NATIONAL NUCLEAR REGULATOR

For the protection of persons, property and the environment against nuclear damage

REGULATORY GUIDE

INTERIM GUIDANCE ON SAFETY ASSESSMENTS OF NUCLEAR FACILITIES

RG-0019

Rev 0

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1 INTRODUCTION

The mandate of the National Nuclear Regulator (NNR) is to, amongst others, exercise regulatory control over the siting, design, construction and operation of nuclear facilities to protect the public, property and environment against nuclear damage. As part of this mandate, the NNR has prepared this guideline to ensure that authorisation holders (or prospective holders of nuclear authorisations) perform the required safety assessments demonstrating safety of the nuclear facility and compliance with applicable regulatory requirements. The authorisation holder of a nuclear facility (the licensee) bears the prime responsibility for ensuring that the nuclear facility is sited, constructed, operated and decommissioned in compliance with applicable safety requirements, approved plans and procedures.

The regulatory guide (RG) supersedes NNR guidance related to the “Safety Assessments of Nuclear Facilities” currently found in:

1. LG-1041 (Rev 0): Licensing Guide on the Safety Assessments of Nuclear Power Reactor Sites; and
2. LG-1042 (draft): Guidance on Licensing Requirements for Non-Reactor Nuclear Facilities.

This document provides guidance on the regulatory requirements as contained in the draft General Nuclear Safety regulations and the draft Specific Nuclear Safety Regulations: Nuclear Facilities as it pertains to Safety Assessments of nuclear facilities.

The NNR strives to ensure that this Regulatory Guidance document is complete and accurate. However, in recognition of the fact that this document is being presented to authorisation holders prior to the promulgation of its associated Regulations, the NNR makes no warranty, express or implied, to the accuracy, completeness, or usefulness of any information, including warranties to the adequacy of its contents. This Regulatory Guidance document is provided as INTERIM guidance in good faith and its aim is to assist authorisation holders to achieve high levels of safety for facilities and activities that are part of the nuclear fuel cycle. The NNR assumes no legal liability or responsibility for any action taken by you due to information in this document and such actions are expressly carried out at your own risk. The information in this document is subject to change due to promulgation of its associated Regulations. Complying with applicable laws remains the responsibility of authorisation holder.

2 PURPOSE

This RG has been issued to provide general guidance to current or prospective licence holders on the documented evidence that are acceptable to the NNR on safety assessments. This RG also addresses the various regulatory interfaces between the licensee (or prospective licensee) and the NNR, and the various licensing stages associated with such a safety assessment.

3 SCOPE

1) The RG focusses on prior nuclear safety assessments to be conducted in order to be granted a nuclear license and addresses the safety case content produced by the licensee (or prospective licensee) for the following purposes:

a) New licence application;

b) Modifications to nuclear facility;

c) Change to the current licensing basis such as:

   i) Change to licence-binding documentation;

   ii) Change to any aspect of the safety envelope;

d) Other:

   i) Operating experience (OE) feedback (international or plant-specific);

   ii) A safety concern raised as a result of a proactive assessment;

   iii) International topical issue and new knowledge;

e) Any safety assessment as may be required by the NNR from time to time.

2) Detailed guidance on operational safety assessments, including periodic safety reviews and worker safety assessments are outside the scope of this RG.

4 TERMS, DEFINITIONS AND ABBREVIATIONS

4.1 Terms and definitions

In this RG any word or expression to which a meaning has been assigned in the NNR Act (henceforth referred to as "the Act") or the Regulations promulgated in terms of the Act, shall have the meaning so assigned. Only additional terms, definitions and abbreviations are provided.

"**current licensing basis**" means the safety case applicable at any time during operation of the plant, comprising applicable regulations and Regulator guidelines and all licence-binding documentation, including project management documentation, safety analysis report, operational limits and conditions, and other safety related programmes applicable during licensing stages (including modifications), which shall be retained as records;

"**early releases**" means situations that would require off-site emergency measures but with insufficient time to implement them;

"**large releases**" means situations that would require protective measures for the public that could not be limited in area or time;

"**practically eliminated**" means the possibility of certain conditions occurring is considered to have been practically eliminated if it is physically impossible for the conditions to occur or if the conditions can be considered with a high degree of confidence to be extremely unlikely to arise;

"**safety assessment**" means an assessment of all aspects of an activity or facility that are relevant to protection and safety; for a facility, this includes assessment of siting, design, construction, operation and decommissioning of the facility;

"**safety case**" means a logical and hierarchical set of documents that demonstrates compliance with the Regulatory requirements and criteria and describes the radiological hazards in terms of a facility, site and the modes of operation, including potential undesired modes, and encompasses the authorisation basis, and safety related documentation applicable during different authorisation stages and will include the safety assessment, operational safety related programmes and supporting documentation;

4.2 Abbreviations

AOO	:	Anticipated Operational Occurrences
CAAS	:	Criticality Accident Alarm System
DBA	:	Design Basis Accident
DBEC	:	Design Basis Extension Conditions
FHA	:	Fire Hazards Analysis
GOR	:	General Operating Rules
IAEA	:	International Atomic Energy Agency
ISI	:	In-Service Inspection
IST	:	In-Service Testing
NCS	:	Nuclear Criticality Safety
NNR	:	National Nuclear Regulator
PHA	:	Process Hazard Analysis
QA	:	Quality Assurance
RG	:	Regulatory Guidance Document
SSC	:	Structure, System and Component
SSR	:	Site Safety Report

5 REGULATORY FRAMEWORK

5.1 Legal basis

1) The legal basis for the NNR relating to safety assessments of nuclear facilities is derived from the NNR Act, specifically Sections 5 (a) and (b), 20(1), 21(1) and 23 of the Act.

2) Section 5 (a) of the Act mandates the NNR to set regulatory standards and practices.

3) Section 5 (b) of the Act grants the NNR powers to, 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 issuing of nuclear authorisations.

4) Section 20 (1) of the Act states that: "No person may site, construct, operate, decontaminate or decommission a nuclear facility, except under the authority of a nuclear installation licence." In terms of the provisions this section the siting, construction, operation, decontamination or decommissioning, or closure (in the case of a radioactive waste disposal facility) of any nuclear facility as defined in section 1(xviii) of the Act must be authorised by way of a nuclear licence granted by the NNR.

5) Section 21(1) furthermore requires that any person wishing to site, construct, operate, decontaminate or decommission a nuclear facility may apply in the prescribed format to the Chief Executive Officer of the NNR for a nuclear licence and must furnish such information as the NNR Board of Directors requires.

6) In terms of Section 23 of the Act, the Chief Executive Officer may impose (and amend) conditions of authorisation which are necessary to ensure the protection of persons, property and the environment against nuclear damage, or to provide for rehabilitation of the site.

5.2 Regulatory Standards

1) The NNR has promulgated in terms of section 36 of the Act regulations on Safety Standards and Regulatory Practices that must be complied with.

2) Part FOUR: Authorisations of Activities, regulation **2**. (2) (l) of the General Nuclear Safety regulations requires that a safety case be submitted to the Regulator in support of an application for, amongst others, nuclear facilities. Part ONE of these regulations define the safety case to include a safety assessment.

3) Part FIVE: Safety Assessments of the General Nuclear Safety regulations set out the safety assessment requirements in general to be complied with by applicants or authorisation holders and specifically address the following:

   a) Safety analyses, both deterministic and probabilistic safety analysis;

   b) Prior safety assessments;

   c) Operational safety assessments;

   d) Accident management;

   e) Periodic safety reviews;

   f) Worker safety assessments; and

   g) Public safety assessments.

4) Regulation 4 of the Specific Nuclear Safety Regulations: Nuclear Facilities stipulates the nuclear safety criteria and principles for nuclear facilities to be complied with in addition to demonstration through deterministic and probabilistic safety analyses compliance with the NNR's fundamental safety criteria and objectives as detailed in Annexure 2 of the General Nuclear Safety regulations.

5) Regulation 5 of the Specific Nuclear Safety Regulations: Nuclear Facilities provides specific requirements on safety assessments for nuclear facilities and specifically addresses, amongst others:

   a) Internal and external hazards;

   b) Events selection and classification;

   c) Acceptance criteria;

   d) Uncertainty analysis;

   e) Preconstruction safety analysis report;

   f) Site safety report;

   g) Pre-operational safety analysis report;

   h) Probabilistic safety assessment;

   i) Periodic safety reviews; and

j) Independent verification.

6 NUCLEAR SAFETY CRITERIA AND PRINCIPLES

6.1 General

1) The safety objectives for nuclear facilities in accordance with regulation 4 of the Specific Nuclear Safety Regulations: Nuclear Facilities are:

   a) Prevention of accidents shall be the focus, by designing for fault tolerance through application of good engineering principles. Fault tolerance is the property of a system to continue operating in the event of failure of one or more components;

   b) For all accidents taken into account in the design basis, there shall be no offsite effects and no significant onsite doses for workers as far as reasonably practical;

   c) The likelihood of an exposure shall decrease as the potential magnitude thereof increases;

   d) Accidents which could lead to early or large releases shall be practically eliminated and have to be considered in the design of the facility; and

   e) Any offsite releases that could occur shall only require limited offsite emergency response.

2) Prevention of accidents:

   a) The primary means of preventing accidents in a nuclear facility and mitigating the consequences of accidents is the application of the concept of Defence-in-Depth (DiD). This concept should be applied to all safety related activities, whether organizational, behavioural or design related, and for all operational states.

   b) Application of the concept of DiD throughout design and operation should provide protection against anticipated operational occurrences and accident conditions, including those resulting from equipment failure or human induced events within the facility, and against consequences of events that originate from outside the nuclear facility.

   c) A second complementary aspect of the DiD principle is the concept of multiple, independent physical barriers to prevent or eliminate uncontrolled release of radioactive material to the environment. The demonstration of the adequacy of these barriers is an important part of the safety analysis.

      i) These barriers should be designed on the basis of the facilities lifetime, both for steady states and transients occurring in any operational conditions.

      ii) These barriers should be designed such that:

         (1) Their integrity is maintained under all facility conditions;

         (2) The integrity of at least one barrier is adequately maintained in Design Base Extension Conditions and to the extent possible for severe events.

   d) Particular attention should be paid to the independence of successive barriers.

3) Postulating initiating events (PIE)

   a) PIE's should be identified on the basis of engineering judgement and a combination of deterministic assessment and probabilistic assessment. A justification of the extent of usage of deterministic safety analysis and probabilistic safety analysis should be provided, to show that all foreseeable events have been considered.

b) PIE's should include all foreseeable failures of structures, systems and components of the plant, as well as operating errors and possible failures arising from internal and external hazards, whether in full power, low power or shutdown states

c) An analysis of the PIE's for the facility should be made to establish the preventive measures and protective measures that are necessary to ensure that the required safety functions will be performed.

d) PIE's used for developing the performance requirements for the items important to nuclear safety in the overall safety assessment and the detailed analysis of the facility should be grouped into a specified number of representative event sequences that identify bounding cases and that provide the basis for the design and the operational limits for items important to safety.

e) Where prompt and reliable action would be necessary in response to a PIE, provision should be made in the design for automatic safety actions for the necessary actuation of safety systems, to prevent progression to more severe plant conditions.

f) Where prompt action in response to a PIE would not be necessary, it is permissible for reliance to be placed on the manual initiation of systems or on other operator actions. For such cases, the time interval between detection of the abnormal event or accident and the required action must be sufficiently long, and adequate procedures (such as administrative, operational and emergency procedures) should be specified to ensure the performance of such actions. An assessment should be made of the potential for an operator to worsen an event sequence through erroneous operation of equipment or incorrect diagnosis of the necessary recovery process.

g) Where the results of engineering judgement, deterministic safety assessments and probabilistic safety assessments indicate that combinations of events could lead to anticipated operational occurrences or to accident conditions, such combinations of events should be considered to be design basis accidents or should be included as part of design extension conditions, depending mainly on their likelihood of occurrence. Certain events might be consequences of other events, such as a flood following an earthquake. Such consequential effects should be considered to be part of the original PIE.

4) Practical elimination

a) Accident sequences with a large or early release can be considered to have been practically eliminated if:

i) It is physically impossible for the accident sequence to occur; or

ii) The accident sequence can be considered with a high degree of confidence to be extremely unlikely to arise.

b) In each case the demonstration should show sufficient knowledge of the accident condition analysed and of the phenomena involved, substantiated by relevant and sufficient evidence.

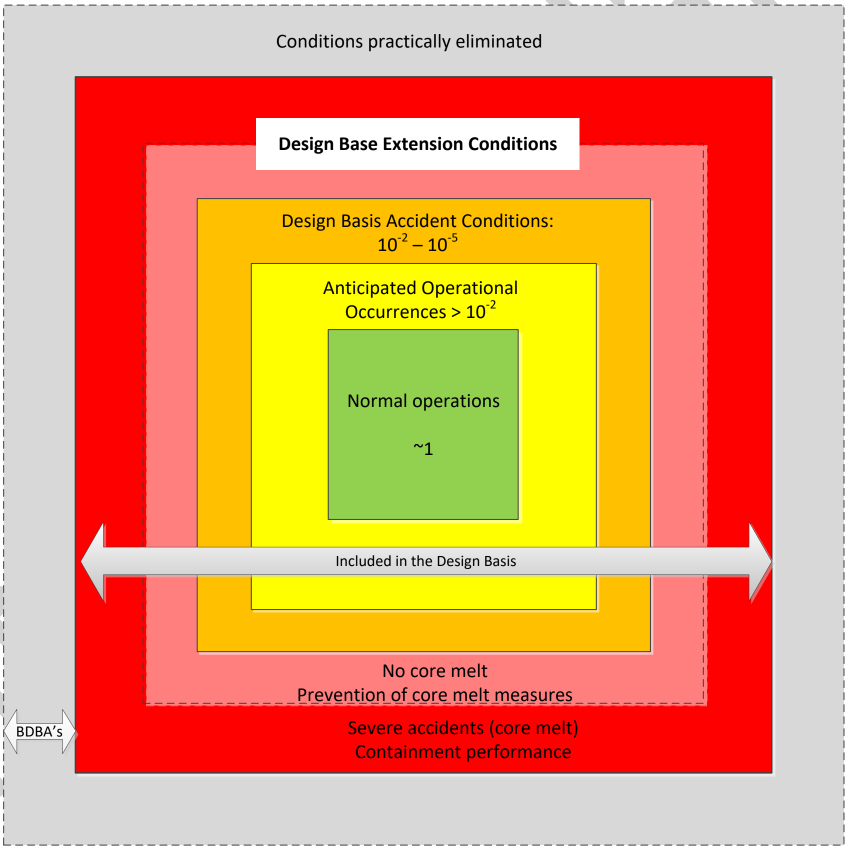
c) The degree of substantiation provided for a practical elimination demonstration should take account of the assessed frequency of the situation to be eliminated and of the degree of confidence in the assessed frequency (uncertainties associated with the data and methods must be evaluated in order to underwrite the degree of confidence that is claimed).

d) Appropriate sensitivity studies should be included to confirm that sufficient margin to cliff edge effects exist. For engineered provisions, the practical elimination can be done for instance by providing substantial increase of the protective means of reliability.

e) Practical elimination of an accident sequence should not be claimed solely based on compliance with a general cut-off probabilistic value. Even if the probability of an accident sequence is very low, any additional reasonably practicable design features, operational measures or accident management procedures to lower the risk further should be implemented.

5) In accordance with the regulations "*events determined to be included in the design basis shall be categorised as normal operation, anticipated operational occurrences, design basis accident conditions and design basis extension conditions*".

