NATIONAL NUCLEAR REGULATOR

LICENCE GUIDE

No.	Title	Rev
LG-1041	LICENSING GUIDE ON SAFETY ASSESSMENTS OF NUCLEAR POWER REACTORS	0

APPROVED:

CHIEF EXECUTIVE OFFICER / RESPONSIBLE MANAGER

DATE APPROVED: 16/08/2002

DATE OF ISSUE:

23/08/2002

REVISION DATE:

23/08/2004

TABLES

FIGURES

1. OBJECTIVE

This licensing guide has been issued to provide general guidance to current or prospective licence holders on the documented evidence that needs to be provided to (or made available to) the NNR on safety assessments requiring NNR approval. This licensing guide also addresses the various regulatory interactions between the licensee (or prospective licensee) and the NNR, and the various licensing stages associated with such a safety assessment.

This licensing guide is applicable to the present licensing strategy of the NNR as well as processed-based licensing.

2. SCOPE

This licensing guide addresses safety cases produced by the licensee (or prospective licensee) for the following purposes:

1. New licence application
2. Modification on a licenced site impacting on safety
3. Change to the current licensing basis
   Change to licence-binding documentation
   Change to any aspect of the safety envelope
4. Other

   Experience feedback concern (international or plant-specific)
   Any safety concern raised as a result of a proactive assessment
   International topical issue
5. Any assessment required by the NNR.

The term "Licence" in this licensing guide means Nuclear Installation Licence, contemplated in section 21 of the National Nuclear Regulator Act.

3. DEFINITIONS

3.1 Safety Case

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 (refer to Figure 1).

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:

- Safety analysis report (SAR)
- General Operating Rules (GOR)
- SAR/GOR supporting documentation
- Other licence binding documents

- Changes to the SAR/GOR and supporting documentation relevant to the particular application
- Project management documentation
- Safety related programmes applicable during a given licensing stage.

3.2 Current Licensing Basis (CLB)

In the context of this licensing guide, the term CLB refers to the safety case applicable at any time during operation of the plant, and all licence-binding documentation and NNR licence documents (Refer to Figure 1). Project management documentation applicable during licensing stages (eg during modifications), which are not relevant to the operational phase, must not be included. The CLB therefore includes:

- Safety analysis report (SAR)
- General Operating Rules (GOR)
- Other safety related programmes applicable during a licensing stage
- SAR/GOR supporting documentation
- Any other licence-binding documentation.

3.3 Safety Analysis Report (SAR)

In the context of this licensing guide, the term SAR refers to the principle document produced by the licensee to demonstrate compliance with nuclear safety criteria and licensing requirements (Refer to Figure 1). The SAR provides the link between all the documentation relevant to the safety case.

For the purposes of this licensing guide, the following are considered part of the SAR:

- Nuclear safety rules/criteria/standards and requirements relevant to the safety analyses
- Safety/risk analysis documentation addressing rules, computer codes, models, methodology, input data, analyses, results and conclusions
- Safety envelope (definition 3.15).

3.4 General Operating Rules (GOR)

In the context of this guideline, the term GOR is used to refer collectively to safety related practices or programmes that are applicable during the operational phase of the plant and may also be applicable during interim licensing stages. Typically these include the following:

- Operating technical specifications
- Operating/incident/accident procedures
- Severe accident management guidelines
- Physical security
- Maintenance programme
- ISI/IST programmes
- Radiation protection programme
- Effluent and waste management programme
- Emergency planning provisions

3.5 SAR/GOR supporting information referred to or implied in the safety analyses including:

- Detailed plant description
- Specifications of all systems, structures components
- On-site/off-site/environmental factors components
- Technical bases to GOR linked to the SAR
- Plant management documentation (ie management manual)
- Documented evidence of all quality objectives relevant to safety (section 7.2)
- Processes relating to maintaining the validity of the safety case (eg screening and safety evaluation process).

3.6 Safety assessment

Process for performing an assessment against nuclear safety criteria including all relevant quantitative and qualitative analyses to justify the methodology, input data, and assumptions, and relevant quality assurance activities.

