power, including emergency supply • Monitoring concept • Maintenance and ISI concept • Operating Envelope • Site Envelope • Safety Classification, • Codes and Standards justification • Material Selection • Implementation of DiD and ALARA • Civil Design including protection against external and internal events • Initiating events • Representative DSA and PRA reports for PIE's • Sources of radioactivity and source term analyses • Qualification of materials • Design specification of SSC • Accident Management • Human Factors, Human Reliability Analysis, and Human interface • Safety case specification	• Safety Concept and Safety Philosophy Document • *Reference Design* Safety Analysis Report (RD-SAR) • Balance of Safety Case Documentation: Inspection, test and qualification bases and plans and acceptance criteria ISI and maintenance bases RP Programme bases Accident management philosophy OTS philosophy and approach Construction and commissioning approach Decommissioning strategy Security strategy and philosophy	• Configuration and change management process and plan • Changes to the *Reference Design* as per change management plan
Outcome	Accept/ reject application	NIL to design	NNR Evaluation Report with comments & conditions	NNR Evaluation Report with comments & conditions	Safety Evaluation Report (SER)	Resolution of comments & conditions; Updated SER