6) The following figure provides a graphical depiction of and guidance on the event categorisation:



7) The following table provide guidance on classification of events, and includes acceptance criteria that must be complied with, for the respective event categories:

Category	Frequency	Acceptance Criteria
Anticipated operational occurrences (AOOs)	Equal to or greater than 10^{-2} per year of operation of the facility	250 µSv to any member of the public

Design base accidents	Events (including combinations of events) equal to or greater than 10^{-5} per year of operation of the facility but less than 10^{-2}	No radiological impact outside the site boundary or exclusion area in excess of 50mSv at the lower end of the frequency scale
Design base extension conditions	All events (including combinations of events as well as multiple failures) with frequencies of less than 10^{-5}, including severe accident conditions	Radiological consequences outside the exclusion area are within specified limits
		Offsite radiological consequences requires limited protective measures in area and time

8) The nuclear facility should be designed so that it brought into a controlled stable state and the confinement function can be maintained.

9) Limited protective measures

   a) The offsite radiological impact of accidents that are not practically eliminated should only lead to limited protective measures in area and time.

   b) There should be no permanent human relocation, no long term restrictions in food consumption, no need for emergency evacuation outside the immediate vicinity of the nuclear facility, or only limited sheltering required.

   c) Iodine prophylaxis should also be limited in area and time.

   d) Sufficient time should be available to implement these measures.

10) For the design stage of a nuclear power plant, the following interpretations of limited protective measures are provided:

   a) Immediate vicinity of the plant: For new reactors, the design should be such that the possible release of radioactive substances in a postulated core melt accident, based on the analysed consequences of the accident, should not initiate a need for emergency evacuation beyond the exclusion boundary;

   b) Limited sheltering and iodine prophylaxis: For new reactors, the design goal should be such that the possible release of radioactive substances in a postulated core melt accident, based on the analysed consequences of the accident, will not initiate a need for sheltering and iodine prophylaxis beyond the suggested urgent protective zone;

   c) No long-term restrictions in food consumption: After a postulated core melt accident, based on the analysed consequences of the accident, agricultural products beyond the urgent protective zone should generally be consumable after the first year following the accident; and

   d) Sufficient time: Protective measures should be initiated early enough. Especially the evacuation should be carried out already when there is a threat of a significant radioactive release into the environment. Sufficient time to implement these protective measures is different for each measure and for each accident scenario and depends on the location of the reactor. Sufficient time for each measure should be estimated and considered in the design of a reactor and during the site licensing.

6.2 Licensee responsibility

1) An independent review of the safety analyses should be performed and documented by suitably qualified and experienced assessors, who are independent of the original authors/preparers and verifiers and those directly responsible for the facility's operations.
2) Where analyses are performed by consultants or contractors, the licensee should produce auditable evidence of its own assessment of the analyses.
3) Where the definitive analyses comprising the basis of the safety assessment are performed by the licensee, the licensee should produce documentary evidence of independent reviews in accordance with quality assurance requirements.
4) As part of the production process, a safety assessment should undergo appropriate verification controls and a formal approval process to check, amongst other things, that:
   a) the safety case is complete;
   b) key safety assumptions are valid and have been subject to a sensitivity check;
   c) appropriate robust methods and data have been used;
   d) calculations are correct; and
   e) the plant and operational details documented are consistent with the actual as-built plant and its operational modes.

7 DEMONSTRATION OF SAFETY

1) In the demonstration of compliance with the fundamental safety criteria, the plant as designed, constructed, and operated, in accordance with well-defined standards and rules should be shown to be acceptably safe.
2) The approach for establishing safety in nuclear facilities begins with robust engineering design with defence-in-depth. The safety case should show how these have been achieved, and how safety functions have been identified and delivered.

7.1 Safety analysis

1) Safety analysis is the process applied to demonstrate compliance with nuclear safety criteria and should include both probabilistic and deterministic analyses.

7.1.1 Deterministic safety analysis

1) Deterministic analysis is the process whereby a set of plant conditions is established and the behaviour of the plant under these conditions is analysed to demonstrate compliance with (safety) criteria.
2) Specific requirements relating to deterministic safety analysis to be complied with are provided in regulation 3 (8) of Part FIVE: Safety Assessment of the General Nuclear Safety regulations.

3) Deterministic safety analysis should be used to assess the adequacy of the design and should cover both normal operations and abnormal behaviour, and should be supported by appropriate probabilistic analysis to judge the significance of uncertainties, show that risks are balanced, and demonstrate compliance with numerical risk criteria.
4) Deterministic safety analysis should be used to analyse AOO's, DBA's and DBEC's.
5) For AOO's and DBAs the safety analyses should be demonstrably conservative with respect to the figures of merit or safety criteria.
6) For DBECs, best estimate analyses plus uncertainty or sensitivity analyses, may be justified.
7) Guidance on "*Deterministic Safety Analysis for Nuclear Power Plants*" can be found in the IAEA Specific Safety Guide, SSG-2.
8) Additional guidance on safety analysis for research reactors is given in IAEA Safety Guide SSG-20.

7.1.2 Probabilistic Safety Analysis

1) Probabilistic safety analysis is the process whereby various consequences are identified (e.g. failure of a protective barrier, release of fission products to the environment, fatalities) and the probabilities of such consequences are computed.
2) According to regulation 3 (9) of Part Five: Safety Assessment of the General Nuclear Safety regulations, probabilistic safety analysis must be performed to demonstrate compliance with the numerical risk criteria unless it can be justified that no credible accident conditions exist.
3) The numerical risk criteria refer to limits on the annual individual peak and average risk to members of the public and plant personnel due to accident conditions and are established according to the following principles (see Appendix 3 for explanation):
   a) The risk presented by a nuclear site must not increase significantly the total risks to which the general population is exposed;
   b) The nuclear risk must compare favourably with those associated with other major industrial enterprises; and
   c) Allowance must be made for possible demands by society for greater standards of safety over the period (assumed to be several decades) of the full life-cycle life of the enterprise.
4) The probabilistic safety analysis should include the determination of damaged states for the facility, an evaluation of the status of radiological barriers, the source term releases and the potential consequence to the public.
5) Either a best estimate analysis, with uncertainties, or a conservative analysis may be performed.
6) For nuclear power plants typical probabilistic safety analysis typically should include calculation of the core damage frequency or plant damage states (PSA Level 1), source term releases (PSA Level 2) and consequence analysis (PSA Level 3).
7) Guidance on "*Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants*" can be found in the IAEA Specific Safety Guide, SSG-3.
8) Additional guidance on "*Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants*" can be found in the IAEA Specific Safety Guide, SSG-4.

7.2 Uncertainty Analysis

1) Uncertainty analysis refers to the statistical combination and propagation of uncertainties in data, whereas sensitivity analysis refers to the sensitivity of results to major assumptions about parameters, scenarios or computer modelling.

2) Specific requirements relating to uncertainty analysis and sensitivity to be complied with are provided in regulation 5(5) of the Specific Nuclear Safety Regulations: Nuclear Facilities.

3) The level of confidence in all assumptions or data should be justified. All safety factors, for which credit is claimed for, in the analysis, should be controlled by appropriate rules, procedures and quality regimes (e.g. monitoring, maintenance, training, etc.) where applicable.

4) In the demonstration of compliance with quantitative safety criteria, the safety case should address uncertainties as follows:

   a) For the design basis, a rigorous approach is required;

   b) For demonstration of compliance with the fundamental safety standards, an uncertainty analysis should be performed using an acceptable methodology;

   c) The uncertainty analysis should be used to establish the level of confidence in the results, and should be considered in the decision making process relating to compliance;

   d) As an alternative to performing an uncertainty analysis, an approach involving use of both conservative (enveloping) analysis and best-estimate analysis is also acceptable.

7.2.1 Conservative Analysis

1) A conservative (enveloping) analysis should be performed for design basis accidents.

2) In instances where the conservative analysis shows noncompliance with the safety criteria, a best-estimate analysis may be performed for those specific factors, which contribute significantly to noncompliance.

3) The level of confidence in the best-estimate analysis for such factors must be justified by means of an uncertainty analysis and sensitivity analysis.

7.2.2 Best Estimate Analysis

1) As the numerical risk criteria refer to mean values, an overall best-estimate analysis (i.e. one employing unrestricted use of best-estimate values) is required to provide a measure of the safety margins. Such an analysis may also be used in the application of the ALARA principle.

2) In the case of demonstrating compliance with the numerical risk criteria, credit may be given for safety factors associated with a high level of uncertainty (e.g. non safety classified systems, structures or components, severe accident management guidelines and the emergency plan). The results of such analyses may be used to demonstrate acceptable safety margins.

7.2.3 Reliance on Countermeasures

1) Reliance may not be placed on highly uncertain factors or countermeasures.

2) No credit may be claimed for off-site countermeasures involving the public (emergency planning). This is a matter of principle and does not only relate to the question of uncertainties.

3) Credit may however be claimed for the implementation of a food ban provided the process has adequate procedures and is shown to be credible.

7.3 Safety Analysis Report

1) In the context of this regulatory guide, the Safety Analysis Report (SAR) refers to the principle document produced by the licensee, to demonstrate compliance with nuclear safety criteria and licensing requirements. The SAR should address the following:
   a) Statutory requirements relating to nuclear safety;
   b) Licensing requirements and fundamental safety criteria;
   c) Safety philosophy and approach;
   d) Design criteria;
   e) Codes and standards (Engineering, Radiation Protection, etc);
   f) Functional testing and qualification;
   g) Safety related commissioning
   h) Description of the plant, site and environs;
   i) Safety analyses;
   j) Safety analysis methodology, computer codes, models and validation;
   k) Identification of a safety envelope (assumptions/data used or implied in the safety/risk analyses);
   l) Effluent and radioactive waste management;
   m) Accident and Emergency management; and
   n) Decommissioning.
2) To enable the NNR to determine whether the construction approval for a facility can be granted, the following should be described in the SAR:
   a) The site description related to the safety assessment of the design basis, including information needed for quantification of the likelihood and severity of the natural phenomena such as earthquakes, floods, natural fires, and windstorms;
   b) A description of the credentials of the persons who carried out the safety assessment of the design bases.
   c) The methodology for conducting the safety assessment of the design basis, including:
      i) Hazard identification;
      ii) Analyzing of select accidents;
      iii) Evaluating of radiological consequences and likelihood to show compliance with the nuclear safety criteria and principles.
   d) The safety assessment of the design bases of the main SSCs of the facility, including:
      i) A hazard identification;
      ii) A process hazard analysis (PHA) that examines selected accidents; and
      iii) An assessment of the likelihood and consequence of the accidents examined in the PHA.
   e) A description of the design bases of the principle SSCs, including:

i) The provisions and design bases for protection against natural phenomena; and

ii) The design bases for protection against other potential accidents.

7.3.1 Licensing Requirements and Fundamental Safety Criteria

1) The SAR should demonstrate compliance with the fundamental safety criteria and other requirements laid down by the NNR which include:

   a) Risk criteria addressing mortality risk to the public (present and future generations) and workforce;

   b) Radiation dose limits to members of the public and workforce arising from normal operations;

   c) Fundamental safety principles (including defence-in-depth and ALARA);

   d) Compliance with international norms and standards;

   e) Requirements for emergency planning; and

   f) Management system requirements.

7.3.2 Safety Concept, Philosophy and Approach

1) The SAR should address the safety concept and philosophy of the design of the facility, including how the applicant intends to meet regulatory requirements, align to international best practices and standards, and manage safety.

2) This should include high level rules and assumptions for the development of the safety case such as:

   a) Approach used in respect of probabilistic and deterministic analyses;

   b) Approach used to categorise events/accidents;

   c) Rules applicable to the different categories of events/accidents;

   d) Establishment of specific design/safety criteria linked to the classification scheme;

   e) Application of defence-in-depth (e.g. single failure criterion); and

   f) Rules for classification of systems, structures and components.

7.3.3 Design Criteria

1) The design criteria should be defined that provide an adequate margin of safety to the fundamental safety standards.

2) These design criteria should include the following:

   a) General Design Criteria: High level criteria expanding on risk and defence-in-depth considerations and respecting the need for a graded approach to redundancy and design specifications based on importance to nuclear safety.

   b) Specific Design Criteria: These are the detailed design criteria relevant to safety, and expanding on the general design criteria.

7.3.4 Codes and standards (Safety assessment, Engineering, Radiation Protection, Surveillance, Operations and Quality Assurance)

1) In accordance with regulation 5 (3) of Part THREE: Management of Safety of the General Nuclear Safety regulations, codes and standards that will be used in the design and operation of a nuclear facility must be identified, justified and evaluated for acceptability, etc.

2) Detailed requirements related to the implementation of codes and standards are provided for in regulation 6 (3) (a) of the Specific Nuclear Safety Regulations: Nuclear Facilities.

3) Codes and standards should therefore be specified and defined for all safety related processes (including safety assessment, engineering, radiation protection, surveillance, operations and quality assurance) as a basis as well as a cornerstone of the safety envelope, and as a point of reference for comparison with practices of similar facilities and actions in other countries.

7.3.5 Testing and Qualification

1) Aspects of the safety analysis, design and manufacturing process that have not been benchmarked or tested previously should be subjected to a test programme.

2) The SAR should address all the aspects of the test programmes relevant to the safety case, including safety during implementation of the programmes, and provide evidence of the acceptability of those aspects of the safety case that are dependent on the outcome of such programmes.

3) All aspects of qualification testing, including prototype testing, pre- and post-installation testing and commissioning should be addressed.

4) Additional guidance on Testing and Testing Programmes are provided in Section 10 of RG-0012 "*Guidance on Construction Management for Nuclear Facilities*".

7.3.6 Description of the Nuclear Facility, Site and Environs

1) The description of the nuclear facility, site and environs should include all factors relevant to the safety case, including location and factors relevant to external hazards, security risks and public risk including geography, meteorology, hydrology, land use, demographics (present and projected), other industrial undertakings, transport systems and military installations.

2) Engineering details may be referred to in references to the SAR.

3) For the preliminary stage (preliminary assessment) this information may relate to a reference (generic) site. For subsequent stages the information should be site-specific.

7.3.7 Safety Analyses

1) Safety analysis includes all analyses to demonstrate compliance with nuclear safety criteria, including deterministic and probabilistic analyses.

2) For the preconstruction stage, the full scope of selected analyses required for the final SAR is required even though the input data and assumptions are of a preliminary nature. The analyses for each stage to cover the hazards relevant to the licensing stage in question as well as all future licensing stages, including decommissioning, are required.

3) The (deterministic) analyses against design criteria should be conservative. The purpose of this position is to establish a clear and unambiguous design.

4) The risk assessment may however be used in support of a change to the design basis. Any decision to change the design basis should take into account international practice and engineering rules.

5) As the risk criteria refer to mean values, a best-estimate probabilistic risk analysis is acceptable.

6) A best-estimate analysis should however be accompanied by an uncertainty analysis and sensitivity analysis to provide an acceptable level of confidence that the fundamental safety standards complies with.

7.3.8 Safety Analysis Methodology and Validation

1) The safety analysis methodology relevant to the safety analyses for each licensing stage should be described in detail along with those of the calculational codes and models used and their validation thereof.

2) It is important that the methodology to be used for any computational analyses should be specified and justified in terms of the overall approach to be adopted, computer codes used, benchmarking, development of models, and standards. As the review of these aspects may be time-consuming, it is preferable that these be addressed in the preconstruction SAR.