3.7 Nuclear Safety Criteria

Criteria established with the objective of assuring an acceptable level of safety to the public and plant personnel from radiation hazards. These include the design criteria of the design basis of the plant, Fundamental Safety Standards of the NNR [4.2], quality assurance, emergency planning criteria and any other safety requirements specified in the licence.

3.8 Fundamental Safety Standards

The NNR established fundamental safety standards [4.2] against which any activity or undertaking, involving the use of radioactive material, and posing a radiological risk to the public and/or workforce, must be assessed for licensing purposes. Protection of the environment is also implied by these standards, which include :

- Risk criteria addressing mortality risk to the public (present and future generations) and workforce
- Radiation dose limits to members of the public and workforce arising from normal operations
- Fundamental safety principles (including defence-in-depth and ALARA)
- General safety principles relating to the requirement to comply with international norms and practices
- Requirements for emergency planning.

3.9 Quality Management Programme Manual

Document specifying the quality management requirements and responsibilities of the project related to quality assurance and quality control.

3.10 Quality Plan

Document setting out the specific quality practices, resources and sequences of activities relevant to the quality assurance aspects of the project.

3.11 Project Management Manual

Document specifying the organisation and responsibilities of the project.

3.12 Project Plan

Schedule of activities involved in the implementation of the project, which include inter alia the licensing/decommissioning plan.

3.13 Licensing/decommissioning Plan

Schedule of activities related to the licensing and/or decommissioning of the project.

3.14 ALARA (As Low As Reasonably Achievable)

The implementation of this principle involves taking the necessary steps to ensure that all means to reduce risk that are reasonably achievable, are taken.

3.15 Safety envelope

The safety envelope is made up of all the conditions, parameter ranges, codes, models, human actions which are used or implied in the safety case to show that the plant meets nuclear safety criteria. This includes all licence-binding documents, including NNR requirements stipulated in licence documents. The safety envelope is defined in the current licensing basis as amended by the safety case.

3.16 Project

This term is used in this licensing guide to refer to activities associated with a safety assessment in respect of any item 1-5 in section 2.

3.17 Defence-in-depth

The principal of Defence in Depth, which concerns the protection of both the public and the workforce, is fundamental to the safety of nuclear installations. This principal is elaborated on in detail in IAEA INSAG-10 [4.7].

The principal of defence in depth, as applied to all safety activities, whether organizational, behavioural or design related, ensures that they are subject to overlapping provisions, so that if a failure were to occur it would be detected and compensated for or corrected by appropriate measures. Application of this principal throughout design and operation provides a graded protection against a wide variety of transients, anticipated operational occurrences and accidents, including those resulting from equipment failure or human action within the plants, and events that originate outside the plant.

The concept of multiple levels of protection, or lines of defence, is the central feature of defence in depth.

3.18 Safety analysis

Safety analysis is the process applied to demonstrate compliance with nuclear safety criteria. This involves both probabilistic and deterministic analysis.

3.19 Deterministic (safety) analysis

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. A conservative analysis must be used in this regard. This type of analysis is normally used to assess the adequacy of the design.

3.20 Probabilistic analysis

Probabilistic 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 probability of such consequences are computed. The outcome of a probabilistic analysis is usually expressed in terms of frequency per annum (core damage frequency, frequencies of various numbers of fatalities etc). Either a best estimate analysis, with uncertainties, or a conservative analysis may be performed in this regard.

3.21 Conservative analysis

A conservative analysis is one in which pessimistic assumptions are used resulting in an overestimate of the consequences and/or probabilities of events and thereby provides an underestimation of safety margins.

3.22 Best estimate analysis

An analysis that is performed on the basis of the mechanistic behaviour of systems and processes, providing most probable values where uncertainties exist and avoiding over conservative unjustified assumptions.

4. REFERENCES

4.1 National Nuclear Regulator Act (Act No. 47 of 1999)

4.2 LD-1091 "Requirements on licensees of nuclear installations regarding quantitative risk assessment and compliance with the fundamental safety standards of the NNR"

4.3 LD-1023 "Quality Management Requirements for the Koeberg Nuclear power Station"

4.4 LD-1094 "Quality Management Requirements for the Pebble Bed Modular Reactor"

4.5 LG-1038 "Requirements for Licensing Submissions Involving Computer Codes and Evaluation Models for Safety Calculations"

4.6 LG-1037 "Basic Licence Requirements for the Pebble Bed Modular Reactor"

4.7 INSAG-10, Defence in Depth in Nuclear Safety, A report by the International Nuclear Safety Advisory Group, IAEA, Vienna, 1996

5. BACKGROUND ON LICENSING PROCESS

The purpose of this section is to outline the licensing process implemented by the NNR with the objective of putting the requirements on safety assessment in context.

5.1 Legislation

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

Application for the granting of a nuclear installation licence must be made to the Chief Executive Officer of the NNR in the prescribed format and the applicant must provide such information as the Board of Directors of the NNR may require.

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

5.2 Fundamental Safety Standards

Safety standards and regulatory practices have been established in respect of which any activity or undertaking, involving the use of radioactive material, which poses a radiological risk to the public and/or workforce, must be assessed for nuclear authorisation purposes. These standards and practices include:

- Risk criteria addressing mortality risk to the public (present and future generations) and workforce
- Radiation dose limits to members of the public and workforce arising from normal operations
- Fundamental safety principles (including ALARA and defence-in-depth)
- General safety principles relating to the requirement to comply with international norms and practices
- Requirements for emergency planning.

The fundamental safety standards of the NNR refer directly to the basic concerns of nuclear safety, namely radiological risk to the public and plant personnel (reference 4.2).
The ALARA principle requires that plant risk and radiation dose be reduced below levels which would already satisfy the risk criteria and radiation dose limits. In this regard, safety objectives or targets must be established and complied with.

The principle of defence in depth must be implemented according to INSAG 10 [4.7].

As explained in reference 4.2, the fundamental standards are also intended to imply protection of the environment against radiological risk.

5.3 Safety Case

The licensee is required to present a safety case, for any of the reasons given in section 2.

The safety case must demonstrate compliance with nuclear safety criteria, which include the Fundamental Safety Standards, and identify all requirements, provisions and undertakings necessary to support the safety assessment. These are typically covered by the documentation shown in Figure 1.

In the demonstration of compliance with the fundamental safety standards, the plant as designed, constructed, and operated, in accordance with well-defined standards and rules must be shown to be acceptably safe. Reliance may not be placed on highly uncertain factors or countermeasures. No credit may be given 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. Credit may however be given for the implementation of a food ban provided the process has adequate procedures and is shown to be credible.

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

Any safety factor having a significant safety impact, and which the licensee wishes to include in the assessment, must be subjected to appropriate controls before any credit is given for it.

5.3.1 Uncertainty analysis

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

For the design basis a rigorous approach is required.

For demonstration of compliance with the fundamental safety standards, an uncertainty analysis must be performed using an acceptable methodology.
The uncertainty analysis must be used to establish the level of confidence in the results, and must be considered in the decision making process related to compliance.

5.3.2 Alternative approach to address uncertainties

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

Conservative analysis

A conservative (enveloping) analysis is performed. In instances where the conservative analysis shows noncompliance with the fundamental safety standards, a best-estimate analysis may be performed for those specific factors, which contribute significantly to noncompliance. The level of confidence in the best-estimate analysis for such factors must be justified, by means of an uncertainty analysis or sensitivity analysis.

Best estimate analysis

As the fundamental safety standards refer to mean values, an overall best-estimate analysis (ie 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.

In this case, credit may be given for safety factors associated with a high level of uncertainty (eg non safety classified systems, structures or components, severe accident management guidelines and the emergency plan). The results of this analysis may be used to demonstrate acceptable safety margins.

5.4 Licence

The NNR is responsible for drawing up a licence for the facility (or activity) in such a manner as to encompass the requirements, provisions and undertakings identified in the safety case. The status of the licence is that of a legal document, to be respected by the licensee. The licence must include all inspectable or auditable safety measures considered necessary to provide adequate assurance that the safety case is not compromised.