3) In the case of safety analyses previously performed in another country in accordance with the nuclear regulatory requirements of that country, the relevant regulatory approval letter(s), along with confirmation of the present regulatory status, provide strong supporting evidence for local acceptability.

4) Where this is not available, or the analysis differs significantly from that approved elsewhere, additional information may be required. For example, an independent in-depth review, including computational analysis, by the licensee or a third party, may be required.

5) Any calculation methods and computer codes used in the safety analysis have to undergo verification and validation of sufficient pedigree.

6) Detailed guidance is provided in RG-0016, “Guidance on the Verification and Validation of Evaluation and Calculation Models used in Safety and Design Analysis”.

7.3.9 Accident and Emergency Management

1) The applicant is required to submit an acceptable level of evidence of planning for accident management and emergency preparedness directed at situations involving real or potential radiological hazards.

2) This should address those design features, facilities, functions, and equipment that may affect some aspect of emergency planning or the capability of an applicant to cope with plant emergencies. In addition, coordination with offsite organizations should be addressed.

7.3.10 Safety Related Commissioning

1) The commissioning programme must explain the details of the pre-operational test. It should be shown that these tests adequately verify the functional requirements of plant SSC's.

2) It should be demonstrated that the sequence of testing is such that safety will not, at any time, depend on unqualified and untested SSC's.

3) Additional guidance on commissioning features in Section 10 of RG-0012 "*Guidance on Construction Management for Nuclear Facilities*".

7.3.11 Decommissioning

1) Information must be provided on arrangements for decommissioning; including provisions for dismantling, transporting and storing radioactively contaminated components without undue risk to site personnel, the public or the environment.

2) An indication should be provided of the important radioactive components that are to be removed from the facility during decommissioning, an estimation of their masses and radiation activity levels accompanied by proposals for their ultimate disposal.

3) The design features incorporated to facilitate future decommissioning and the conceptual decommissioning plan/ strategy should be described in details.

7.4 Safety Envelope and Design Bases

1) The SAR should result in the definition of a safety envelope in such a way as to provide an adequate operational margin for the plant and to make allowance for future changes considered to be of low regulatory concern and therefore not requiring approval by the NNR.

2) The safety envelope should effectively be defined in the current licensing basis (and the updates thereto) with a view to minimising unnecessary licensing activities on issues of low safety significance, while ensuring compliance with nuclear safety criteria.

3) The SAR should include an auditable trail linking the data used in the plant-specific analyses as this is relevant to the safety envelope. The inclusion of data explicitly in the SAR may be discussed on a case-by-case basis, with the objective to facilitate verification of conformance with the safety envelope for any envisaged future changes or modifications to the nuclear facility or its General Operating Rules (GORs).

4) The applicant should begin the safety analysis with an identification of all hazards (chemicals, radiological materials, fissile materials, etc.) that may present a potential threat to the public, facility workers, or the environment (Appendix 1).

5) Based on a systematic analysis of each plant process, the safety analysis process hazard analysis (PHA) identifies a set of individual accident sequences or process upsets that could result from the hazards. The applicant's safety analysis methodology should therefore generally address:

   b) Hazard identification;

   c) PHA (accident identification);

   d) Initiating event identification;

   e) Accident sequence construction and evaluation;

   f) Consequence determination; and

   g) Likelihood categorization for determining compliance.

7.5 Format and Content of the SAR

1) Guidance on the format and content of the SAR for Power Reactors, Nonpower Reactors and nonreactor nuclear facilities are provided in Part I, II and III of Appendix 4 respectively.

2) The format and structure of the SAR should be agreed with the NNR sufficiently in advance and prior to the submittal of the respective safety case.

8 SAFETY CASE

8.1 General

1) The safety case should demonstrate compliance with nuclear safety criteria and identify all requirements, provisions and undertakings necessary to support the safety assessment.

2) The safety case should establish and demonstrate in written form that the facility, process, activity, modification, etc. being proposed:

   a) are soundly assessed and meet required safety principles;

   b) conform to good nuclear engineering practice and to appropriate criteria, standards and codes of practice;

   c) are adequately safe during both normal operation and accident conditions;

   d) are, and will remain fit for purpose;

   e) give rise to a level of nuclear risk to both public and workers which is optimised; and

   f) have a defined and acceptable operating envelope, with defined limits and conditions, and the means to keep within it.

3) In the context of this licensing guide, the term safety case refers to all documentation relevant to the demonstration of compliance with nuclear safety criteria and should be structured in a logical manner and be demonstrably complete. It should contain all the information necessary to demonstrate safety. This information should be easily accessible and understandable.

4) This encompasses the current licensing basis (except for NNR licence documents), and safety related documentation applicable during different licensing stages (where applicable). The safety case typically includes:

   a) Safety analysis report (SAR);

   b) General Operating Rules (GOR);

   c) SAR/GOR supporting documentation;

   d) Other licence binding documents;

   e) Changes to the SAR/GOR and supporting documentation relevant to the particular application;

   f) Project management documentation; and

   g) Safety related programmes applicable during a given licensing stage.

5) There are also a number of different types of documented information that should underpin the safety arguments. These may include:

a) Identification of events and hazards and compilation of a comprehensive list if initiating events and postulated initiating events;

b) Criteria for choosing the Design Basis events, Design Basis Extension Conditions and hazards (i.e. those events and hazards for which design measures are explicitly claimed in the safety case);

c) Deterministic analysis of the design against these events;

d) Determination of the safety functional requirements of the structures, systems and components important to nuclear safety;

e) Determination of limits, conditions and associated trip and alarm setpoints and a comprehensive protection schedule;

f) Task analysis of important operations;

g) Probabilistic safety analysis; and

h) Identification of suitable accident management and emergency arrangements.

6) The safety case is a document or set of documents produced (and maintained) by the licensee to demonstrate that the facility complies with nuclear safety criteria and to establish the conditions and undertakings to ensure their validity.

8.2 Notification and Initial Discussions

1) Safety assessments should typically be initiated for any of the following purposes:

a) New licence application;

b) Modification on a licensed facility or site impacting on nuclear safety;

c) Change to the current licensing basis including:

i) Change to licence-binding documentation; and

ii) Change to any aspect of the safety envelope;

d) Others such as:

i) Experience feedback concern (international or plant-specific);

ii) Any safety concern raised as a result of a proactive assessment; and

iii) International topical issue; and

e) Any additional assessment required by the NNR.

2) With regard to items 1) b) – 1) d) above, the licensee should perform a screening assessment in accordance with the condition of authorisation to establish any impact on the current licensing basis.

3) The notification and initial discussions with the NNR should take place through the relevant NNR project department and include the following information:

a) Description of the project (sufficient detail to motivate need for safety case);

b) Identification of any safety measures while the safety assessment is in progress (i.e. in respect of new safety concerns); and

c) Identification of licensing stages of the project.

4) Depending on the reason or need for the safety assessment, the different licensing stages should be identified and agreed with the NNR on a case-by-case basis. Typical licensing stages are shown in Appendix 2 with guidance as to possible reasons for introducing the various stages.

5) The various licensing stages should be established with a view to streamlining the licensing process and avoiding unnecessary delays and time-pressure. Allowance should be made for assessments that may prove to be time-consuming.

6) The applicant or authorisation holder is required to produce a safety case for each licensing stage.

8.3 Preliminary safety case

1) The licensee may be required to produce a preliminary safety case for the proposed project as part of a Design Assessment.

2) The focus of the preliminary assessment is on basic principles, scope of safety case, proposals for aspects of the safety case and project plans for subsequent phases. No actual hazard potential is incurred during this phase of the project. The safety case for this phase is not necessarily site specific.

3) The objectives of the preliminary safety case are as follows:

   a) To provide confidence that the project is licensable;

   b) To lay down the framework for the final safety case;

   c) To identify potential problem areas that need early intervention measures; and

   d) To assist in the preparation of detailed project plans, test and qualification plans and quality plans.

4) The preliminary safety case should as far as possible define a safety envelope in such a way as to make provision for changes in the design and safety case during the development of the project to minimise the need to review whether the facility is licensable. The safety envelope should be refined as necessary in subsequent licensing stages.

5) The preliminary safety case should address the complete life cycle (where applicable) of the site from siting, construction, component manufacturing, prototype testing, pre-operational testing, commissioning, operation and decommissioning. In this regard the scope of the preliminary safety case is wider than that of the final safety case, and should include quantitative results, even though these may change as the project advances. The basic principles of the assessment of the various stages of the project should be addressed.

6) At this preliminary stage the project management documentation should be of sufficient maturity to establish confidence in the information supplied in the preliminary safety case and the processes used to develop it. In view of the preliminary nature of this phase, the project management documentation need only contain a brief description of the project management aspects relating to subsequent phases.

7) The preliminary safety case should identify the scope of the GOR and how it is intended that the various aspects be developed and linked to the safety case. The GOR need not be produced at this phase of the project.

8) The preliminary safety case should identify the processes relating to the development of all supporting documentation and linkage to the safety case. These documents need not be submitted at this phase of the project.

8.4 Safety case for different licensing stages

The scope of the safety case typically required by the NNR for different licensing stages of a project is expanded on as follows:

8.4.1 Siting

1) Refer to RG-0011 for detailed guidance on the siting of nuclear facilities and specifically to section 6.6 on the "Format and content of the safety case (NSL, NL)"

8.4.2 Preconstruction safety case

1) Section 14.3 of RG-0012 guidance on review of safety case for construction
2) If this phase of the project results in potential hazards, these should be addressed by the safety case (for example if construction or installation were to be performed on a licensed site). The safety case for this phase should be site specific.

8.4.2.1 Preconstruction SAR

1) The format and content of the Preconstruction SAR are site and facility specific and should be agreed with the Regulator.
2) The preconstruction SAR should include:
    a) General facility and process overview;
    b) Management of safety;
    c) Site evaluation;
    d) General design aspects;
    e) Description and conformance to the design of plant systems;
    f) Safety Analyses;
    g) Commissioning;
    h) Operational aspects;
    i) Operational Limits and conditions;
    j) Radiation Protection;
    k) Emergency Preparedness;
    l) Environmental aspects and safety;
    m) Radioactive waste management; and
    n) Decommissioning and end of life aspects.
3) Supporting documents that should accompany the Preconstruction SAR includes but are not limited to:

a) Detailed plant description used or implied in the safety analyses;

b) Specifications of all systems, structures components used or implied in the safety analyses;

c) On-site/off-site/environmental factors components used or implied in the safety analyses;

d) Design, manufacturing;

e) Technical bases to GOR linked to the safety analyses;

f) Safety-related plant management documentation;

g) QA/QC documentation and audit trail;

h) Processes relating to maintaining the validity of the safety case (eg screening and safety evaluation process).

4) General guidance on the format and content of a SAR for NPPs is in Part I of Appendix 4 and IAEA safety guide GS-G-4.1.

8.4.2.2 Preliminary GORs

1) The preliminary safety case should identify the scope of the GOR and how it is intended that the various aspects be developed and linked to the safety case.

2) The preliminary GORs should include a description of planned:

a) Radiation protection provisions;

b) Operating technical specifications;

c) Operating/incident/accident procedures;

d) Accident management, including severe accident management guidelines as appropriate;

e) Physical security;

f) Maintenance programme;

g) ISI/IST programmes;

h) Radiation protection programme;

i) Effluent and waste management programme; and

j) Emergency planning.

3) The final GOR need not be submitted in the preliminary stage, only strategies and preliminary GORs. For any other licensing stage, relevant GOR or GOR changes should be submitted with the application to the NNR for review and acceptance.

8.4.2.3 Interim Safety Related Programmes

1) The interim safety related programmes should include interim activities or programmes applicable during the various stages up to operation relevant to safety and should include the following as applicable:

a) Pre-installation/prototype testing

b) Construction/installation

c) Testing/commissioning

d) Decommissioning.

1) RG-0012 provides detailed guidance that should be implemented on construction management and associated safety related programmes.

8.4.3 Introduction of Radioactive Material on Site/Fuel Loading/Testing/Commissioning

1) Where potential hazards are introduced in the phase of the project, these should be addressed by the safety case.

2) The safety case for this phase must be site specific.

8.4.4 Decommissioning

1) The safety case for decommissioning should demonstrate compliance with the relevant requirements as contained in regulation 12 of PART VI of the General Nuclear Safety Regulations, and amongst others:

   a) Demonstrate that safety of both workers and the public are not compromised during decommissioning activities up to the end the decommissioning process;

   b) That all reasonable measures will be implemented to reduce doses to the workers; and

   c) That adequate financial and human resources are available for the duration of all phases of decommissioning.

2) The safety case for decommissioning must be supported by a final decommissioning plan that should include the contents as provided in Appendix 5.

8.5 Facility and Process Overview

1) The applicant should provide a facility and process overview that describes the purpose of the facility.

2) The following should be described:

   a) The overall facility layout on scaled drawings identifying the following types of features:

      i) The location of facility buildings such as plants, structures, buildings, towers, and tanks and other major manmade or geographical features;

      ii) Transportation rights of way;

      iii) Major ingress and egress routes for the site, including public access, – where applicable; and

      iv) The controlled areas, restricted areas, and/or other appropriate boundaries proposed by the applicant.

   b) The movement of personnel, material, and equipment during facility operation.

   c) A description of the major chemical or mechanical processes, including:

      i) The chemical and physical forms of material in the processes;

      ii) The maximum amounts of material in the processes;

iii) The building location of major components in the processes;

iv) A description of the processing steps; and

v) The types, quantities, and discharge points of waste discharged into the environment.

8.6 Nuclear Criticality Safety (NCS)

1) The applicant should demonstrate that:

a) An adequate organization with which to implement the NCS program is established;

b) An adequate NCS program to ensure safe operation of the facility is established including an adequate criticality accident alarm system (CAAS);

c) Adequate controls and limits on parameters relied on to prevent nuclear criticality are implemented; and

d) Accident sequences as documented in the safety analysis leading to nuclear criticality have been assessed.

8.6.1 Organization and Administration

1) The applicant is required to describe the responsibilities and authorities for organizations and individuals implementing the NCS program. This should include:

a) The general administrative organization methods used by the applicant;

b) The administrative organization of the NCS program, including authority and responsibilities of each position identified, and organizations and individuals with responsibility for NCS; and

c) Experience and education requirements of management and staff positions with NCS responsibility.

8.6.2 Management Measures

1) The applicant's management measures in support of the applicant's ability to implement and maintain the NCS program and to ensure the continued availability and reliability of items important to nuclear safety should be described.

2) The following areas of the application related to the applicant's management measures should be detailed:

a) Management functions, specifically as they relate to NCS.

b) The commitment to measures implementing the requirements to ensure that the initial facility design meets these design criteria and standards for NCS.

c) The implementation of the requirements to ensure that:

i) Facility changes are managed to maintain the integrity of the facility's safety basis and to ensure they receive the appropriate level of NCS review; and

ii) Facility changes requiring NNR approval are appropriately identified and treated.

8.6.3 Technical Practices

1) The applicant's implementation of NCS technical practices to ensure the safe operation of the facility should be described. This should include:

a) The commitment to implement NCS controls and limits in accordance with technical practices as described in the application, by incorporating them into the applicant's NCS program;

b) Technical practices, including a description of the management measures that ensure operability of the criticality accident alarm system and incident response procedures;

c) The technical practices to ensure that limits on controlled parameters have an adequate safety margin. These practices should include those used to ensure that the methods to develop NCS limits are properly validated;

d) The technical practices to ensure that sufficient NCS controls developed and taken up in the safety analysis, are identified for each process;

e) The areas of review with specific reference to:

i) Potential accident sequences that could result in nuclear criticality;

ii) Specific controls relied on to provide reasonable assurance that an inadvertent criticality will not occur; and

A demonstration that the likelihood of failure is sufficiently low so as to demonstrate compliance with the double contingency principle.