The structure and contents of the licence is determined by the NNR. It is the responsibility of the licensee to identify and implement the necessary safety measures to ensure that safety criteria are met.

A compliance inspection and audit programme is implemented by the NNR to ensure that the licensee complies with the conditions of the licence.

6. LICENSING SCHEDULE AND SUBMISSIONS

The purpose of this section is to outline the sequence of interactions between the licensee and the NNR associated with safety submissions requiring NNR approval.

6.1 Notification and initial discussions

Safety assessments are typically initiated for any of the following purposes:

1) New licence application

2) Modification on a licensed site impacting on safety

3) Change to the current licensing basis
   Change to licence-binding documentation
   Change to any aspect of the safety envelope

4) Other
   Experience feedback concern (international or plant-specific)
   Any safety concern raised as a result of a proactive assessment
   International topical issue

5) Any assessment required by the NNR

With regard to items 2-4 above, the licensee would have performed a screening assessment to establish any impact on the *current licensing basis*.

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

1. Description of the project (sufficient detail to motivate need for safety case)
2. Identification of any safety measures while the safety assessment is in progress (ie in respect of new safety concerns)
3. Identification of licensing stages of the project.

Depending on the reason or need for the safety assessment (items 1-5 abive), different licensing stages must be identified and agreed on by both parties on a case-by-case basis. Typical licensing stages are shown in Table 1 with guidance as to possible reasons for introducing the various stages. The various licensing stages also need to be established with a view to streamlining the licensing process and avoiding unnecessary delays and time-pressure. Allowance must be made for assessments that may prove to be time-consuming.

The licensee is required to produce a safety case for each licensing stage. These must involve an application to the NNR, which may include inter alia the following applications:

Preliminary assessment stage:

Acceptance of concept safety case

Construction/modification/installation:

Siting/Construction/installation licence (new site)
Application or licence change request (LCR) for construction/installation/modification on licensed site

Fuel on site/fuel loading/testing/commissioning:
Licence change request

Plant Operation
Licence change request

Decommissioning
Licence change request or new application as appropriate

Following initial notification, licensing project meetings may be set up between the NNR and the licensee to monitor progress with the project and development of the safety case for the agreed licensing stages.

6.2 Submission of safety case

As a basic principle, the safety case for each licensing stage of the project presenting a nuclear hazard must address the relevant hazards and include all safety provisions necessary to ensure compliance with nuclear safety criteria. Conditional approvals must be avoided as far as possible.

The licensing process may then follow the steps shown in Table 1 as applicable.

The contents of a safety case are defined in section 7.

7. CONTENTS OF SAFETY CASE

The purpose of this section is to provide guidance on the general principles, scope and contents of a safety case, covering project management, SAR, GOR, supporting documentation and plant management. These are addressed under sections 7.1 – 7.8.

7.1 Safety case for different licensing stages

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

The scope of the safety case typically required by the NNR for different licensing stages of a project is shown in Table 2. This is expanded on as follows:

7.1.1 Preliminary assessment

The licensee may be required to produce a preliminary safety case for the proposed project.

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.

The objectives of the preliminary safety case are as follows:

- To provide confidence that the project is licensable
- To lay down the framework for the final safety case
- To identify potential problem areas that need early attention
- To assist in the preparation of detailed project plans and quality plans

The preliminary safety case must 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 revisit the question of whether the facility is licensable. The safety envelope must be refined as necessary in subsequent stages.

The preliminary safety case must 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 must include quantitative results, even though these may change as the project develops. The basic principles of the assessment of the various stages of the project must be addressed.

At this preliminary stage the project management documentation must be sufficient 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.

The preliminary safety case must 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.

The preliminary safety case must 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.

7.1.2 Construction/modification/installation

If this phase of the project results in potential hazards, these must be addressed by the safety case (for example if construction or installation were to be performed on a licenced site). The safety case for this phase must be site specific.

7.1.3 Fuel on site/fuel loading/testing/commissioning

Where potential hazards are introduced in this phase of the project, these must be addressed by the safety case. The safety case for this phase must be site specific.