2) A commitment to prepare and maintain applicable safety basis documentation, which will be in sufficient detail so that criticality controls and contingency analysis can be reviewed and inspected by the NNR and applicant.

8.7 Fire Protection

1) The applicant should demonstrate that there is reasonable assurance that the applicant designed a facility that provides for "adequate protection against fires and explosions" and is based on defence-in-depth practices. This should also establish that the radiological consequence from fires is considered in determining how the facility will meet the fundamental safety requirements.

2) The adequacy of the following areas of fire protection should be addressed:

a) Organization and Conduct of Operations, which include:

i) Organization and management;

ii) Training and qualifications;

iii) Fire prevention;

iv) Engineering review of design changes;

v) Quality Management (QM), and

vi) Documentation and record keeping.

b) Fire Protection Features and Systems, which Plant include:

i) Construction features;

ii) Passive fire-rated barriers;

iii) Process and operational features;

iv) Fire detection and alarm systems;

v) Fire suppression systems and equipment; and

vi) Inspection, maintenance, and testing of fire protection features and systems.

c) Manual Fire Fighting Capability: A baseline needs assessment should establish the minimum required capabilities of site fire fighting forces. This assessment should include:

i) Minimum staffing;

ii) Organization and coordination of onsite and offsite firefighting resources;

iii) Personal protective and firefighting equipment, training, and

iv) Emergency planning.

d) Fire Hazards Analysis (FHA): The FHA consists of a systematic analysis of the fire hazards, an identification of specific areas and systems important to plant fire safety, the development of design basis fire scenarios, an evaluation of anticipated consequences, and a determination of the adequacy of plant fire safety.

8.8 Chemical Safety

1) Chemical safety addresses chemical hazards of radioactive materials and hazardous chemicals. In addition, it also address facility conditions that may affect the safety of authorised material (e.g., an inert gas incapacitating or suffocating operators or precluding entry to an area of the facility handling authorised materials), and the controls used to prevent the occurrence or mitigate the consequences of accidents.

2) The applicant should demonstrate reasonable assurance that the facility has been designed to provide for adequate protection against chemical hazards related to the storage, handling, and processing of the authorised material. This should also establish that the applicant's facility and system design and facility layout pertaining to chemical safety is based upon defence-in-depth practices and, where practical, favours passive over active control systems.

3) The applicant should describe the facility design and items important to nuclear safety and provide reasonable assurance of chemical safety at the facility for routine operations, off-normal conditions, and potential accidents.

4) The applicant is required to establish a safety program to demonstrate compliance with the fundamental safety requirements. This does not necessarily require the applicant to establish a separate chemical safety program, but the chemical hazards and accident sequences that affect radiological materials should be considered and should be adequately prevented or mitigated.

5) The following areas should be described:

a) Chemical Process description - including process chemistry, process flow diagrams, mass/energy balances, inventories, major/significant process steps, safe operating limits for key parameters (e.g., temperature and pressure), and major pieces of equipment;

b) List of Hazardous Chemicals Affecting Radioactive Materials - including potential interactions between chemicals and other materials as described in the SAR.

c) Chemical Accident Sequences - including unmitigated analyses involving the hazardous chemicals and authorised materials, as described in the SAR.

d) Chemical Accident Consequences - including assumptions, bases, and methods used to estimate the consequences of accidents for the workers, co-located workers, and the public identified in the safety analysis that involve hazardous chemicals and authorised materials.

e) Chemical Safety Controls - including the quantity and quality of controls used to mitigate or protect against accidents involving the release of hazardous chemicals and/or authorised materials, as determined by the safety analysis.

f) Chemical Process Safety Interfaces - including a description of how chemical safety interfaces with and is affected by other areas of review, including quality assurance, training, configuration management, maintenance, etc.

6) Information contained in the application should be of sufficient quality and detail to allow for an independent review, assessment, and verification by the NNR. Some information may be referenced to other sections of the application, or incorporated by reference, provided that these references are clear, specific, and essentially complete.

7) The NNR oversees chemical safety issues related to

a) Radiation risk produced by radioactive materials;

b) Chemical risk produced by radioactive materials; and

c) Plant conditions that affect the safety of radioactive materials and thus present an increased radiation risk to workers.

8) The NNR does not oversee facility conditions that result in an occupational risk but do not affect the safe use of radioactive materials.

8.9 Radiation Safety

1) Specific requirements to be complied with on Radiation Protection are detailed in Part SIX: Radiation Protection, Waste management and Decommissioning of the General Nuclear Safety Regulations.

8.9.1 Radiation safety design features

1) The applicant is required to demonstrate, with reasonable assurance, that the design for construction and operation of the facility is adequate to protect the radiological health and safety of workers and to comply with the regulatory requirements during routine and non-routine operations, including anticipated events and accident conditions.

2) The applicant is required to use, to the extent practical, engineered controls based on sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as reasonably achievable.

3) The following should be described:

a) Optimisation Design Considerations

i) Organizational relationships and responsibilities with respect to performing radiological design reviews;

ii) Application of optimisation into design-stage maximum individual and collective dose estimates;

iii) Descriptions and elements of the design review process for radiation protection; and

iv) How the applicant used experience from past designs and from operating plants to develop improved radiation protection design.

b) Facility Design Features

i) Proposed equipment and facility design features and facility layout as they relate to occupational radiation protection and ALARA concepts;

ii) Design features incorporated to minimize contamination and waste production, and facilitate ease of operations, maintenance, replacement, and decommissioning consistent with maintaining doses at levels that are ALARA;

iii) Facility design goals as they relate to radiation safety; and

iv) An assessment of the individual and collective doses via a summary figure or table of predicted annual occupational doses for the types of work functions (e.g., operations, routine maintenance, special maintenance, in-service testing and surveillance, and waste management) provided at the facility.

c) Source Identification

i) The sources of radiation and contamination in the facility during routine and non-routine operations (e.g., maintenance), including anticipated events.

ii) The sources of radiation that are used to evaluate consequences in the Safety Analysis Report.

iii) Source identification describes the pertinent information needed for:

(1) Input to shielding codes used in the design process;

(2) Establishing related facility design features;

(3) Plans and procedures development; and

(4) Assessment of occupational doses.

iv) The methods for estimating source term magnitudes and locations at the design stage and how this information is incorporated into the design.

d) Ventilation Systems and Glovebox Design

i) The design and operation of the ventilation systems and gloveboxes as described in support of, "Plant Systems," as related to radiological safety, including the:

(1) Proposed design objectives;

(2) Design and operation; and

(3) Monitoring and alarms.

e) Shielding Evaluations

i) Shielding information for each of the radiation sources;

ii) The criteria for penetrations;

iii) Shielding materials;

iv) The methods (e.g., codes) by which the shield parameters (e.g., attenuation coefficients, build-up factors) were determined; and

v) Special protective features that use shielding, geometric arrangement, or remote handling to ensure that occupational radiation exposures will be optimised in normally occupied areas.

f) Safety Analysis Report

i) Postulated types of accident sequences in the Safety Analysis Report that have radiation safety consequences for workers, including all high-risk and a sample of lower risk accident sequences that result in radiation doses of concern and accidents that result from operations and natural phenomena.

ii) The training program and postings for the individuals if the applicant's proposed controlled area includes individuals who are not radiation workers.

iii) The methodology in assessing the accident consequences. In particular, the source terms, transport, and dosimetry analyses.

iv) The items important to nuclear safety, and associated management measures, to prevent or mitigate each accident sequence that results in radiological consequences in excess of the fundamental safety requirements.

8.9.2 Radiation Protection Programme

1) Specific requirements on Radiation Protection Programmes are detailed in regulation 5 (2) (c) in Part SIX: Radiation Protection, Waste management and Decommissioning of the General Nuclear Safety Regulations.

2) The applicant should demonstrate whether the radiation protection program is adequate to protect the radiological health and safety of the workers and to comply with the regulatory requirements.

3) The applicant should develop, document, and implement a radiation protection program commensurate with the scope and extent of authorised activities.

4) The following should be described:

a) Management policy and commitments to optimisation

i) Optimisation considerations for design (see Section 8.1);

ii) Optimisation considerations for operations, including:

(1) The system for operational Optimisation goals, along with their bases, and a qualitative description of how the applicant will achieve the goals (i.e., numerical goals are not expected, but the applicant should commit to achieving Optimisation goals and describe a methodology for achieving them); and

(2) Trend analysis.

iii) The planned organizational structure and how units of that structure interact to maintain occupational doses optimised (e.g., the ALARA Committee);

iv) The applicable activities and audits carried out by the individuals in management having responsibility for radiation safety and trend analyses.

b) Organizational Relationships and Personnel Qualifications

   i) The applicant's organization of the radiological protection program and the organizational relationships between the positions identified as responsible for radiation protection functions and other line managers;

   ii) The qualification requirements for the radiological protection personnel; and

   iii) The assignment of specific responsibilities and authorities for key functions.

c) Radiation Safety Procedures and Radiation Work Permits (RWPs)

   i) The applicant's commitments regarding the development, control, and use of approved written radiation safety procedures and RWPs for activities related to radiological safety.

d) Training

   i) The applicant's radiological safety training for all personnel who have authorized access to a restricted area, including:

      (1) Training objectives;

      (2) Management oversight;

      (3) Methodology of training;

      (4) Who receives the training;

      (5) A description and the frequency of the training and refresher training;

      (6) The monitoring of the effectiveness of the training.

e) Radiological Monitoring

   i) The applicant's radiological monitoring objectives, methods, and criteria in developing sampling procedures, including:

      (1) The frequency and methods of analysis of airborne concentrations;

      (2) Sampling methods and frequency;

      (3) Counting techniques;

      (4) Lower limits of detection for specific radionuclides;

      (5) Specific calculations for concentrations;

      (6) Establishment of action levels;

      (7) Location of continuous air monitors (CAMs), if used; and

      (8) Annunciators and alarms associated with CAMs.

f) Contamination Control

   i) The applicant's control of radiological contamination within the facility, including:

      (1) The types and frequency of surveys;

      (2) Administrative contamination threshold levels;

      (3) The methods and choice of instruments used in the surveys;

(4) Establishment of action levels; and

(5) The design features to control access, including:

(a) Technical criteria and levels defining contamination and high-contamination areas;

(b) The types and availability of contamination monitoring equipment;

(c) Specific limits established for personnel decontamination;

(d) Minimum provisions for personnel decontamination;

(e) The minimum types of clothing needed to enter contaminated areas;

(f) The release criteria for contaminated materials; and

(g) The frequency of periodic review of all aspects of access control.

g) External Exposure

i) The applicant's program for monitoring personnel external radiation exposure, including:

(1) The means to measure, assess, and record personnel exposure to radiation; and

(2) The method and criteria to select the type, range, sensitivity, and frequency for analysing personnel dosimeters and the action levels.

h) Internal Exposure

i) The applicant's method and criteria to develop a program for monitoring personnel internal radiation exposure, including:

(1) Criteria for determining when it is necessary to monitor an individual's internal exposure;

(2) Methods for determining the worker intake;

(3) Frequency of analysis;

(4) Minimum detection levels; and

(5) Setting action levels.

i) Summing Internal and External Exposure

i) The applicant's program for summing internal and external exposure to demonstrate compliance with dose limits, including the method used to develop procedures for assessing worker's exposures in accordance with regulatory requirements.

j) Respiratory Protection

k) The applicant's respiratory protection program, including:

i) The equipment to be used;

ii) The conditions under which respiratory protection will be required for routine and non-routine operations;

iii) The protection factors that will be applied when respirators are being used; and

iv) The criteria for locating the respiratory equipment within the plant.

l) Instrumentation

i) The applicant's methods for selection of radiological measurement instrumentation, including:

(1) The policy for the maintenance and use of operating instrumentation; and

(2) The types of instruments available, including their:

(a) Ranges;

(b) Counting mode;

(c) Sensitivity;

(d) Alarm setpoints;

(e) Planned use; and

(f) Frequency of calibration.

m) Other aspects of operational radiation protection

i) The following aspects should be included in the operational radiation protection program:

(1) Transport

(2) Waste and effluent management and minimization

(3) Transfer of radioactive material between classified areas

(4) Control of sealed sources

(5) Access, Egress Control

(6) Medical surveillance

(7) Material accounting systems

8.10 Radioactive Waste Management

8.10.1 Predisposal management of radioactive waste

1) Predisposal of radioactive waste can take place at a licenced nuclear waste management facility or be part of an operating nuclear facility.

2) Notwithstanding the licensing regime, the respective safety case should address the following with respect to predisposal management of radioactive waste:

a) Site and engineering aspects

i) Quantitative assessment of potential radiological impacts should result in conclusions on the adequacy of the chosen or proposed site, as well as on the intended design of the predisposal waste management facility or activity.

ii) The conclusions drawn from quantitative assessment should be supplemented by qualitative arguments and assessments.

iii) The integrated set of qualitative and quantitative assessment results should be sufficient to demonstrate the adequacy of the site and engineering aspects, compliance of the site and engineering aspects with the relevant safety requirements set out by the NNR and that the safety strategy set out for the facility is fulfilled.

b) Engineering analysis

i) This safety case should identify the safety functions and associated structures, systems and components that are relied on for preventing accidents and for mitigating the consequences of initiating events.

ii) This should be done by applying appropriate engineering codes and standards, commensurate with the importance of the safety functions (e.g. the consequences of their failure to perform).

iii) The operator/licensee should determine whether the existing structures, systems and components are suitable and sufficient to perform their functions during normal operation, anticipated operational occurrences and accident conditions, and whether they will achieve the required control of doses and risks.

iv) In addition, the licensee should also verify if (demonstrate) existing structures, systems and components will continue to perform their safety functions for as long as is required by the stage in the lifetime of the facility, with account taken of ageing, other degradation mechanisms and invasive maintenance activities (e.g. demolition of supporting walls or creation of dusty environmental conditions).

v) The operator/licensee should identify any safety functions that require new engineered structures, systems and components, and should verify that these will be suitable and sufficient to meet relevant safety requirements and criteria.

vi) The operator/licensee should also identify any ongoing engineering requirements that need to be applied during operation (e.g. requirements relating to inspection, maintenance and testing of structures, systems and components) and services that need to be maintained, including those at other related facilities.

c) Passive safety

i) The operator/licensee should demonstrate that passive safety features are applied both to the extent possible and as soon as possible; for example, when long storage periods are involved (e.g. prevention of criticality accidents, etc.).

d) Defence-in-Depth and barrier concept and analysis

i) Application of the concept of defence in depth to predisposal waste management facilities or activities requires the operator to demonstrate that several safety functions have been taken into account in the design of the facility.

ii) Application of this concept should ensure that safety is not unduly dependent on a single component or control procedure, or on the fulfilment of a single safety function

e) Scientific and engineering principles

i) The operator/licensee should address how the principles of good engineering practice have been applied as well as demonstrate in the safety case that the materials, equipment and processes foreseen for the facility or activity are well understood and that knowledge gained from similar applications confirms that these materials, equipment and processes are well suited for the intended use.

ii) Wherever possible, the operator/licensee should use well established techniques and should give due consideration to feedback from experience gained in the use of these techniques

f) Operational aspects

i) The assessment of non-radiological operational safety should ensure possible synergies (e.g. fires, explosions or the presence of toxic material).

ii) The assessment of non-radiological impacts arising from the predisposal waste management facility or activity (e.g. transport of material to and from the site, effluent releases and noise) should be governed by environmental protection legislation, its associated regulations and transport related regulations

iii) Requirements arising from environmental protection legislation should be adequately considered in the facility design. Thus, the integration of safety arguments should also take into account non-radiological impacts and should demonstrate the overall safety of the facility or activity and its overall compliance with all relevant legislative and regulatory requirements

g) Radiological impact assessment

i) Assessment of radiological impacts forms the core of the safety case for a predisposal waste management facility or activity. In addition to qualitative assessments, this involves a comprehensive quantitative analysis of possible challenges to the safety functions and the resulting potential radiological impacts.

ii) In this approach, scenarios should be used to describe possible conditions or events at the facility or during the activity and the resulting radiation risks are quantitatively analysed by means of conceptual and mathematical models

h) Non radiological environmental impact assessment

i) The operator/licensee should assess/integrate non-radiological impacts arising from the predisposal waste management facility or activity (e.g. transport of material to and from the site, effluent releases and noise) that may result in an indirect radiological impact.

8.10.2 Predisposal management of radioactive waste

1) The safety case must demonstrate compliance with content of the NNR regulations, specifically the Regulations on Disposal Facilities[1].

2) The general requirements on the content of the safety of a disposal facility is given in regulation 10 of the Regulations on Disposal Facilities. The development of the safety case must consider the lifecycle stage of the facility.

3) The safety case should address the following

a) Demonstration of safety

[1] The regulations are in draft and will become enforceable once promulgated or so directed.

i) The safety objective is to site, design, construct, operate and close a disposal facility so that protection after its closure is optimized, social and economic factors being taken into account.

b) Graded approach

It should be ensured that the safety case and supporting assessment are based on an appropriate level of understanding of the disposal system and its potential behaviour, and that all safety relevant issues are considered and addressed.

c) Testing of initial ideas for safety concepts;

d) Site selection;

e) Demonstration of the safety of the disposal facility;

f) Optimization of the facility design;

g) Identification of safety related issues to be addressed by research and development programmes;

h) Definition or revision of limits, controls and conditions such as waste acceptance criteria;

i) Assessment of the maximum inventory that can be disposed of (the 'radiological capacity' of the facility);

j) Rationale for the duration of institutional control;

k) Input to monitoring and data acquisition programmes;

l) Periodic re-assessment as required by law or regulation;

m) Application to extend or upgrade the facility or to co-locate new plant or waste management facilities;

n) Closure of the facility, either at the planned end of the lifetime of the facility or as a consequence of non-compliance with the regulations;

o) Application to re-open the facility after closure for non-compliance or for other reasons;

p) Determination of whether remedial action is necessary.

4) Detailed guidance on the typical content of a safety case is provided in Appendix 6.

8.11 Environmental Protection and Control of Radioactive Releases

1) The applicant should demonstrate the establishment of environmental protection measures that are adequate to protect public health and the environment and comply with the regulatory requirements for the construction, operation and decontamination or decommissioning of a facility.

2) The NNR review will focus on that part of the applicant's facility-wide safety program that is established to control and assess the level of radioactive releases (gaseous, liquid, and solid) to the environment during normal and anticipated operations. Therefore, the effluent controls of the applicant's radiation protection program, as well as effluent and environmental monitoring

practices, should be described. This should complement the section addressing the radiation protection program as it applies to worker safety.

3) The environmental review should include the identified normal operation and potential accident conditions that result in radiological releases to the environment, the items important to nuclear safety that are specified by the applicant to control releases to the environment, and the associated management measures that provide reasonable assurance that the items important to nuclear safety will perform their designated safety functions.

4) The following effluent and radioactive release controls should be described:

   a) In-place filter testing procedures for air cleaning systems;

   b) Known or expected concentrations of radionuclides in effluents;

   c) Physical and chemical characteristics of radionuclides in discharges;

   d) Discharge locations;

   e) Environmental media to be monitored and the sample locations;

   f) Sampling collection and analysis procedures, including the minimum detectable concentrations of radionuclides, equipment used, and calibration information;

   g) Action levels and actions to be taken when the levels are exceeded;

   h) Leak detection systems for ponds, lagoons, and tanks;

   i) Pathways analysis methods to estimate public doses;

   j) Recording and reporting procedures, including event notification;

   k) Solid waste handling and disposal programs; and

   l) Proposed annual allowable discharge quantities of individual radionuclides.

8.12 Supporting Documentation for Safety Case

1) Supporting documentation for safety case includes all documentation, in addition to the GOR, to underpin the safety case and ensure its validity such as:

   a) Detailed specifications of all systems, structures components used or implied in the safety analyses;

   b) Processes and Procedures for design control and configuration management

   c) Design, manufacturing, construction specifications;

   d) QA/QC documentation and audit trail confirming conformance with quality objectives;

   e) On-site/off-site/environmental data used or implied in the safety analyses; and

   f) Bases for the GOR linked to the safety analyses.

2) Documentation on all data relevant to the safety case including an auditable trail to all information relevant to the safety case should be available.

3) The preliminary safety case should identify the processes relating to the development of the above supporting documentation and linkage to the safety case.

8.13 Documentation Management

1) The following documentation relating to plant management is considered relevant to the safety case:
    a) Organisational structure and responsibilities;
    b) Training and staffing; and
    c) Management System.
2) The safety case should include project management documentation relevant to the licensing stage, addressing the development of the safety case.
3) The project management documentation provided for each licensing stage should provide confidence in the quality of the safety case of that stage and the processes for developing it. In this regard, project management proposals for future phases of the project should also be provided.

8.13.1 Organisational structure and responsibilities

1) The project management documentation should address the following aspects of the project where applicable:
    a) Organisation
    b) Responsibilities
    c) Interfaces
    d) Licensing
    e) Resources
    f) Legal
    g) Financial
    h) Competencies
    i) Processes for the development of the safety case
    j) Hold and witness points
    k) Quality assurance
2) The applicant should demonstrate that its organizational structure and administrative policies and procedures provide reasonable assurance that the applicant will plan, implement, and control site activities in a manner that ensures the safety of the workers, the public, and the environment.
3) The applicant should submit organizational and administrative information with the documentation for the construction approval.

9 REFERENCES

The following references were consulted during the compilation of this document:

[1] Act No. 47, 1999, National Nuclear Regulator Act

[2] Regulations in terms of section 36, of the National Nuclear Regulator Act, 1999 (Act no. 47 of 1999), on Safety Standards and Regulatory practices (GN R388).

[3] RG-0007, Regulatory Guide on Management of Safety, March 2015

[4] RG-0011, Guidance on, March 2105

[5] RG-0012, Guidance on Construction Management for Nuclear Facilities, March 2105

[6] RG-0016, Guidance on the Verification and Validation of Evaluation and Calculation Models used in Safety and Design Analysis, (draft)

[7] IAEA Safety Guide SSG-2, Deterministic Safety Analysis for Nuclear Power Plants

[8] IAEA Specific Safety Guide, SSG-3, Development and Application of Level 1 Probabilistic Safety Assessment for Nuclear Power Plants

[9] IAEA Specific Safety Guide, SSG-4, Development and Application of Level 2 Probabilistic Safety Assessment for Nuclear Power Plants

[10] IAEA Safety Guide, GS-G-4.1, The format and content of a SAR for NPPs

[11] IAEA Safety Guide DS441, draft IAEA Safety Guide on construction of nuclear facilities

[12] NP-T-2.7 "Project Management in Nuclear Power Plant Construction: Guidelines and Experience", IAEA Nuclear Energy Series.

[13] Occupational Health and Safety Act, Act No. 85 of 1993.

[14] Pressure Equipment Regulations. Regulation 734 of 2009. Published in the Republic of South Africa Government Gazette, No. 32395, 15 July 2009.

[15] Incorporation of Health and Safety Standards into the Pressure Equipment Regulations, 2009. Regulation 735 of 2009. Published in the Republic of South Africa Government Gazette, No. 32395, 15 July 2009.

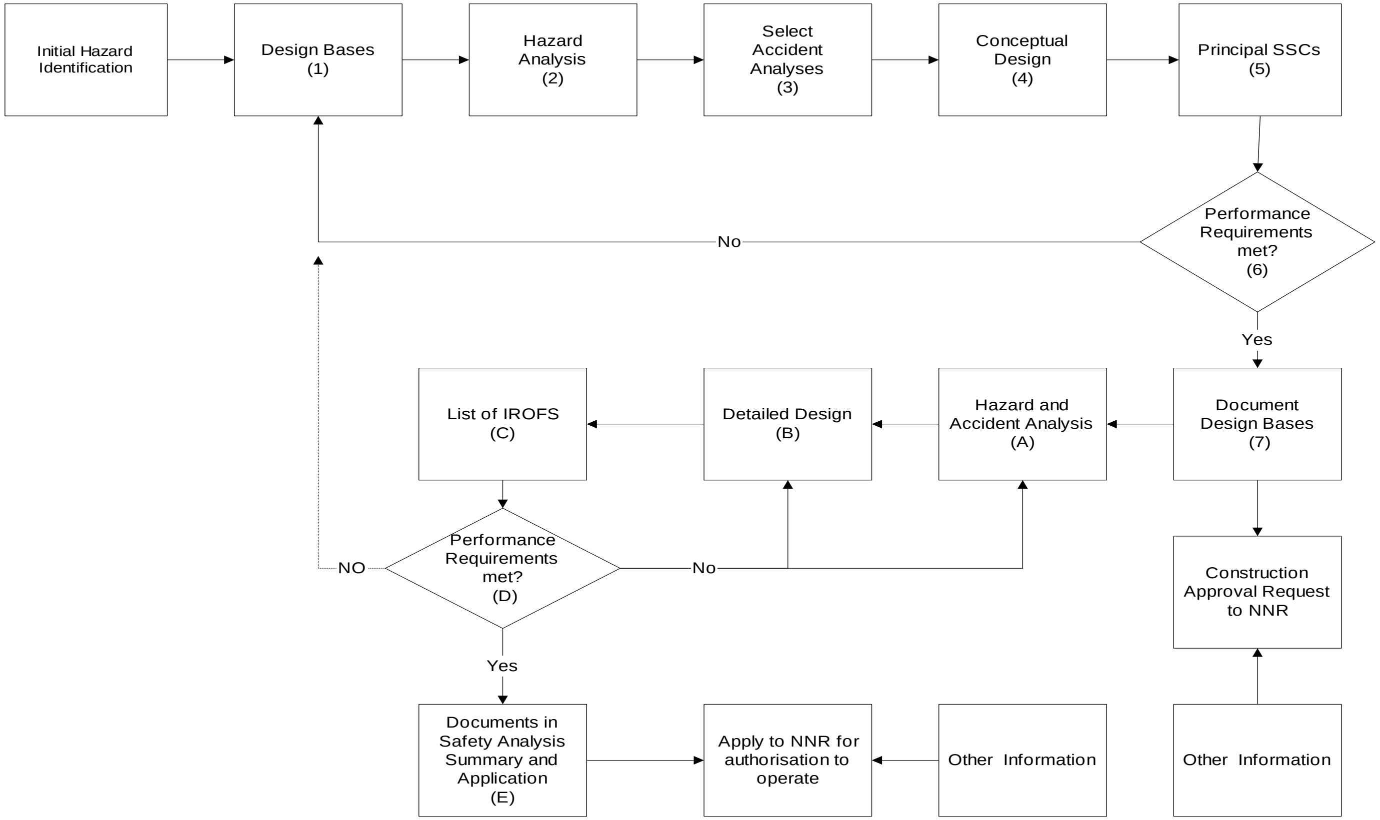
[16] SANS 347, Categorisation and Conformity Assessment Criteria for all Pressure Equipment, Standards South Africa, 2007.

[17] SANS 10227, Criteria for the Operation of Inspection Authorities Performing Inspection in terms of the Pressure Equipment Regulations, Standards South Africa, 2007.

[18] PP-0016: Conformity Assessment of Pressure Equipment in Nuclear Service.

[19] PP-0017: Design and Implementation of Digital Instrumentation and Control for nuclear installation

APPENDIX 1: RELATIONSHIP BETWEEN THE DESIGN BASES AND THE SAFETY ANALYSIS



APPENDIX 2: TYPICAL LICENSING STAGES FOR DIFFERENT LICENSING APPLICATIONS

LICENSEE APPLICATION **LICENSING STAGE**	**NEW LICENCE APPLICATION**	**MODIFICATION**	**CHANGE TO CURRENT LICENCING BASIS**	**OTHER (TOPICAL ISSUES)**	**DECOMMISSIONING**
PRELIMINARY STAGE	Preliminary safety case covering all stages - to facilitate licensing process.	Preliminary safety case covering all stages to facilitate licensing process.	Preliminary safety case covering all stages to facilitate licensing process.	Preliminary safety case covering all stages to facilitate licensing process.	Preliminary safety case covering all stages to facilitate licensing process.
CONTRUCTION/ INSTALLATION/ MODIFICATION IMPLEMENTATION	Preconstruction safety case to address nuclear safety hazards applicable during these phases. Safety case covering following stages may still be preliminary.	Preconstruction safety case to address nuclear safety hazards applicable during these phases. Safety case covering following stages may still be preliminary.	Depending on the particular application, additional licensing stages may be introduced to facilitate the licensing process and/or to address potential nuclear safety hazards that may be applicable during different stages of the project.		
FUEL ON SITE **FUEL LOADING** **TESTING** **COMMISSIONING**	Pre-operational safety case to address nuclear safety hazards applicable during these phases including plant operation. Preliminary safety case for decommissioning.	Pre-operational safety case to address nuclear safety hazards applicable during these phases including plant operation.			
PLANT OPERATION/ DECOMMISSIONING	Final safety case to address nuclear safety hazards applicable during plant operation and to establish the current licensing basis.	Final safety case to address nuclear safety hazards applicable during plant operation and to establish the current licensing basis.	Final safety case to address nuclear safety hazards applicable during plant operation and to establish the current licensing basis.	Final safety case to address nuclear safety hazards applicable during plant operation and to establish the current licensing basis.	Final safety case to address nuclear safety hazards applicable during decommissioning.

APPENDIX 3: QUANTITATIVE RISK CRITERIA

Risk to members of the public due to accidents

Risk criteria are expressed in terms of fatality likelihood to both individuals and to the whole population. The limit of 10^{-7} fatalities per person per annum refers to the average risk criterion for the national population due to all nuclear facilities and -sites. This figure is based on comparisons with other risks imposed on society by industry and various natural disasters. See section B-6 for details.

Based on the assumption of there being no more than ten major nuclear sites in South Africa, a factor of 0.1 has been applied to this figure to obtain the risk limit of 10^{-8} fatalities per person per annum for each nuclear site. The risk to the public is to be computed using acceptable projections on the relevant site-specific data (e.g. demographic, meteorological, agricultural, farming practices, food consumption data).

A peak-to-average ratio of 50 has been adopted to ensure an equitable variation in risk in the country. Adoption of this value provides an upper risk limit for an individual of 5.10^{-6} fatalities per annum. It is intended to limit the risk to any individual or representative group of individuals.

Risk to plant personnel due to accident conditions

Similar considerations apply to the risk due to accidents to the workforce in a facility, resulting in a limit on the average risk of 10^{-5} fatalities per annum, and a maximum individual risk of 5.10^{-5} fatalities per annum. The latter has been based on a maximum peak to average value of 5 for the workforce of a facility.