7.1.4 Plant Operation

Potential hazards relevant to this phase of the project must be addressed by the (site specific) safety case.

7.1.5 Decommissioning

Potential hazards relevant to this phase of the project must be addressed by the (site specific) safety case.

7.2 Project management

The safety case must include project management documentation relevant to the licensing stage, addressing the development of the safety case.

The project management documentation provided for each licensing stage must 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 must also be provided.

The project management documentation must address the following aspects of the project where applicable:

- Organisation
- Responsibilities
- Interfaces
- Licensing
- Resources
- Legal
- Financial
- Competencies
- Processes for the development of the safety case
- Hold and witness points
- Quality assurance

- Quality control

The following documentation may be required by the NNR:

- Project Management Manual
- Project Plan
- Quality Management Programme Manual
- Quality Plan
- Licensing/decommissioning Plan

The Quality Management Programme must also ensure that specific quality objectives and associated quality requirements are identified and addressed for each aspect of the safety case, addressing for example:

Criteria	Referencing all relevant nuclear safety criteria (i.e. criteria as per NNR requirements and/or design base criteria)
Methodology	Documented evidence that the methodology is recognised/approved internationally. Validated, benchmarked. Codes, models, software comply with NNR guidelines LG-1038 [4.5]
Data	Data sources, processing, storage, documentation as per LG-1038 [4.5]
Codes/Standards	Documented evidence of international recognition/approval
Design	Designers quality objectives documented and are in conformance with LD-1091 [4.2] and LG-1037 [4.6]
Construction and manufacturing	Manufacturing as per design, construction and manufacturing specifications
GOR + bases	All operational safety related practices and programmes relevant to the safety case are proceduralised, reviewed, documented as per LD-1023 [4.3] and LD-1094 [4.4]. Personnel training as per LD-1023 [4.3] and LD-1094 [4.4]
Implementation planning (Installation/Decontamination/Removal/ Commissioning/pre-operational testing)	These processes must be justified on the basis of safety, and be procedurised, reviewed, documented as per LD-1023 [4.3] and LD-1094 [4.4]
Organisation	LD-1023 [4.3] and LD-1094 [4.4]
Documentation	LD-1023 [4.3] and LD-1094 [4.4]
Review	LD-1023 [4.3] and LD-1094 [4.4]

7.3 Safety Analysis Report

In the context of this licensing guide, the SAR refers to the principle document produced by the licensee, encompassing the overall safety case for the site, to

demonstrate compliance with nuclear safety criteria and licensing requirements (Refer to figure 1). The SAR must address the following:

- Statutory requirements relating to nuclear safety
- Licensing requirements and fundamental standards
- Safety philosophy and approach
- Rules applicable to the safety case
- Design criteria
- Codes and standards (Engineering, Radiation Protection, etc)
- Testing
- Description of the plant, site and environs
- Safety/risk analyses
- Safety analysis methodology, computer codes, models and validation
- Identification of a safety envelope (assumptions/data used or implied in the safety/risk analyses).

The above aspects of the SAR are explained in more detail in sections 7.3.1 – 7.3.9.

The safety case must effectively define a safety envelope in such a way as to provide adequate safety margins and to make allowance for changes, which may be considered of low regulatory concern and therefore do not require approval by the NNR. The safety envelope must 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.

7.3.1 Licensing requirements and fundamental standards

Ultimately the SAR must demonstrate compliance with the fundamental safety standards and other requirements laid down by the NNR [4.2] which include:

1. Risk criteria addressing mortality risk to the public (present and future generations) and workforce
2. Radiation dose limits to members of the public and workforce arising from normal operations
3. Fundamental safety principles (including defence-in-depth and ALARA)
4. Compliance with international norms and standards
5. Requirements for emergency planning
6. QA requirements [4.3, 4.4].

7.3.2 Safety philosophy and approach

The SAR must address the safety philosophy of the licensee, including how they intend to meet licensing requirements (item 7.3.1), align to international norms and standards, and manage safety.

7.3.3 Rules applicable to the safety case

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

- Approach used in respect of probabilistic and deterministic analyses
- Approach used to categorise events/accidents (normal operation/design base/beyond design base)
- Rules applicable to the different categories of events/accidents

- Establishment of specific design/safety criteria linked to the classification scheme
- Application of defence-in-depth (eg single failure criterion)
- Rules for classification of systems, structures and components.

7.3.4 Design criteria

The design criteria must provide an adequate margin of safety to the fundamental safety standards, and be aligned with those of another country with a good safety record. These must include the following:

General design criteria:
High level criteria expanding on risk and defence-in-depth considerations (section 7.3.1) and respecting the need for a graded approach to redundancy and design specifications based on importance to safety.

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

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

Codes and standards must be identified for all safety related processes (including safety assessment, engineering, radiation protection, surveillance, operations and quality assurance) as a basis for these processes, as a cornerstone of the safety envelope, and as a basis for comparison with practices in other countries.

7.3.6 Testing

Aspects of the safety analysis, design and manufacturing process which have not been benchmarked or tested previously may have to be subjected to a test programme. The SAR must address all the aspects of the test programmes relevant to the safety case, including safety during implementation of these programmes, and provide evidence of the acceptability of those aspects of the safety case dependent on the outcome of such programmes. All aspects of testing, including prototype testing, pre- and post-installation testing and commissioning must be addressed.

7.3.7 Description of the plant, site and environs

The description of the plant, site and environs must include all factors relevant to the safety case, including location and all 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, military installations. Engineering details may be referred to in references. For the preliminary stage (preliminary assessment) this information may relate to a reference (generic) site. For subsequent stages the information must be site-specific.

7.3.8 Safety/risk analyses

This includes all analyses to demonstrate compliance with nuclear safety criteria, including deterministic and probabilistic analyses. For the preliminary stage (preliminary assessment), the full scope of 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.

The (deterministic) analyses against design criteria are required to be conservative. The purpose of this requirement is to establish a clear and unambiguous design. A risk assessment may however be used in support of a change to the design basis. Any decision to change the design basis must take into account international practice.

As the risk criteria refer to mean values [4.2], a best-estimate probabilistic risk analysis is acceptable. A best-estimate analysis must be accompanied by an uncertainty analysis and sensitivity analysis to provide an acceptable level of confidence that the fundamental safety standards are complied with.

Refer to section 5.3 for rules applicable to risk assessment.

An independent review of the safety analyses must be performed and documented.

Where analyses are performed by consultants or contractors, the licensee must produce auditable evidence of its own assessment of the analyses. Where the definitive analyses comprising the basis of the safety case are performed by the licensee, the licensee must produce documentary evidence of independent reviews in accordance with QA requirements [4.3, 4.4, 4.5].

7.3.9 Safety analysis methodology and validation

The safety analysis methodology relevant to the safety analyses for each licensing stage must be described in detail along with details of the computer codes and models used and the validation thereof.

It is important that the methodology to be used for any computational analyses 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 preliminary SAR.

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 the methodology. 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.

7.4 Safety envelope

The safety case must result in the definition of a safety envelope (definition 3.15) 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. The safety envelope must be defined with a view to minimising unnecessary licensing activities on issues of low safety significance, while ensuring compliance with nuclear safety criteria.

The safety case must 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 in mind to facilitate verification of conformance with the safety envelope for any envisaged future changes to the plant or GOR.

7.5 General Operating Rules

The preliminary safety case must identify the scope of the GOR (definition 3.4) and how it is intended that the various aspects be developed and linked to the safety case.

The GOR need not be submitted in the preliminary stage. For any other licensing stage, relevant GOR or GOR changes must be submitted with the application.

7.6 Interim safety related programmes

These must include interim activities or programmes applicable during the various stages up to plant operation relevant to safety and must include the following as applicable:

- Pre-installation/prototype testing
- Construction/installation
- Testing/commissioning
- Decommissioning.