Risk to members of the public due to normal operations

Whereas for accident conditions the corresponding safety criteria relate directly to risk as determined using a probabilistic risk assessment methodology, the relevant criteria for normal operations refer directly to deterministic dose levels to the most exposed member of the public.

Risk to plant personnel due to normal operations

The risk to plant personnel due to normal operational events is controlled by the design criteria and intervention applied through the operational radiation protection programme for the site that requires doses to be maintained ALARA and limits to individual doses not to be exceeded.

Rationale behind and bases of the fundamental quantitative risk criteria

Since in general, anthropogenic artefacts (e.g. cars, factories, electrical equipment, power plants, aeroplanes, and satellites) cannot be made absolutely safe, the National Nuclear Reagulator (NNR) has adopted a risk based licensing philosophy.
It was decided to use historical data on risks to which society is subject and which it apparently tolerates, as an aid in setting standards for nuclear risks. In this regard the following principles were adopted [1]:

- The risk presented by a nuclear site shall not increase significantly the total risks to which the population is exposed.

- The nuclear risk shall compare favourably with those associated with other major industrial enterprises.
- Allowance shall be made for possible demands by society for greater standards of safety over the period (usually several decades) of the working life of the enterprise.

Careful consideration of the historical risk data (to which the public is subjected and which it apparently tolerates) in conjunction with these principles led to the adoption of the quantitative risk criteria presented in Table 1 of Section 2. The quantitative criteria also compare favourably with risk limits used worldwide as indicated by a review of international literature [2, 3].

[1] JO Tattersall, DM Simpson, RA Reynolds, “A discussion of nuclear plant safety with reference to other hazards experienced by the community”, Fourth United Nations International Conference on the peaceful uses of atomic energy”, Geneva, Switzerland, 6-16 September 1971.

[2] F.J. Remick, Commissioner U.S. Nuclear Regulatory Commission, “Regulatory risk coherence”, Plenary session American Nuclear Society topical meeting on “Risk management - expanding horizons”, Boston, Massachusetts, June 8, 1992.

[3] M.F. Versteeg, R.M. Andrews, “Consideration of probabilistic safety objectives in OECD/NEA member countries; Short overview and Update.”

Details of the risk aversion criterion

The risk aversion criterion is derived as follows:

The probability density function, $F(N)$, for having N fatalities per annum is chosen with the following form:

$$F(N) = \frac{A}{N^2} \ .$$

The parameter, *A*, is independent of *N* and is derived below. The number of fatalities, *N*, serves as a measure of the magnitude of large accidents. The form of $\frac{A}{N^2}$ for $F(N)$ effects the bias against larger accidents by suppressing $F(N)$ for large *N*.

Historical data on risks to which society is subject and which it apparently tolerates, correspond to a form for $F(N)$ of $\frac{A}{N^x}$ with $x = 1.5$ but, due to imprecision in the data, *x* could be considered to fall in the range $1 \leq x \leq 2$. The choice of the $x = 2$ extreme is conservative as far as larger accidents are concerned as it effects the bias against larger accidents to the greater extent [1].

Let

$$N_p \equiv \text{Acceptable projection of the population}$$

The average annual population risk (i.e. the fatalities/a, averaged over the population) is then given by:

$$
\begin{aligned}
<N> &= \frac{1}{N_p}\int_1^{N_p} F(N)N\mathrm{d}N \\
&= \frac{1}{N_p}\int_1^{N_p} \frac{A}{N^2} N\mathrm{d}N \\
&= A\frac{\ln N_p}{N_p}
\end{aligned}
$$

The annual frequency of events in which N is equal or exceeded is given by:

$$
\begin{aligned}
f(N) &= \int_N^{N_p} F(N')\mathrm{d}N' \\
&= A\left(\frac{1}{N} - \frac{1}{N_p}\right)
\end{aligned}
$$

The quantity A, is determined by the condition:

$$<N> = C$$

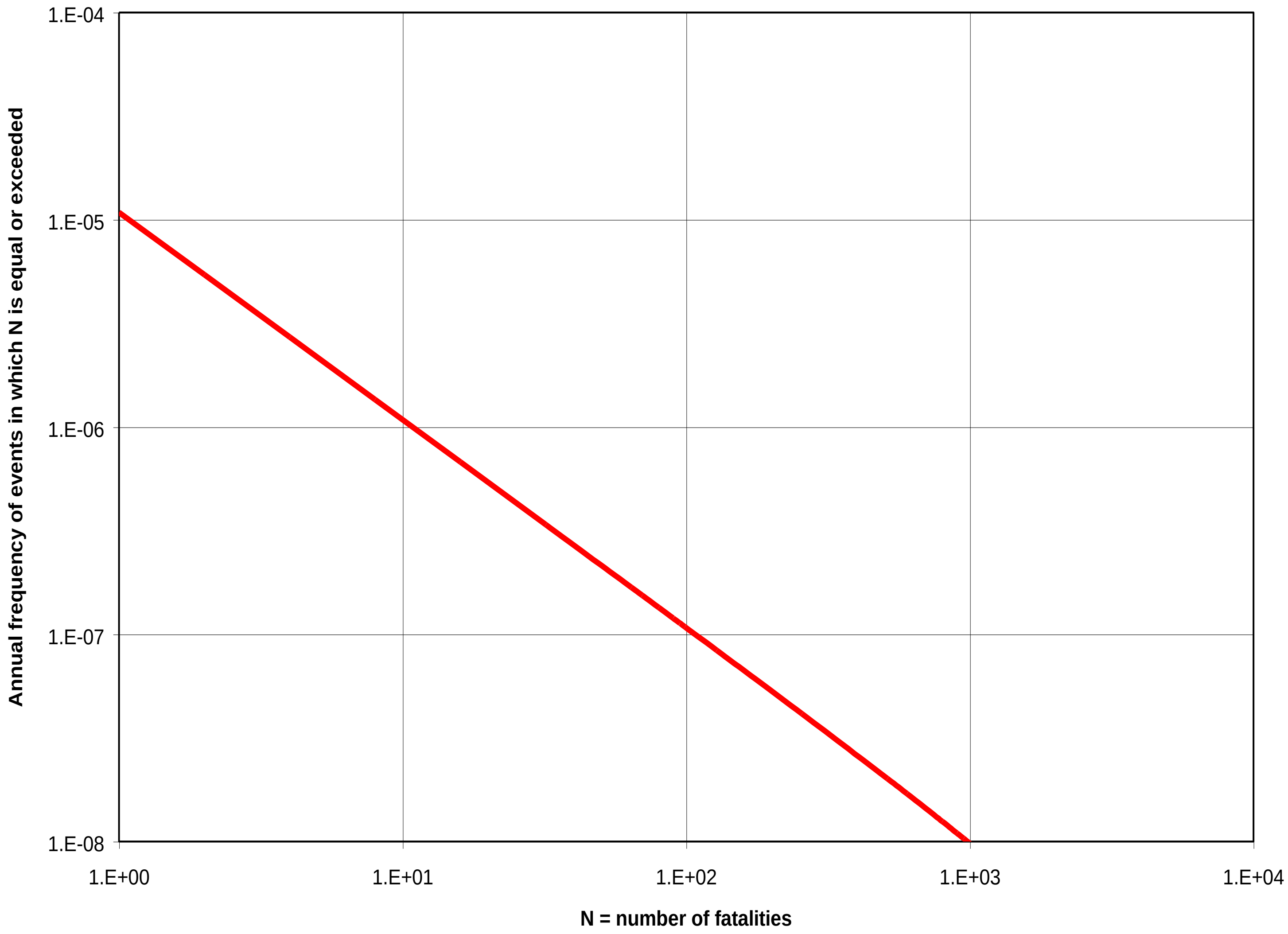
where C is average population risk criterion of $10^{-8}.y^{-1}$ per site, i.e.:

$$A = \frac{CN_p}{\ln N_p}$$

For illustration purposes, Figure 1 shows a graph of f(N) for the choice of N_p = 10 000

[1] JO Tattersall, DM Simpson, RA Reynolds, “A discussion of nuclear plant safety with reference to other hazards experienced by the community”, Fourth United Nations International Conference on the peaceful uses of atomic energy”, Geneva, Switzerland, 6-16 September 1971.

Figure 1- Risk Aversion Criterion



APPENDIX 4: TYPICAL FORMAT AND CONTENT OF THE SAR

Part I: Standard Format and Content of Power Reactors of LWR Design
Useful references are:

[1]. REGULATORY GUIDE 1.206 COMBINED LICENSE APPLICATIONS FOR NUCLEAR POWER PLANTS (LWR EDITION)
[2]. NUREG-0800: Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition

1. Introduction, Safety Concept and General Description of the Plant

This chapter should provide an introduction to the SAR, the safety concept adopted for the facility and a general description of the nuclear power plant. This chapter should provide the NNR or reader with a basic understanding of the overall facility without needing to refer to subsequent chapters. The review of the subsequent detailed chapters is then accomplished with a better standpoint and recognition of the relative safety-significance of each individual item in the overall plant design.

2. Site Characteristics

This chapter should provide information concerning the geological, seismological, hydrological, and meteorological characteristics of the site and vicinity, in conjunction with present and projected population distribution and land use and site activities and controls. The purpose of this information is to demonstrate that the applicant has accurately described the site characteristics and appropriately used them in the plant design and operating criteria.

3. Design of Structures, Systems, Components, and Equipment

This chapter should identify, describe, and discuss the principal architectural and engineering design of those SSCs, and equipment that are important to safety.

4. Reactor

This chapter should provide an evaluation and supporting information to establish the capability of the reactor to perform its safety functions throughout its design lifetime under all normal operational modes, including transient, steady-state, and accident conditions. This chapter should also include information to support the accident analyses provided in Chapter 15.

5. Reactor Coolant and Connecting Systems

This chapter should provide information regarding the RCS and systems to which it connects. Special consideration should be given to the RCS and pressure-containing appendages out to and including isolation valving, which is the Reactor Coolant Pressure Boundary.

6. Engineered Safety Features

This chapter should provide a discussion of how the design of ESF meets the applicable regulatory requirements and available regulatory guidance. ESFs are provided to mitigate the consequences of postulated accidents in the unlikely event that an accident occurs.

7. Instrumentation and Controls

Nuclear power plant instrumentation senses various plant parameters and transmits appropriate signals to the control systems during normal operation and to the reactor trip and ESF systems during abnormal and accident conditions. The information provided in this chapter should emphasize those instruments and associated equipment that constitute the protection and safety systems.

8. Electric Power

The electric power system is the source of power for station auxiliaries during normal operation, and for the reactor protection system and ESF during abnormal and accident conditions. Thus, the applicant should provide information in Chapter 8 on the functional adequacy of the offsite power systems and safety-related onsite electric power systems (as applicable to passive and nonpassive designs) and ensuring that these systems have adequate redundancy, independence, and testability in conformance with the current established safety criteria.

9. Auxiliary Systems

Chapter 9 of the SAR should provide information about the facility's auxiliary systems. In particular, this chapter should identify systems that are essential for safe shutdown of the plant or for protection of the health and safety of the public. For each system, the description should provide the design bases for the system and its critical components, a safety evaluation demonstrating how the system satisfies the design bases, the testing and inspection to be performed to verify system capability and reliability, and the required instrumentation and controls. For systems that have little or no role in protecting the public against exposure to radiation, the description should provide enough information to allow the NNR to understand the design and operation and their effect on reactor safety, with emphasis on those aspects of design and operation that might affect the reactor and its safety features or contribute to the control of radioactivity. In addition, the information provided (e.g., a failure analysis) should clearly show the system's capability to function without compromising the safe operation of the plant under both normal operating and transient situations.

10. Steam and Power Conversion System

Chapter 10 of the SAR should provide information concerning the plant steam and power conversion system. For purposes of this chapter, the steam and power conversion system includes the following:

- the steam system and turbine generator units of an indirect cycle reactor plant, as defined by the secondary coolant system
- the steam system and turbine generator units in a direct-cycle plant, as defined by the system extending beyond the RCS isolation valves

This section should describe the secondary plant (steam and power conversion system); emphasizing those aspects of the design and operation that affect or could potentially affect the reactor and its safety features or contribute toward the control of radioactivity. The information provided should in addition show the capability of the system to function without compromising (directly or indirectly) the safety of the plant, under both normal operating and transient situations. This should include aspects of how the system design meets the applicable regulatory requirements and is consistent with the applicable regulatory guidance.

11. Radioactive Waste Management

Chapter 11 of the SAR should describe the capabilities of the plant to control, collect, handle, process, store, and dispose of liquid, gaseous, and solid wastes that may contain radioactive materials, and the instrumentation used to monitor and control the release of radioactive effluents and wastes. This should cover normal operation, including AOO (e.g., refueling, purging, equipment downtime, maintenance). The proposed radioactive waste (radwaste) treatment systems should have the capability to meet the safety limit requirements and the recommendations of appropriate regulatory guides concerning system design, control, and monitoring of releases, and to maintain releases of radioactive materials at the ALARA level.

12. Radiation Protection

This chapter of the SAR should provide information on radiation protection methods and estimated occupational radiation exposures of operating and construction personnel during normal operation and AOO. (In particular, AOO may include refueling; purging; fuel handling and storage; radioactive material handling, processing, use, storage, and disposal; maintenance; routine operational surveillance; ISI; and calibration.) Specifically, this chapter should provide information on facility and equipment design, planning and procedures programs, and techniques and practices employed by the applicant to meet the radiation protection standards, and to be consistent with the guidance given in the appropriate regulatory guides, where the practices set forth in such guides are used to effect the NNR regulations.

13. Conduct of Operations

This chapter of the SAR should provide information relating to the preparations and plans for design, construction, and operation of the plant. Its purpose is to provide adequate assurance that the license applicant establish and maintain a staff of adequate size and technical competence and that operating plans to be followed by the licensee are adequate to protect public health and safety. Applicants have the choice of including information that is site specific or different from a generic SAR as applicable. Applicants may use a table or appendix to facilitate the update of information.

14. Verification Programs

In Chapter 14 of the SAR, the license applicant should provide information concerning its initial test program for SSCs and design features for both the nuclear portion of the facility and the balance of plant. The information provided should address major phases of the test program, including preoperational tests, initial fuel loading and initial criticality, low-power tests, and power-ascension tests. In so doing, the applicant should describe the scope of the initial test program as well as its general plans for accomplishing the test program in sufficient detail to demonstrate that due consideration has been given to matters that normally require advance planning.

15. Transient and Accident Analyses

The evaluation of the safety of a nuclear power plant includes analyses of the plant's responses to postulated disturbances in process variables and postulated equipment failures or malfunctions. Such safety analyses provide a significant contribution to the selection of LCOs, limiting safety system settings, and design specifications for components and systems from the standpoint of public health and safety. These analyses are a focal point of the license reviews.

16. Technical Specifications

Each operating license that the Commission issues for a nuclear power plant must contain TS that set forth all limits, operating conditions, and other requirements that the NNR imposes on operation of the facility to protect the health and safety of the public (among other purposes). Consequently, each applicant for a licence for a nuclear power plant must submit the proposed TS for the facility. The STS differ according to the design of the nuclear steam supply system (NSSS) and include bases for safety limits, limiting safety system settings, LCOs, and associated action and surveillance requirements.

17. Quality Management and Reliability Assurance

The license applicant is responsible for the establishment and implementation of a QM program applicable to activities during design, fabrication, construction, testing, and operation of the nuclear power plant. Regardless of the approach taken, the NNR would review and evaluate QAPDs before issuing the license. Chapter 17 of the SAR should incorporate the QAPD (or QAPDs) by reference.