7.7 Supporting documentation for safety case

This includes all documentation, in addition to the GOR, to underpin the safety case and ensure its validity:

- Detailed specifications of all systems, structures components used or implied in the safety analyses
- Design, manufacturing, construction specifications
- QA/QC documentation and audit trail confirming conformance with quality objectives identified in section 7.2
- On-site/off-site/environmental data used or implied in the safety analyses
- Bases for the GOR linked to the safety analyses.

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

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

7.8 Plant Management Documentation

The following documentation relating to plant management is considered relevant to the safety case:

- Organisational structure and responsibilities
- Training and staffing
- Quality management programme.

Table 1. 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	Final safety case to address nuclear safety hazards applicable during these phases. Safety case covering following stages may still be preliminary.	Final 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	Final safety case to address nuclear safety hazards applicable during these phases including plant operation. Preliminary safety case for decommissioning.	Final 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.

Table 2. Contents of safety case for different licensing stages

Application/ licensing stage Licensing schedule and submissions	**Preliminary stage** Acceptance of concept safety case	**Construction/installation/ Modification** (Nuclear Licence or LCR)	**Fuel on site, fuel loading, testing/ commissioning** (LCR)	**Plant Operation** (LCR)	**Decommissioning** (LCR)
Safety Case (7)	Rev 0	Rev 1	Rev 2	Rev 3	
Safety case for different licensing stages (7.1)	Focus on basic principles, scope of safety case, plans, proposals. Not necessarily site specific.	Address potential hazards relevant to this phase (relevant if on licenced site). Site specific.	Address potential hazards relevant to this phase. Site specific.	Address potential hazards relevant to this phase. Site specific.	Address potential hazards relevant to this phase. Site specific
Project management (7.2)	PM documentation to be supplied to provide confidence in quality of preliminary safety case and processes for development of safety case. Include proposals for PM aspects of future phases.	PM documentation to address implementation of this phase of the project, and processes for development of safety case. Include proposals for PM aspects of future phases.	PM documentation to address implementation of this phase of the project, and processes for development of safety case. Include proposals for PM aspects of future phases.	PM documentation to address implementation of this phase of the project, and processes for development of safety case. Include proposals for PM aspects of future phases.	PM documentation to address implementation of decommissioning, and processes for development of the safety case.
Safety analysis report (7.3)	Preliminary SAR, not necessarily site specific, but full scope addressing all future phases.	Final site-specific analysis in terms of the design and addressing hazards relevant to this phase. Preliminary analysis on later phases.	Final site-specific analysis in terms of hazards relevant to this phase. Preliminary analysis on later phases.	Final site-specific safety analysis for operation, preliminary analysis for decommissioning phase.	Final site-specific safety analysis for decommissioning.
GOR (7.5)	Proposal for technical bases.	Final GOR relevant to this phase. Proposals for GOR for later phases.	Final GOR relevant to this phase. Proposals for GOR for operational phase.	Final GOR for plant operation.	GOR for decommissioning.
Interim safety-related programmes (7.6)					
Supporting Docs (7.7)	Technical inputs to safety case. QA/QC docs for safety case.	Technical inputs to safety case. QA/QC docs for safety case.	Technical inputs to safety case. QA/QC docs for safety case. QA/QC for previous phase.	Technical inputs to safety case. QA/QC docs for safety case. QA/QC for previous phase.	Technical inputs to safety case. QA/QC docs for safety case.
Plant management documentation (7.8)	Preliminary proposals	Final proposals, including plant management during next intermediate phases.	Final proposals, including plant management during next intermediate phases.	Final proposals	Final proposals.
Licensing interactions (6)	Application: Request for opinion on licensability. Acceptance of concept safety case.	Application for nuclear installation licence e.g construction phase (new installation) or LCR for implementation of construction/installation (previously licensed installation).	LCR for fuel on site, or fuel loading or reactor testing or commissioning	LCR for plant operation	LCR
Outcome	Issue of opinion on licensability. Acceptance of feasibility	Nuclear Licence granted or LCR approval.	LCR approval	LCR approval	LCR approval
Licensee follow-up action	NA	NA	Update safety case documentation	Update safety case documentation Final QA/QC documentation	Update safety case documentation

Figure 1. Licensing Documentation Hierarchy