18. Human Factors Engineering

Chapter 18 of the SAR should describe how state-of-the-art HFE principles are incorporated into (1) the planning and management of HFE activities; (2) the plant design process; (3) the characteristics, features, and functions of the human-system interfaces (HSIs), procedures, and training; (4) the implementation of the design; and (5) monitoring of performance at the site. This SAR chapter should illustrate how human characteristics and capabilities are successfully integrated into the nuclear power plant design in such a way that they result in a state-of-the-art design and support successful performance of the required job tasks by plant personnel. It is expected that all the HFE elements will be completed prior to fuel load except as appropriate.

19. Probabilistic Risk Assessment and Severe Accident Evaluation

The licence applicant should provide in Chapter 19 of the SAR an adequate level of documentation to enable the NNR to determine the acceptability of the risks to public health and safety associated with operation of a proposed new plant. The acceptability of the risks to public health and safety is determined from the interpretation of the results and insights of the applicant's (1) plant-specific PRA and (2) severe accident evaluations.

Part II: Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors

The principal purpose of this guidance is to ensure the quality and uniformity of reviews by resenting a definitive base from which to evaluate applications for license or license renewal. Further reference may be found in the following documents:

[1]. NUREG-1537, Part 1 Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors Format and Content

[2]. NUREG-1537, Part 2 Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors Standard Review Plan and Acceptance Criteria

1. THE FACILITY

Chapter 1 of the SAR is an overview or an executive summary of topics covered in detail in other chapters. The applicant should include a general introduction to the SAR and the non-power reactor facility. The applicant should state the purpose of the SAR and briefly describe the application.

2. SITE CHARACTERISTICS

This chapter provides guidance for reviewing and evaluating Chapter 2 of the applicant's SAR in which the applicant discusses the geological, seismological, hydrological, meteorological, geographic and demographic characteristics of the site and vicinity, in conjunction with present and projected population distributions, industrial facilities and land use, and site activities and controls. The site characteristics should be described in sufficient detail to verify input to design and analyses presented in other chapters of the SAR, e.g., Chapter 3, 11 & 13. In each case, the NNR determines how much emphasis to place on the various topics covered by this chapter of the SAR. The NNR's judgment on the areas to be given attention during the review should be based on an examination of the information presented, the similarity of the information to that recently reviewed for other reactors, and whether any special site characteristics or reactor design or operating features raise questions of safety significance.

3. DESIGN OF STRUCTURES, SYSTEMS, AND COMPONENTS

This chapter gives guidance for reviewing and evaluating the principal architectural and engineering design criteria for the structures, systems, and components that have been identified by the analyses in this and other chapters of the SAR to ensure reactor facility safety and protection of the public. The bases of some design features may be developed and presented in other chapters of the SAR (e.g., the confinement or the containment, air exhaust stack, and environmental requirements for safety systems) and need only be referenced in this chapter.

4. REACTOR DESCRIPTION

This chapter gives guidance for evaluating the description in the SAR of the reactor and how it functions as well as the design features for ensuring that the reactor can be safely operated and shut down from any operating condition or accident assumed in the safety analysis. Information in this chapter of the SAR should provide the design bases for many systems and functions discussed in other chapters of the SAR and for many technical specifications. The systems that should be discussed in this chapter of the SAR include the reactor core, reactor tank, and biological shield. The nuclear design of the reactor and the way systems work together are also addressed. In this chapter the applicant should explain how the design and proper operation of a non-power reactor make accidents extremely unlikely. This chapter of the SAR along with the analysis in Chapter 13 should demonstrate that even the consequences of the design-basis accident would not cause unacceptable risk to the health and safety of the public.

5. REACTOR COOLANT SYSTEMS

This chapter gives guidance for evaluating the design bases, descriptions, and functional analyses of the reactor coolant systems. The principal purpose of the coolant system is to safely remove the fission and decay heat from the fuel and dissipate it to the environment. However, the coolant in the primary systems of most non-power reactors serves more functions than just efficient removal of heat. It can act as radiation shielding for the reactor,' fuel storage facilities, and in some designs, experimental facilities and experiments. In open-pool reactors, the coolant is the only vertical shielding. In many designs the reactor coolant also acts as a core moderator and reflector. Because of these many functions of the reactor coolant, the design of the reactor coolant systems is based on choosing among interdependent parameters, including thermal power level, research capability, available fuel type, reactor core physics requirements, and radiation shielding. The principal licensing basis of non-power reactors is the thermal power developed in the core during operation. This basis also applies to the few non-power reactors licensed to operate at such low power levels that no significant core temperature increases would occur during normal operation. Such reactors may not require an engineered coolant system. For those reactors, the applicant should, in Chapter 4 of the SAR, discuss the dissipation of the heat produced, estimate potential temperature increases during reactor operation, and justify why an engineered coolant system is not required. In this chapter the applicant should summarize those considerations and conclusions.

6. ENGINEERED SAFETY FEATURES

This chapter gives the review plan and acceptance criteria for active or passive engineered safety features (ESFs) of the reactor facility that are designed to mitigate the consequences of accidents. The concept of ESFs evolved from the defense-in-depth philosophy of multiple design features to prevent or mitigate the release of radioactive materials to the environment during accident conditions. The applicant determines the need for ESFs from the SAR analyses of accidents that could occur, even though prudent and conservative designs of the facility have made these accidents very unlikely. The NNR may find that the SAR analyses show that ESFs are not needed for a proposed design.

7. INSTRUMENTATION AND CONTROL SYSTEMS

Instrumentation and control (I&C) systems comprise the sensors, electronic circuitry, displays, and actuating devices that provide the information and the means to safely control the reactor and to avoid or mitigate accidents. Instruments are provided to monitor, indicate and record such operating parameters as neutron flux density, fuel temperature coolant flow, temperature, and level and radiation intensities in selected areas around the reactor. Certain I&C systems will automatically shut down (scram) the reactor when any safety parameter reaches a predetermined setpoint as analyzed in the SAR. I&C subsystems may also be designed to actuate engineered safety features (ESFs) upon the detection of abnormal conditions.

8. ELECTRICAL POWER SYSTEMS

In this chapter of the SAR, the applicant discusses and describes the electrical power systems at a non-power reactor facility designed to support reactor operations. All non-power reactors require normal electrical service. Some non-power reactors may also require emergency electrical service to perform certain functions related to reactor safety to ensure that, given a loss of normal electric service, sufficient power will be available for mitigating the events discussed in SAR Chapter 13. The design bases for these functions are provided on a case-by-case basis in other chapters of the SAR, such as Chapter 4, Chapter 5, Chapter 7, Chapter 9, Chapter 10, Chapter 11 and Chapter 13. Design and functional information in Chapter 8 should be provided under the two categories: normal and emergency electrical power systems.

9. AUXILIARY SYSTEMS

This chapter contains guidance for evaluating the information on auxiliary systems in the reactor facility. Auxiliary systems are those systems not fully described in other chapters of the SAR that are important to the safe operation and shutdown of the reactor and to the protection of the health and safety of the public, the facility staff and the environment. There are also auxiliary systems or subsystems that do not have a direct impact on protecting the reactor or the public from exposure to radiation. However, for all auxiliary systems at a non-power reactor, sufficient information should be provided so that the NNR can understand their design and functions. Emphasis should be placed on those aspects of auxiliary systems that might affect the reactor, its safety features, and its safe shutdown, or contribute to the control of radioactivity and radiation exposures.

10. EXPERIMENTAL FACILITIES AND UTILIZATION

This chapter contains guidance for evaluating the information on the experimental facilities at the reactor, their use, and associated safety considerations. The applicant should provide sufficient information in the SAR to demonstrate that no proposed operations involving experimental facilities would result in unacceptable radiological risk to reactor operations personnel, experimenters, or the general public. The safety analyses of the reactor facility should include the experimental facilities and their interactions with the core and its other reactor systems. If changes in reactor operating characteristics are proposed, the reviewers should check to see that potential interactions between the core and the experimental facilities are analyzed as appropriate.

11. RADIATION PROTECTION-PROGRAM AND WASTE MANAGEMENT

This chapter provides guidance for the review and evaluation of Chapter 11 of the applicant's SAR, which should contain information about radiation protection and radioactive waste management provisions at the facility. Information should include radiological design bases of the reactor structures, systems, components, experimental facilities, and laboratories under the reactor license; procedures, policies, and practices employed to ensure compliance with applicable standards and regulations on radiation doses and protection; procedures, policies, and practices to ensure that radioactive wastes are managed in compliance with appli6able regulations and standards; and the program to keep radiation exposure at the facility as low as is reasonably achievable (ALARA). The responsibilities of the health physics organization at the reactor facility and of any other onsite radiation protection and radioactive waste management organizations should also be described.

12. CONDUCT OF OPERATIONS

This chapter contains guidance for evaluating the information on the conduct of operations at a non-power reactor facility. The conduct of operations involves the administrative aspects of facility operation, the facility emergency plan, the quality assurance plan, the security plan, the reactor operator requalification plan, the startup plan, and environmental reports. The administrative aspects of facility operations are the facility organization, review and audit activities, organizational aspects of radiation safety, facility procedures, required actions in case of license or technical specifications violations, reporting requirements, and recordkeeping. These topics form the basis of the technical specifications.

13. ACCIDENT ANALYSES

In this chapter the applicant should present a methodology for reviewing the systems and operating characteristics of the reactor facility that could affect its safe operation or shutdown. The methodology should be used to identify limiting accidents, analyze the evolution of the scenarios, and evaluate the consequences. The analyses should start with the assumed initiating event. The effects on designed barriers, protective systems, operator responses, and mitigating features should be examined. The endpoint should be a stable reactor. The potential radiological consequences to the public, the facility staff, and the environment should be analyzed. The information and analyses should show that facility system designs, safety limits, limiting safety system settings, and limiting conditions for operation were selected to ensure that the consequences of analyzed accidents do not exceed acceptable limits. The applicant should also discuss and analyze postulated accident scenario whose potential consequences are shown to exceed and bound all credible accidents otherwise known as the maximum hypothetical accident (MHA).

14. TECHNICAL SPECIFICATIONS

This chapter provides guidance for reviewing and evaluating the technical specifications submitted to NRC by applicants for non-power reactor licenses. The format for the acceptance criteria follows the format of American National Standards Institute/American Nuclear Society (ANSI/ANS) 15.1-1990. In addition to providing the information specified in ANSI/ANS 15.1, the technical specifications shall be consistent international best practice. The content of technical specifications for non-power reactors is considerably simpler than that for power reactors, consistent with the difference in size and complexity between non-power reactors and power reactors. Maintaining system performance should provide the basis for the technical specifications of non-power reactors. By addressing limiting or enveloping conditions of design and operation, emphasis is placed on ensuring the safety of the public, the facility staff, and the environment. Because the performance-based concept is used for non-power reactors, standardization is possible across the entire set of technical specification parameters, even for the diverse types of non-power reactors.

15. FINANCIAL QUALIFICATIONS

This chapter provides review and acceptance criteria for financial information submitted to NRC by applicants for non-power reactor licenses. This information is used to establish that the applicant is financially qualified to own, construct, operate, and decommission a non-power reactor. This information is usually submitted along with the application for a construction permit and an initial operating license or along with the application for license renewal. Financial qualifications cover three areas:

- financial ability to construct the non-power reactor facility authorized by the construction permit
- financial ability to safely operate the facility
- financial ability to safely decommission the facility so that the NRC can terminate the facility license at the end of the facility’s use

16. OTHER LICENSE CONSIDERATIONS

This chapter contains guidance for evaluating license considerations that do not belong elsewhere in the SAR. One of these considerations is prior use of reactor components. A recent consideration discussed in this chapter is 'medical use of non-power reactors. There may be other topics that should appear in this chapter, but the applicant should determine these on a case -case basis.

17. DECOMMISSIONING AND RELATED ACTIVITIES

This chapter contains guidance for evaluating decommissioning plans (DPs), requests for license termination, and applications for possession-only license amendments for non-power reactors. These applications are submitted by non-power reactor licensees who wish to terminate operations and decommission their facilities.

18. HIGHLY ENRICHED TO LOW-ENRICHED URANIUM CONVERSIONS

The conversion of a non-power reactor from the use of highly enriched uranium (HEU) to the use of low-enriched uranium (LEU) as a fuel is good international practice. The general basis for the was that that HEU posed a nuclear weapon proliferation risk through theft or diversion, and that limiting the availability of BEU would also limit this risk, promote the common defense and security, and protect the health and safety of the public. Also, the licensee can consult such documents as the International Atomic Energy Agency (IAEA) documents IAEA-TECDOC-223, -324, and -643, for additional guidance.

PART III: TYPICAL FORMAT AND CONTENT OF SAFETY ANALYSIS REPORT FOR NON-REACTOR NUCLEAR FACILITY

1) General Description

a) The following aspects should be addressed:
   i) Scope, structure and content of the Safety Case documentation.
   ii) Appropriate information for general familiarization and understanding of the proposed facility and related processes.
   iii) Descriptions of the overall layout on suitable scaled documents including civil design.
   iv) Major chemical or mechanical processes involving special materials used in the facility.
   v) Identification and quantification of the raw materials, by-products, wastes and finished products.
   vi) Type, maximum quantities, and form of special nuclear material, nuclear material and other radioactive material including all stored material.
   vii) The principal "Design Basis" parameters (Design Envelope) shall be provided, with reference to the applicable frozen design baseline.
   viii) Decommissioning preparedness and planning program; description of any features considered to facilitate decommissioning.
   ix) A safety concept that demonstrates the evolution of the design process into operation.
   x) A summary conclusion that the design complies with the Licensing Criteria and describing the associated compliance with dose and risk limits.

2) Site Information

a) The following aspects should be addressed:
   i) Site geography, including its location relative to prominent natural and man-made features, impact to existing plants / facilities.
   ii) Population distribution as a function of distance from the facility. Demography (Including envisaged population growth).
   iii) Regional Meteorology and Climatology and special weather conditions applicable to the site.
   iv) Identification of Potential Hazards in vicinity of the site.
   v) Description of the hydrology and geology including seismicity, providing earthquake accelerations for the site/ for the area,
   vi) Nearby Industrial, Transportation (including aircraft flight patterns), and Military Facilities.
   vii) Site Access and Egress arrangements.
   viii) The information must be consistent with the current Site Safety Report.

3) Safety Features and Design Criteria

a) The following aspects must be addressed:
   i) Design criteria for the processes. The design criteria must provide adequate design margins in terms of the NNR licensing criteria.
   ii) Nuclear criticality safety features including detailing of SSC functions, programmes and administrative measures.
   iii) Chemical safety design features including detailing of SSC functions, programmes and administrative measures.
   iv) Safety functions and DiD implementation for event mitigation.

v) Control and documentation of all special nuclear material, nuclear material and other radioactive material.
vi) Instrumentation for control, limitation, detection and monitoring.
vii) Fire and other internal hazard protection features and emergency response measures.
viii) External hazard protection features and emergency response measures.

4) Design Requirements

a) The following information should be provided:
   i) Classification of the SSC according to their functions in terms of importance to –
      (1) Safety Function
      (2) Seismic Reliability
      (3) Environmental Reliability
      (4) Functional Reliability / Quality

   ii) Design, quality assurance, testing and qualification requirements for the SSC corresponding to their classification.
   iii) Identification and categorisation of operational and accidental conditions like thermal stresses, pressure variations and dynamic effects in terms of the resulting mechanical loading, loading combinations, and stress limits.
   iv) Design analysis and SSC qualification to confirm the adequacy of the design to meet the demands of operational conditions, particularly for First of a Kind SSC.
   v) Analyses and qualification measures employed to ensure structural and functional integrity of piping and vessel systems including supports under induced loadings, including those due to the process and postulated events.
   vi) Design and installation criteria applicable to the mounting of pressure-relieving devices for the overpressure protection of components.
   vii) Codes and standards for the design of the SSC. Such a system must comprise national and international quality and design standards.
   viii) Codes and standards for all safety related design and qualification processes (including safety assessment, engineering, radiation protection, surveillance, operations and quality assurance).
   ix) Qualification of the suppliers.
   x) Manufacturing and Quality plans specifying the hold and witness points according to the selected and agreed standards.
   xi) Test and Qualification Plans for the SSC's.
   xii) Civil design and material specification, codes and standards including confinement design and discussion on ageing, seismic, aircraft crash, fire protection, radiation shielding and zoning.
   xiii) Auxiliary systems relevant to nuclear safety or confinement/ control of all radioactive material e.g.:
      (1) Gas Supply Systems
      (2) Supply systems for raw materials, by-products, wastes and finished products used
      (3) Water Systems
      (4) Compressed Air System
      (5) Heating, Ventilation and Air-conditioning including filtration systems
      (6) Specialized Doorways

(7) Fire Protection System
(8) Special Tools and Equipment Handling Systems
(9) Waste Management Systems

5) Plant Protection, Instrumentation and Controls

a) The following aspects should be addressed:
   i) Description of automation, control and protection –
      - Equipment Protection System
      - Operational Control and Monitoring System
      - Control Room Equipment
      - Instrumentation for monitoring of releases
      - Meteorological data interface

   ii) Features provided to protect against operator error.
   iii) Measures which mitigate and prevent the consequence of an accident or malfunction.
   iv) Fail Safe, Diversity and other measures to mitigate and prevent the consequence of malfunctions.

6) Electrical Systems

a) The following aspects should be addressed:
   i) Main Power Supply
   ii) AC/DC Electrical Systems
   iii) Grounding & Lightning Protection
   iv) Response and features on “Blackout”
   v) Backup power and Uninterruptible supplies

7) Operational Experience Feedback And Implications For Design

a) The following aspects should be addressed:
   i) Description of the process for gathering operation experience feedback from similar plants both locally and internationally.
   ii) Description of lessons learnt and how this has influenced plant design

8) Sources of Radioactivity & Radioactive Waste Management

a) The following aspects should be addressed:
   i) Source terms during normal operation and after events causing release of radioactive material.
   ii) Gaseous and Liquid Waste Management.
   iii) Solid Waste Management.
   iv) Process and Effluent Radiological Monitoring and Sampling Systems.
   v) Storage and transport of radioactive waste.
   vi) ALARA implementation.

9) Radiation Protection Requirements

a) The following aspects should be addressed:
   i) Implementation of the ALARA Programme including ALARA targets.

ii) Compliance of Occupational Radiation Exposures with the ALARA targets.
iii) Radiation Sources and Radiation Protection Design Features.
iv) Dose Assessment and Health Physics Programme.
v) Compliance with the prescribed dose and risks limits .
vi) Establishment of constraints on airborne emissions of radioactive material.
vii) Staff training on Radiation Protection.
viii) Ventilation and respiratory protection programme.
ix) Radiation survey and monitoring programme.
x) Environmental protection and monitoring measures including effluent and gaseous release monitoring.
xi) Minimisation of contamination of SSC.
xii) Minimisation of generation of radioactive waste.
xiii) Transport of radioactive material (including plant feed material, radioactive products, and radioactive waste).

10) Conduct Of Operations

a) The following aspects must be addressed:
   i) Organisation, operations and training programmes, and operating staff requirements.
   ii) Major support programmes (e.g. GOR documents for Maintenance, Surveillance, Chemistry and Radiation Protection)
   iii) Regulations for emergency planning, acceptance criteria for the emergency planning provisions.
   iv) Features provided for use during plant emergencies (e.g. on-site medical, decontamination and transportation of individuals to off-site facilities).
   v) Administrative and operating procedures for safe handling of normal, abnormal and emergency situations.
   vi) Physical protection of the facility.
   vii) Operational safety assessments commensurate with the nature of the operation and the involved nuclear risks as a basis for all the operational safety-related programmes, limitations and design requirements.

11) Qualification Programme

a) The following aspects must be addressed:
   i) Test and Qualification Programme development process.
   ii) Scope and aspects of the qualification and test programmes relevant to the identified safety functions.
   iii) Definition of testing, including prototype testing, pre- and post-installation testing and commissioning.
   iv) Environmental Qualification.
   v) Seismic Qualification.
   vi) Special, unique, or First-Of-Kind design features qualification.
   vii) Organisational structure for the commissioning phase.
   viii) Roles, responsibilities, resources of the involved organisations.
   ix) Commissioning Programme comprising the testing of single SSC and the integral acceptance tests of the whole facility
   x) Instrumentation concept for commissioning.

xi) Verification of plant operating and emergency procedures.
xii) Utilisation of experience at other facilities.
xiii) Schedule of the test programme related to the licensing stages.

12) Deterministic Safety Analysis

a) The following aspects must be addressed:
   i) General Features of the Safety Analyses.
   ii) Exploration and selection of a sufficiently broad spectrum of internal and external Initiating Event (IE), with adequate justification for exclusion of events.
   iii) Explanation of the process for identification and classification of bounding Postulated Initiating Events (PIE) for safety analysis.
   iv) Identification of the source term and release paths.
   v) Deterministic source term analyses for normal operations, anticipated operational occurrences, design base accidents and design base extension conditions and demonstration of compliance with acceptance criteria.
   vi) Determination and probabilistic justification of beyond design base accident events.
   vii) Models and computer codes and their corresponding Verification and Validation Plans.
   viii) Justification of assumptions and input data including justification for best estimate or conservative data.
   ix) Analysis results and the sensitivity of the results to the assumptions and the limits.

13) Technical Specifications

a) The following aspects must be addressed:
   i) Operational Safety Limits (process variables) to provide for sufficient operating margin to ensure the integrity of the physical barriers against the release of radioactive or nuclear material.
   ii) Determination and Features for Limiting Conditions for Operation (LCO)
   iii) Maintenance and Inspection Requirements
   iv) Surveillance Requirements
   v) Administrative Controls

14) Quality and Safety Management

a) The following aspects must be addressed:
   i) Organizational structure, authorities and responsibilities.
   ii) Description of the Quality Management System
   iii) Quality and Safety Policy and Manual
   iv) Quality and Safety Objectives
   v) Training and qualifications of Quality Management Personnel
   vi) Process Control of design, procurement, documents, materials, components, quality plans, fabrication, test, inspection etc.
   vii) Management Review
   viii) Application of codes and standards
   ix) Supplier Qualification program
   x) QM audit program
   xi) Safety Management System
   xii) Safety Policy Principles and Management Responsibility

xiii) Safety implementation process and review
xiv) Safety, health and environmental safety committees
xv) Safety Culture Enhancement Program
xvi) Self Evaluation Management Review
xvii) Safety Management audit program

15) Human Factors Engineering

a) The following aspects must be addressed:
   i) HFE Programme management plan to demonstrate the role of HFE and to define the means by which HFE activities are accomplished.
   ii) Aspects of the Human System Interface (HSI).
   iii) Related procedures and training programs using accepted HFE principles.
   iv) Human Factors design team composition.
   v) Safety Culture.
   vi) Habitability assessments

16) Probabilistic Risk Assessment (PRA)

a) The following aspects must be addressed:
   i) Assessment of the frequencies of all applicable Initiating Events (IE).
   ii) Determination and justification of reliability data of SSC.
   iii) Determination and justification of event sequences.
   iv) Definition of PRA end states derived from deterministic analysis.
   v) Demonstration of compliance with risk acceptance criteria for design base accidents and design base extension conditions by application of established Probabilistic Risk Analysis Methods.
   vi) Demonstration of a balanced design (exclusion of disproportionately large contribution of a particular feature or event to overall risk)

17) Emergency Management and Off Site Response

a) The following aspects must be addressed:
   i) Emergency Plan and related procedures for the representative accident scenarios identified in the Safety Analysis, considering the appropriate information related to the surrounding areas.
   ii) Delineation and description of the applicable emergency planning zones.
   iii) Availability of emergency measures concerning the design and the administrative procedures for Onsite and Offsite responses.
   iv) Detection and monitoring of the relevant accidents violating the limits according to the prescribed regulations that require emergency responses.
   v) Mitigation of accident consequences by emergency management.
   vi) Conservatively expected kind and amount of releases of radioactive or nuclear material and/or hazardous chemicals.
   vii) Responsibilities for emergency management of the operating organisation.
   viii) Plans for restoring the Facility to a safe status after an accident and recovery after an emergency.
   ix) Education and training to demonstrate the capability of the organization to perform an effective response to an emergency case.

18) Supporting documentation for the safety case

a) The supporting documentation must cover the following areas:
   i) Detailed description used or implied in the safety analyses
   ii) Detailed specifications of the SSC that are classified or implied in the safety analyses like design, manufacturing and construction specifications.
   iii) QA documentation and audit results confirming conformance with quality and safety objectives
   iv) On-site/off-site/environmental data used or implied in the safety analyses
   v) Documentation on all information, data and analyses relevant to the safety case including an auditable trail to this information.
   vi) References to the GOR covering the following areas:
      (1) Operating Technical Specifications
      (2) Technical Surveillance Requirements
      (3) Maintenance and ISI/IST Programmes
      (4) Physical Security
      (5) Environmental Surveillance
      (6) Operating and Incident/Accident Procedures
      (7) Severe Accident Mitigative Design Alternatives/ Guidelines
      (8) Emergency Planning Programme
      (9) Radiation Protection Programme and Provisions
      (10) Effluent and Waste Management Programmes
      (11) Occurrence Notification and Control Programme
   vii) Reference to the Project Management submissions addressing the following areas
      (1) Overall management control of the activities affecting nuclear safety.
      (2) Project Management System and documentation.
      (3) Planning and overall design and construction process
      (4) Development and control of plans and schedules.
      (5) Configuration Management Programme (i.e. control of design changes affecting the safety case and / or license)
      (6) Processes for control of interfaces with supplier during design, manufacture, construction and commissioning phases.
      (7) Control of Construction activities on the site
      (8) Safety-related management documentation
      (9) Processes relating to maintaining the validity of the safety case (e.g. screening and safety evaluation process).
      (10) QA/QC processes and audit trail
      (11) Others as Legal, Financial and Competencies
      (12) Any other supporting information needed for the safety case.

APPENDIX 5: TYPICAL FORMAT AND CONTENT OF THE DECOMMISIONING PLAN

1. Introduction
2. Facility Description
   - 2.1.Site location and description
   - 2.2. Building and system description
   - 2.3. Radiological status
     - 2.3.1. Contaminated structures
     - 2.3.2. Contaminated systems and equipment
     - 2.3.3. Surface soil contamination
     - 2.3.4. Subsurface soil contamination
     - 2.3.5. Surface water contamination
     - 2.3.6. Groundwater contamination
   - 2.4. Facility operating history
     - 2.4.1. Authorized activities
     - 2.4.2. Licence or authorization history
     - 2.4.3. Spills and occurrences affecting decommissioning
     - 2.4.4. Previous decommissioning activities
     - 2.4.5. Prior on-site burial

3. Decommissioning Strategy
   - 3.1. Alternatives considered
   - 3.2. Rationale for chosen strategy

4. Project Management
   - 4.1. Legal and regulatory requirements
   - 4.2. Project management approach
   - 4.3. Project management organization and responsibilities
   - 4.4. Task management organization and responsibilities
   - 4.5. Safety culture
   - 4.6. Training
   - 4.7. Contractor support

5. Decommissioning Activities
   - 5.1. Contaminated structures
   - 5.2. Contaminated systems and equipment
   - 5.3. Soil
   - 5.4. Surface and groundwater
   - 5.5. Decommissioning schedules

6. Surveillance and Maintenance
   - 6.1. Equipment and systems requiring surveillance and maintenance
   - 6.2. Schedule for surveillance and maintenance

7. Waste Management
   - 7.1. Identification of waste streams
   - 7.2. Solid radioactive waste
   - 7.3. Liquid radioactive waste
   - 7.4. Waste containing both radionuclides and other hazardous material

8. Cost Estimate and Funding Mechanisms
   - 8.1. Cost estimate
   - 8.2. Funding mechanisms

9. Safety Assessment
   9.1. Identification of relevant safety criteria
   9.2. Operational limits and conditions
   9.3. Hazard analysis of normal decommissioning activities
   9.4. Hazard analysis of abnormal events and incidents
   9.5. Assessment of potential consequences
   9.6. Preventive and mitigating measures
   9.7. Risk assessment
   9.8. Comparison of analysis results with relevant safety criteria
   9.9. Conclusions

10. Environmental Assessment
   10.1. Background data
   10.2. Description of project
   10.3. Environmental protection programme
   10.4. Effluent monitoring programme
   10.5. Effluent control programme

11. Health and Safety
   11.1. Radiation protection plan
   11.2. Nuclear criticality safety
   11.3. Industrial health and safety plan
   11.4. Audits and inspections
   11.5. Record keeping programme
   11.6. Optimization analyses and programme
   11.7. Dose estimation and optimization for major tasks
   11.8. Clearance criteria
   11.9. Final release criteria

12. Quality Assurance
   12.1. Organization
   12.2. Quality assurance programme
   12.3. Document control
   12.4. Control of measuring and test equipment
   12.5. Corrective actions
   12.6. Quality assurance records
   12.7. Audits and surveillance
   12.8. Lessons learned programme

13. Emergency Planning
   13.1. Organization and responsibilities
   13.2. Emergency situations
   13.3. Records

14. Physical Security and Safeguards
   14.1. Organization and responsibilities
   14.2. Physical security programme and measures
   14.3. Safeguards programme and measures

15. Final Radiation Survey

APPENDIX 6: TYPICAL FORMAT AND CONTENT OF THE SAFETY CASE OF A DISPOSAL FACILITY

Safety strategy

The safety strategy is the high level integrated approach adopted for achieving safe disposal of radioactive waste.

Description of the disposal system

The description of the disposal system should record all of the information and knowledge about the disposal system and should provide the basis on which all safety assessment is carried out.

Safety assessment

The following sections provide an overview of the key elements of the safety assessment:

- *Radiological impact assessment for the period after closure;*
- *Site and engineering aspects;*
- Passive safety;
- Multiple safety functions;
- Robustness;
- Scientific and engineering principles;
- Quality of the site characterization;
- *Operational safety aspects;*
- *Non-radiological environmental impact;*
- *Post-closure safety assessment*

Management of uncertainties

Uncertainties in the safety analysis have to be characterized with respect to their source, nature and degree, using quantitative methods, professional judgement or both.

Iteration and design optimization

Good engineering and technical solutions should be adopted, and good management principles should be applied to ensure the quality of all safety related work throughout the development, construction, operation and closure of the disposal facility.

Limits, controls and conditions

The safety case should be used to assist in the establishment of limits, controls and conditions to be applied to all work and activities that have an influence on the safety of the facility and to be applied to the waste that will be disposed of in the facility.

Integration of safety arguments

- *Comparison with safety criteria;*
- *Complementary safety indicators and performance indicators;*
- *Plans for addressing unresolved issues.*

Involvement of interested parties

Early involvement of interested parties should be ensured as part of the process of building confidence in the safety of the disposal facility.

Independent review

Independent peer review should play an important role in building confidence in the safety case for a radioactive waste disposal facility.